

EVALUATION OF DIGITAL MEDICAL TECHNOLOGIES

SUPPLEMENT



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All experts and stakeholders consulted within this report were selected because of their involvement in the topic of Digital HTA. Therefore, by definition, each of them might have a certain degree of conflict of interest to the main topic of this report.

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- Finally, this report has been approved by common assent by the Executive Board.
- Only the KCE is responsible for errors or omissions that could persist. The policy recommendations are also under the full responsibility of the KCE.

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■ APPENDIX REPORT

TABLE OF CONTENTS

1.	BELGIAN SITUATION	4
1.1.	PRESENTATION OF THE 24 PILOT PROJECTS.....	4
1.2.	EVALUATION OF THE 24 PILOT PROJECTS.....	6
1.3.	SOME EXAMPLES OF USE OF DMTS IN THE NIHDI CONTEXT.....	9
1.3.1.	Kinesitherapy at distance	9
1.3.2.	Dermatology (HealthConnect SA).....	11
1.3.3.	Telemonitoring Covid	12
1.3.4.	Diabetes convention (FreeStyle Libre Flash Glucose Monitoring System)	14
2.	ADDITIONAL COUNTRY SPECIFIC INFORMATION	16
2.1.	THE NETHERLANDS.....	16
2.2.	SUMMARY TABLES OF THE SCOPE AND EVIDENCE REQUIREMENTS BY COUNTRY	23
2.3.	MMA MODULE FOR HEALTH TECHNOLOGY ASSESSMENT	33
3.	IDENTIFIED EXAMPLES OF DMT EVALUATED IN OTHER COUNTRIES	35
4.	QUESTIONNAIRE USED FOR THE STAKEHOLDER CONSULTATION	35
5.	EU LEGAL FRAMEWORK REGARDING MEDICAL DEVICES.....	41
5.1.	QUALIFICATION AND CLASSIFICATION OF APPS AND THE COMPONENTS OF THE SYSTEM THEY ARE PART OF	42
5.1.1.	Qualification of wearables	42
5.1.2.	Classification of wearable	44
5.1.3.	Qualification of software	45
5.1.4.	Classification of software	49



	5.1.5. Qualification of non-medical components	51
5.2.	GENERAL SAFETY AND PERFORMANCE REQUIREMENTS FOR MEDICAL DEVICES	51
5.3.	CLINICAL EVALUATION	52
6.	EU LEGAL FRAMEWORK REGARDING CYBERSECURITY, INTEROPERABILITY AND PRIVACY	54
6.1.	CYBERSECURITY REQUIREMENTS	55
	6.1.1. Cybersecurity aspects in the medical devices Regulations	55
	6.1.2. Initiatives to regulate other digital products	57
	6.1.3. Cybersecurity obligations for certain public and private organisations (NIS Directives)	57
	6.1.4. Standards and certifications	57
6.2.	INTEROPERABILITY REQUIREMENTS	58
	6.2.1. Interoperability aspects in the Medical Devices Regulation	58
	6.2.2. European Health Data Space	58
	6.2.3. Standards and certifications	59
6.3.	DATA PROTECTION REGULATION	59
	6.3.1. General GDPR principles applied to apps	60
	6.3.2. Legal ground for data processing	64
	6.3.3. Primary vs. secondary purpose	66
	6.3.4. Information and rights of the data subject	67
	6.3.5. GDPR certifications and Guidelines	69
6.4.	QUALITY LABEL FOR MOBILE HEALTH APPLICATIONS	71



LIST OF FIGURES

Figure 1 – MoveUp app and his actions	10
Figure 2 – Interprofessional collaboration framework for COVID-19 patients at home	13
Figure 3 – Conceptual model for wearables	43
Figure 4 – ‘Is your software a medical device software’	48
Figure 5 – Cybersecurity requirements contained in MDR – Annex I	56

LIST OF TABLES

Table 1 – Health topics for the Health Inspection assessment of adult telemonitoring	16
Table 2 – Guidance for the evaluation of digital applications, algorithms, and artificial intelligence 'Kenniscentrum Digitale Zorg Nederland'	18
Table 3 – DMTs used as part of existing care reimbursements - performances	22
Table 4 – Summary countries FULL	23
Table 5 – Summary countries_Short Nominal	29
Table 6 – Summary countries_Short generic	31
Table 7 – A module which can be used in addition to existing core HTA domains to adapt HTA and/or reimbursement evaluation frameworks to assess Medical Mobile Applications*	33
Table 8 – Examples of software per risk class	50



1. BELGIAN SITUATION

1.1. Presentation of the 24 pilot projects

Name project	Name App	Indication	Chronic -Acute	Type DMT*	Description
Blended ACT	Learn2ACT	Mental health	Chronic	Therapeutic Monitoring	- Patient support in between consultations with a psychologist.
E-mental health	e-mental health	Mental health	Chronic	Prevention	Gives advice when confronted with light psychological complaints.
Beeldbellen	Obasi	Mental health	Chronic	Teleconsultation	Visual sessions between patients and healthcare professionals to reinforce the qualitative functioning of the mobile teams, improve their efficacy and avoiding hospitalisations.
Myglycmon	Cozo mobile app	Diabetes	Chronic	Preventive Monitoring	- To have a better overview of the glycemia, better communication and involvement of the patient, less acute complications, and a better long-term regulation of diabetes.
Diabetesontherun	Healthlook (i-mens)	Diabetes	Chronic	Monitoring	To monitor type II diabetes patients, provide personal coaching by educators, and to improve self-control of diabetes.
Interpret-DIA	Guardian Connect	Diabetes	Chronic	Monitoring	To monitor continuously the glucose data in paediatric Type I diabetes patients to adjust therapy and avoid hospitalisations.
Beroertecoach	beroertecoach.be	Stroke	Acute	Monitoring	Online coaching and consultation platform proposed for the patient after a stroke episode.
In-Ambulance telstroke	Zebra technology software	Stroke	Acute	Diagnostic triage	& Tool to support rapid diagnosis during transport (patient triage) by stroke centres.
Nefrocare	mynexuzhealth	Cardiovascular	Chronic	Monitoring	Telemonitoring of patients with chronic renal failure to improve management and medication, as well as efficacy during a consultation.
TOC-mhealth	Philips Medido	Cardiovascular	Chronic	Prevention Monitoring	- Improve medication compliance for cardiovascular diseases when taking more than 5 drugs, to improve quality of life and self-reliance and prevent complications.
24.7 monitoring of vital signs in home care	MijnWGK-Platform	Cardiovascular	Chronic	Monitoring	Telemonitoring of vital signs to reduce the number of complications, the average number of hospital stays, the number of intensive care unit readmissions and the costs of care.
mHartslag-Heart-On-Track	Philips Lion e-care	Cardiovascular	Chronic	Monitoring	Telemonitoring of patients with a heart attack and heart failure (HF) to improve quality and effectiveness of the treatment and avoid (re)hospitalisation.
HartfalenCoach	Remedus	Cardiovascular	Chronic	Monitoring	Telemonitoring of patients with heart failure, to prevent significant deterioration, maximize medication adherence, manage HF-symptoms, and reduce HF-related hospitalisations.



Cardio@home	2net Qualcomm life (Philips)	Cardiovascular	Chronic	Monitoring		Monitoring of patients who experienced an episode of heart failure and were discharged home; to reduce hospitalisations and motivate patients to adopt healthy lifestyles.
Management of patients with heart failure	Le Well (Wallonia e-health Living Lab) avec l'app HealtLook	Cardiovascular	Chronic	Monitoring		Home monitoring of HF patients to detect changes in the patient's clinical condition at an early stage and adapt treatment early avoiding or reducing duration of hospitalisation.
Fibrichck	Qompium	Cardiovascular	Chronic	Diagnostic Monitoring	+	Provides daily measurements and analysis of the heart rhythm in the home environment, to diagnose de novo AF, or to prevent embolism, control heart rhythm and frequency.
Move Up	MoveUp	Chronic pain	Chronic	Treatment Monitoring	+	Tele-revalidation program for patients after orthopaedic surgery to shorter medical stays, reduce readmissions and improve patient management.
Dolora@home	mynexuzhealth	Chronic pain	Chronic	Treatment Monitoring	+	Personalised patient coaching program with continuous evaluation and adjustment of the care process to achieve optimal care, decrease use of medication or doctor visits, and to have a better patient empowerment and health literacy.
PRENOM	Qompium	Combi	Chronic	Monitoring		Monitoring system to prevent gestational hypertensive disorder by following blood pressure and activity of pregnant women.
3S Homecare	3S Homecare	Combi	Chronic	Monitoring		Digital information exchange platform for strengthening communication between beneficiaries, their family and friends and service providers, to have real-time monitoring of health parameters and to simplify the work of service providers.
Stay on track	Remecare	Oncology	Chronic	Monitoring		Systematic symptoms checker for cancer patients to control early symptoms, improve therapy outcomes, and reduce long-term sequelae and better reintegration into society.
Sleep cloud	Airview Resmed	Sleep apnoea	Chronic	Monitoring		Monitoring of patients with obstructive sleep apnoea to decrease the cost treatment initiation and reduce follow-up costs by eliminating systematic annual renewal visits for patients who prefer to be followed remotely.
BPCO	Le Well (Wallonia e-health Living Lab) with HealtLookn app	COPD	Chronic	Monitoring		Home monitoring of clinical signs of patients suffering from chronic obstructive pulmonary disease to reduce the number and/or duration of hospitalisations.

*DMT : Digital Medical Technologies



1.2. Evaluation of the 24 pilot projects

Name of the project	Study Result	Mobile health Application	Conclusion
Blended ACT	Descriptive study with 84 patients included. A certain effect is seen on the waiting lists/waiting time and on complications/escalations without this was scientifically proven	The app is well advanced in security/authentication adjustments compared to the eHealth platform.	very useful app in Mental Health very difficult to derive conclusive clinical evidence from this study
E-mental health: zelf aan de slag!	Descriptive study with 169 patients included. High proportion of drop-out	Not quite mature yet despite positive points as the fact that many patients indicated that the application was useful and helped them	Cost efficiency cannot be demonstrated at the moment
Beeldbellen	Descriptive study with 68 patients included. The target group was not the most suitable for video calling user friendliness of the solution has to be improved	Technical problems, fewer people reached than expected	A project with few immediately usable results, difficult to draw conclusions
Myglycmon	Comparative study with 39 patients included (54% of the targeted number of patients) Difficulty to find a supplier. Only Roche take part of it, and with an older device.	The choice of Cozo was good as a central platform, and allow to reduce the building of custom links, and the patient data to be visible across the hospitals.	This project showed that interoperability has to be one of the validation criteria of mHealth applications.
Diabetesontherun	Comparative study with 100 patients included. Satisfaction of caregivers, high adherence of the patients.	Good support, functionality, stability and user-friendliness of the HealthLook application and the devices.	Very positive result, even if not necessarily scientific evidence. Little involvement of the GP due to a separate log in to the platform.
Interpret-DIA	Descriptive study with 47 patients included. Satisfaction of both patients and healthcare providers.	Follow-up was provided by a multidisciplinary team in UZB. Measurements from Medtronic Guardian Connect were transmitted to the multidisciplinary team: a great example of linking a supplier platform to a hospital.	Very valuable project that has a demonstrable effect on the young patients in the adjustment of their treatment and behaviour.
beroertecoach	Descriptive study with 147 patients included (50% of the expected patients). Difficulty to include elderly patients.	Application easy to use, reliable and useful. Good improvement of security of this application.	The solution does not save time to neurologist. Lack of clinical evidence and clear evidence of cost effectiveness.
In-Ambulance telstroke	Descriptive study with 10 patients included. The study was running only 2 months due to the multiple objections of ethics committees.	The principle is demonstrated and the technical feasibility proven. Some technical issue need to be validated.	Very limited results, extensive study is needing to show more evidence and cost-effectiveness.
Nefrocare	Descriptive study with 69 patients included. There is involvement of the patient, the GP and the specialist.	The wintermute CDS engine provides automation and standardisation and is very useful.	Very useful well-executed project with a good scientific-clinical follow-up that showed results.



TOC-mhealth	Descriptive study with 406 patients included. The dispenser clearly helps to take medication on time, it is very user-friendly and the patients' satisfaction is high as well as the satisfaction of the pharmacist.	The system is perceived as safe, but still needs to be optimized.	The pilot project was too limited to be scientific/statistical to provide conclusive evidence. The target audience will have to be defined more clearly (the therapy compliance can differ depending on the pathology or type of patient)
24.7 monitoring van vitale lichaamsfuncties in de thuiszorg	Descriptive study with 14 patients (initially 240 expected).	Technical problems (connections, battery, unreadable results...) Connectivity and interoperability were insufficient	The attempt to organising cardio follow-up from the 1st line was commendable but is not successful proved and was probably not the right approach.
mHartslag- Heart-On-Track	Comparative study with 142 patients included (on the 200 targeted), explain by the delay to have the approval of the ethical committee.	Controlled technical complexity. An important positive effect was the standardisation of heart failure process across the hospitals	A very useful project that has proven its effect towards the patient. In terms of cost-effectiveness more evidence needs to be generated.
HartfalenCoach	Descriptive study with 90 patients included. Clear increase of adherence, decrease of number of consultations and slight increase of number of unscheduled. Also satisfaction from healthcare providers appointments	A lot of efforts were made regarding privacy, security and interoperability of the RemeCare application.	Great maturity in terms of clinical evidence and in terms of interoperability. Has to demonstrate the quality and the efficiency of the follow up which not guaranty clinical evidence versus cost efficiency
Cardio@home	Descriptive study with 90 patients included. Positive results for 32 patients of them followed for at least 3 weeks, high compliance. Satisfaction was good and all care providers were also very positive.	Good set up involving medical devices and nurses for the follow up.	The results were positive but not statistically conclusive. The calculated cost per patient was less high than for other patients similar projects
Assistance des patients insuffisants cardiaques	Descriptive study with 18 patients included (on the 50 targeted).	No clear involvement of GP, frequent calls, difficulty in the use of the platform, multiple technical problems	Risks appeared for patients, many improvements need to be made.
Fibricheck	Comparative study with 441 patients included. High satisfaction among patients (86%) and healthcare providers (92%)	Innovative mobile health application, self-used by the patient, including measurements and algorithm.	Clear financial picture adjusted on the basis of a Holter exam.
Move Up	Descriptive study with 190 patients included.	The power of remote performance tracking, exercises, medication and diary/PROMs has been demonstrated in a certain population of patients.	Within this treatment period, a cost-effective reimbursement model was clearly demonstrated even if it cannot be simply extrapolated



Dolora@home	Descriptive study with 287 patients included. Time gains and better communication with the patient were reported, also reduction in the number of consultations.	Many technical problems were reported. Application adapted to the requested security level, but it only works with the NexUZ network	The precise cost-benefit calculation had not yet been sufficiently worked out and argued. Many patients could not be included for various reasons.
PRENOM	Descriptive study with 287 patients included. Good compliance (around 80%) and reactions were positive for both patients and healthcare providers	Sufficient attention was paid to security/privacy.	The extensive calculations in terms of costs and savings are concrete, detailed and convincing. Not so clear what the effect of the doctor (gynaecologist) and his team had on the success of the treatment
3S Homecare	Descriptive study with 28 patients included. Over 7 months it was not possible to present statistically relevant data that would demonstrate an impact on the health of patients.	At the technical level and communication with the Walloon Health Network the evaluation is positive.	At the functional level a lot of improvements are to be made. The financial cost/benefit model is not convincing.
Stay on track	Descriptive study with 184 patients included. Satisfaction of the patients and healthcare providers, very good compliance	The application was significantly improved on aspects of security and authentication.	Complex but strongly designed multi-hospital project. Significant cost savings and resulting in quality improvement, for patients, care providers and society.
Sleep cloud	Descriptive study with 27 patients included. Good satisfaction of patients and medical team.	Introduction of telemetry in the management of BPCO patients	This model is interesting and would allow a reduction in public expenditure. The limited number of patients calls for caution regarding the results of this project.
BPCO	Comparative study with 50% of patients included on the 25 initially targeted.	Too many calls received and no improvement in communication with the patient. Technical improvements have to be done.	There is involvement of GP but they expressed reservation as no gain in time in patient follow-up. The clinical results and their projection are too low due to the limited number of patients



1.3. Some examples of use of DMTs in the NIHDI context

1.3.1. Kinesitherapy at distance

In July 2020, a convention was signed by the NIHDI to study and temporary reimburse remote kinesitherapy supported by the use of a mobile app (MoveUp) in the rehabilitation of patients after an implantation of a knee or hip prostheses^a.

The study aimed at recruiting about 1000 patients across 11 hospital sites until the 30th June 2023, but was interrupted after 2 years because of recruitment problems (40% of the original sample size was achieved – 394 patients at the end of June). The reasons given for these recruitment difficulties differ depending on the stakeholders interviewed and included patients' preferences (preferring to do their rehabilitation with their own physiotherapist, as opposed to the physiotherapist contracting with the apps provider), digital illiteracy (some patients unable to use digital tools appropriately) and administrative burden for both patients and health care professionals.

The results of this study on clinical effectiveness and cost-effectiveness of this intervention (based on the recruited patients) are expected by mid-2024.

Despite the early termination of the study, since October 2022, orthopaedists can prescribe remote rehabilitation via mobile apps (at the moment only move-UP) if the hospital where they work has signed the agreement with the NIHDI. Further, the physiotherapist delivering this remote care must also have followed an e-learning course at moveUP. More information about the convention can be found on the NIHDI website^b.

The convention specified that patients should be randomised into 3 groups:

- Arm 1 standard of care. Patients follow the classical rehabilitation with only the support of the physiotherapist during sessions with physical presence (not use the app).
- Arm 2 digitalised supported rehabilitation with fixed physical sessions. The patients follow the rehabilitation with the mobile application application with a fixed number of classical physiotherapy sessions with the physical presence of the physiotherapist;
- Arm 3 digitalised supported rehabilitation with physical sessions based on patient needs. The patients follow the rehabilitation with the mobile application without a fixed minimum number of conventional physiotherapy sessions with the physical presence of the physiotherapist.

The convention was initially planned to be in place until the 30th June 2023. The evaluation of the results from the study was planned to be carried out by a KCE research team.

Aim of the study: The following 4 points for rehabilitation (before or after a primary knee or hip prosthesis) supported by a mobile application (moveUP), whether or not combined with face-to-face sessions are studied:

- qualitative results of the rehabilitation, reported by the patient
- patient's quality of life following treatment
- incidence of complications, prolonged use of heavy analgesics, unplanned visits and readmissions
- total costs to health care payers after implementation of the application.

Healthcare process: For patients who undergo a primary unilateral primary unicompartamental knee arthroplasty (UKA); primary bicompartamental knee arthroplasty; a primary total knee (TKR) or a primary total hip replacement

^a https://www.riziv.fgov.be/SiteCollectionDocuments/convention_app_mob_medicale_reeducation_genou_hanche.pdf

^b <https://www.inami.fgov.be/fr/themes/cout-remboursement/Pages/remboursement-soins-distance-reeducation-prothese-genou-hanche-application-mobile.aspx>

(THR) and for which the specialist in orthopaedic surgery or physical medicine and rehabilitation has established, after consultation with the patient, a prescription for "telekinesitherapy".

Before the surgery: The patient sees the physiotherapist once (fee 30.65€).

The mobile app and devices are prescribed by the specialist during the hospital stay. The patient may already enter his data and parameters for training. (fees: 10€ for the mobile app, 60€ for the follow up of data during the hospitalisation, 50€ per 2 weeks for the 6 first week after the hospitalisation; and 35€ per 2 weeks for the 7-12 weeks after the hospitalisation – this last fee is available max one time for the hip).

The follow up and the treatment post-surgery by the physiotherapist for a maximum of 12 weeks (fees: 100€ per 2 weeks for the follow up and treatment for the 4 first week after the hospitalization, 75€ per 2 weeks for the knee and 67.50€ per 2 weeks for the hip from the 5th week; and 57.5€ per 2 weeks only from the 9th week – this last fee is available for the hip only if the treatment is needed for medical reasons).

In total the rehabilitation after a knee operation is reimbursed for 12 weeks. After a hip operation, this is standard 8 weeks. This can be prolonged to up to 12 weeks in case of medical necessity motivated by your surgeon.

Healthcare professionals involved:

- Health organisation: The team have to have minimum three members: a specialist in orthopaedic surgery, a specialist in physical medicine and rehabilitation and a physiotherapist.
- Physiotherapist

Mobile App: The mobile app has to respond to the following points: Minimum M2 of the validation pyramid of mHealth Belgium, respects the RGPD rules, follows the protocol of the study and allows to generate an activity report for the physiotherapist.

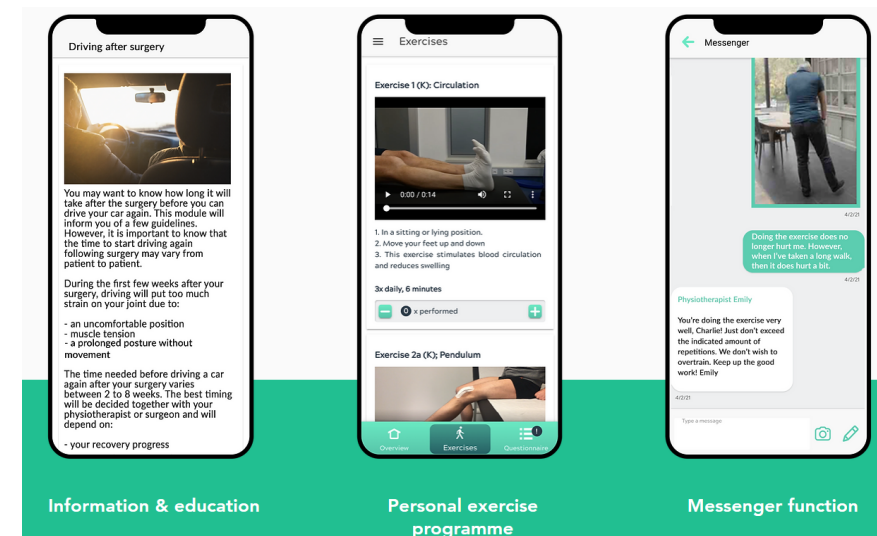
No specific mobile app is cited in the convention, but it is mentioned that the convention is effective for the apps present on a nominative list where only one app is present: *moveUp*.

The mobile app *moveUp* was one of the 24 projects assessed in the framework of the "Point d'action 19 – Actiepunt 19: the Mobile health". The project proposes to patients a personalised tele-revalidation program after orthopaedic surgery.

Three main actions are available via the app (Figure 1):

- Information and education: for all questions that the patient has.
- Personal exercise program: the patient receives every day an exercise plan, based on his personal progress.
- Messenger function: in order to communicate directly with your care team.

Figure 1 – MoveUp app and his actions



Source: <https://www.moveup.care/orthopaedics>



Budget: *MoveUp* is also the first application in level M3 of validation pyramid. This reimbursement – in the form of a convention – applies to the whole of Belgium and ran in two phases:

- In the study phase, 15 hospitals included patients in the study initiated by RIZIV and KCE. In total, more than thousand patients were supposed to be compared on their end result and use of care resources. The financial intervention was planned for the preoperative phase, for the mobile app and components, and for the follow up of the patients by care givers after the intervention. For 12 weeks support, the total budget reach 820.65€ for the knee and for 8 weeks support it reaches 620.65€ for the hip.
- Orthopaedists can now prescribe remote rehabilitation via mobile apps (at the moment only move-UP) if the hospital where they work has signed the (new) agreement with the NIHDI. Further, the physiotherapist delivering this remote care must also have followed an e-learning course at moveUP. More information about the convention can be found on the NIHDI website . More details:

<https://www.inami.fgov.be/fr/themes/cout-remboursement/Pages/remboursement-soins-distance-reeducation-prothese-genou-hanche-application-mobile.aspx>

<https://www.clinicaltrials.gov/ct2/show/NCT04628468?term=NCT04628468&draw=2&rank=1>

1.3.2. Dermatology (*HealthConnect SA*)

A pilot project was launched in 2020, concerning remote opinion from a dermatologist for GP on a clinical question that arises during the treatment of one of his patients. The idea is to demonstrate that this way of giving dermatological advice via remote consultation is good, fast, accessible, safe and cost-effective.

The convention was signed by the NIHDI, HealthConnect SA, the academic center for general medicine of the KU Leuven, and UGent.

Aim of the study: The aim was to develop a method for three parties: the GPs, dermatologists and patients in order to exchange medical information and pictures via secure communication channels for the diagnosis, treatment or prevention of skin diseases.

The target group is patients with any type of skin condition treated by the general practitioner, who want to get advice from the dermatologist.

For this purpose, **the convention** specifies that about 2000 remote expert opinions performed via this pilot project, by 30 participating dermatologists who will work with participating GPs (about 400).

Healthcare process and healthcare professionals involved:

Dermatologists : A number of 30 dermatologists participated in this study. They accepted to be available and to respond the requests of the GPs within the day, including a diagnosis, a proposition of treatment and responses to additional questions. Also, they had the possibility to schedule teleconsultation if needed. Finally, about a hundred of tele expertise were asked to each dermatologist.

GP: A total of 20 GPs were in contact with each dermatologist. They included patients (by asking the informed consent form), gave correct information, contact the dermatologist and sent pictures via the electronic form. They received and followed the advices received by the dermatologist.

Mobile App: HealthConnect SA has to develop an electronic questionnaire used for the communication between the GP and the dermatologist via the secure platform e-health. All the actions, collected data have to be done via the integrated electronic patient record.

Budget: One nomenclature code was created – remote dermatologic advice, which was billed 22.33€.



This tele-expertise project was completed in December 2021, and a report summarising its results is available on the NIHDI website^c. Discussions are ongoing on the a reimbursement framework for this pathway.

1.3.3. *Telemonitoring Covid*

The NIHDI launched in December 2020 a call for bottom-up driven community management projects that implemented remote monitoring for COVID-19 patients. The follow up at home of COVID-19 patients by healthcare providers is a pilot project that was launched by the NIHDI. Recently, KCE investigated the different interventions that participated in the project (Cornelis, Van Grootven et al. 2022).

Aim of the study: Telemonitoring is an interaction between a healthcare professional at a certain place and a patient at another place, in which a certain number of patient's parameters are assessed and followed up for a certain duration of time. Setting up continuous and qualitative telemonitoring is a complex task, where collaboration with various actors (across care lines) must be organised in a clear interprofessional collaboration framework. This framework, visualised in Figure 2 should take into account:

- the different actors involved,
- the role that each actor takes up, and
- the interaction between the actors.

The interprofessional collaboration and integration of care, including the communication between the various actors is of great importance.

Healthcare process:

The process of telemonitoring in this study involves a lot of actors. The patient can be included via two ways.

- The phase of prehospitalisation, consists of patients with a recent detected Sars-Cov-2 infection with severe symptoms or risks of complications and who are not been (yet) hospitalised. The inclusion of these patients can be done via the emergency unit or via the GP.
- The phase of post-hospitalisation, consists of patients who are discharged from a hospital and for whom additional telemonitoring is necessary on the basis of symptoms or risks of complications.

Monitoring is done via telemetry (at least oxygen saturation, breathing frequency, temperature, and heart rate, possibly activity level, sleep) and at least one daily structured questionnaire. If, on the basis of the severity of the symptoms and the risk factors present, the physician treating the patient considers that telemonitoring can be done without telemetry, the patient can also be monitored using at least daily structured questionnaires. All exchanges and collaborations between actors require the use of secure platforms that are compliant with the (GDPR) and applicable standards on privacy, information security and data sharing in healthcare.

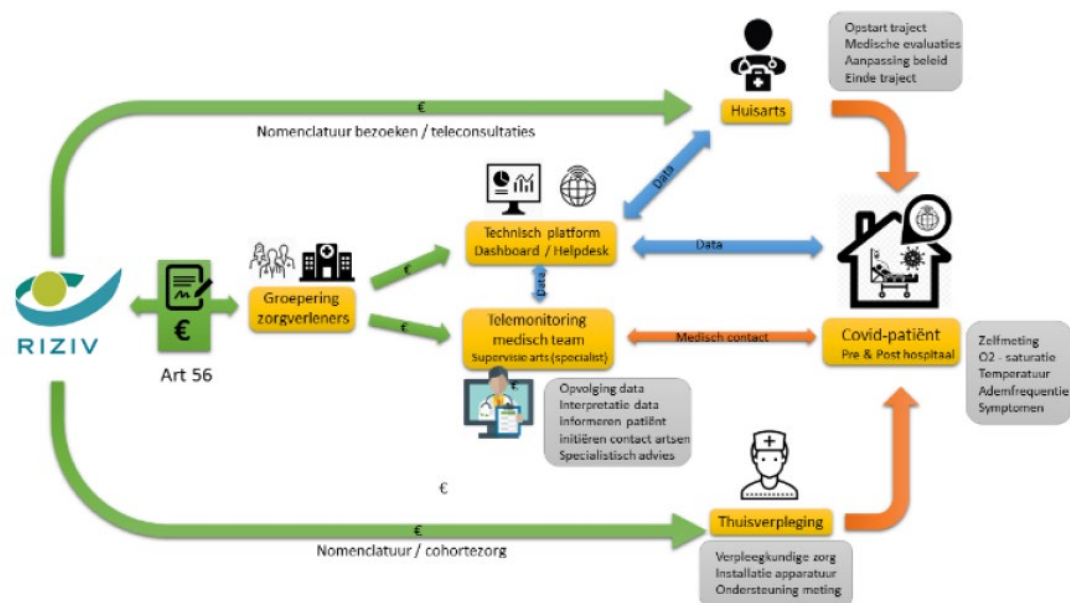
The telemonitoring team is responsible for the 24/7 monitoring of the delivered data. The team uses validated medical protocols to monitor data and evaluate the health status of the patient based on the outlined thresholds or parameters adapted to the specific health status of the patient. To ensure continuity of care, the telemonitoring team

- reports regular to the GP, such as at intake or discharge from the care pathway or important changes in medical treatment or in nursing care support,
- collects contact information of all involved healthcare providers necessary to ensure continuity of care.
- Informs and reassure the patient about the course of the illness.

^c <https://www.inami.fgov.be/fr/professionnels/sante/medecins/soins/Pages/tele-expertise-projet-pilote-dermatologie.aspx>



Figure 2 – Interprofessional collaboration framework for COVID-19 patients at home



Healthcare professionals involved:

- The group of healthcare providers: He concludes the agreement with the NIHDI, and is responsible for organising the process.
- The technical platform: It concerns the technical support for logistical processes behind the telemetry equipment, the storage and exchange of the data and a helpdesk for technical problems.
- The telemonitoring team: is a team of healthcare professionals (nurses and/or physicians) who will monitor a patient remotely by technological means.
- The general practitioners: Each patient followed up via telemonitoring must have a GP available who can come on-site if necessary to examine the patient and can make medical decisions.
- The ambulatory care nurse: consist on an ambulatory nursing care for the installation of the telemetry equipment and the performance of the measurements if the patient or his/her informal caregiver is unable to do.
- The patient: The intervention is given for his/her health, but the patient is also responsible for his/her follow-up, including the measurement and delivery of data.



Mobile App: Different providers participate, varying according to the group of healthcare providers. As providers, BeWell, Remecare, 3S Homecare and CC@H were participating in the project, but only the app of Remecare, BeWell and CC@H (cardiocare) are also mentioned in the e-Health validation pyramid (level 1 or 2).

Budget: The expected duration of telemonitoring is maximum 3 weeks for the prehospitalisation phase, and 6 weeks for the post-hospitalisation phase (3 weeks with telemonitoring equipment, and 3 weeks without). For this, codes of nomenclature were created.

- Lump sum for the administrative start-up of the care path, the installation of the equipment, the use of the digital support platforms and logistics: 34€ one time per patient.
- Lump sum for monitoring a patient via telemonitoring who is staying at home and was not hospitalised (pre-hosp), without telemetry equipment: 65€ one time per week per patient.
- Lump sum for monitoring a patient via telemonitoring who is staying at home and was not hospitalised (pre-hosp), with telemetry equipment: 75€ one time per week per patient.
- Lump sum for monitoring a patient via telemonitoring who is staying at home after hospitalisation (post-hosp), without telemetry equipment: 65€ one time per week, maximum three times per patient.
- Lump sum for monitoring a patient via telemonitoring who is staying at home after hospitalisation (post-hosp), with telemetry equipment: 100€ one time per week, maximum three times per patient

Evaluation: The KCE report (Cornelis, Van Grootven et al. 2022) evaluated the healthcare process and some recommendations have been made to the Belgian authorities, including some to better implement the telemonitoring in the future.

- Useful investment in experiential learning
- Provide appropriate frameworks and stimulate new collaborations
- Improving data quality and data capture

- Responding to patients' needs
- Reduce burden on healthcare staff and provide appropriate financial support
- Focus on user-friendliness, overcoming fear of innovation and making time for admissions
- Focus on equity, justice and fairness
- Looking ahead

<https://www.inami.fgov.be/fr/covid19/Pages/soins-distance-patients-covid19-domicile-telemonitoring.aspx>

Following this report, the le telemonitoring will be further explore in order to integrate it in the healthcare system. .

The NIHDI convention for telemonitoring of Covid patients ended on the 30th of June 2022, but the patients can be followed yet until the 31th of August.

1.3.4. Diabetes convention (FreeStyle Libre Flash Glucose Monitoring System)

A convention between the NIHDI, the hospital (healthcare providers) and the patients about the multidisciplinary care program of self-management of diabetes mellitus in children and adolescents.

Aim of the study: The patient and/or his or her relatives, in collaboration with the diabetes team, take responsibility for all aspects of diabetes treatment, including the management of the disease with the aim of avoiding or delaying the complications of diabetes. It includes blood glucose determination, glycosuria, ketonuria and ketonemia, adjustment of insulin doses in relation to the results of the measurements, the technique of insulin administration (by injections or insulin pump), identification of signs of hypo- or hyperglycaemia and their correction, integration of exercise into the insulin and meal plan, establishment of a balanced diet.

Healthcare process: This multidisciplinary care program of self-management of diabetes mellitus begins during a hospitalisation, where the patients learns all the aspect of the management with the multidisciplinary



team. The patient has to have minimum 3 physical contact with his pediatrician, and a therapeutic non-medical member of the diabetes team.

The equipment to the beneficiary (and/or his close relatives) to measure his blood glucose, glycosuria, ketonuria and ketonemia or for his insulin therapy (if necessary, via an insulin pump), cannot be dissociated from the intervention of the team, i.e. the education and the support of the patient and/or his immediate entourage, in order to teach them the technique of blood sugar measurement and to monitor and maintain this knowledge.

Healthcare professionals involved:

The diabetes team, composed by one or more pediatrician specialized in diabetology, a nurse, dietician, social worker, psychologist, secretary,

Mobile App: The equipment that is provided to the patient to measure blood glucose must be CE marked.

A list of devices is mentioned in the convention:

- The *FreeStyle LibreLink* (Abbott) application allows data to be collected from the FreeStyle Libre sensor using a smartphone via a simple contact connection (NFC). The FreeStyle Libre system is reimbursed under the diabetes convention.
- GlucoMen Day CGM (Menarini)
- Guardian Connect Systeme (Medtronic)

- Dexcom G5® Mobile continue glucose monitoring system (Zkope healthcare)
- Guardian 4 Sensor (Medtronic)

Another reference is set for other devices, not yet identified. But in practice, we see that other apps are used. Some examples (non-exhaustive) are cited: the app Carby, the app mysugr (free basic version), the sensor from the AccuCheck firm, app Mijn Eetmeter (free version), the app Fat Secret or even the app Sweetbee carb, for patients with an insulin pump to learn to count their carbohydrates. Digital platforms also are used as Glooko or platforms of Medtronic (WeCare) or Abbott for reading glucometers and glucose sensors.

Budget: Nomenclature codes have been created for the diabetes team. The NIHDI pays a **fixed amount per day** directly to the center and this covers all the material required including (listed) finger pricks and sensors (which might include the use of apps, platform software). Mobile apps are not mentioned in this convention, as they are considered to be part of the sensors they are linked to. These apps have therefore not been evaluated.

<https://www.inami.fgov.be/fr/themes/cout-remboursement/maladies/endocriniennes-metaboliques/Pages/diabete-intervention-couts-suivi-enfants-adolescents-centre-specialise.aspx>

https://www.inami.fgov.be/SiteCollectionDocuments/convention_diabete_autoregulation.pdf



2. ADDITIONAL COUNTRY SPECIFIC INFORMATION

2.1. The Netherlands- Health Inspection assessment of adult telemonitoring

Table 1 – Health topics for the Health Inspection assessment of adult telemonitoring

Standards	Assessment criteria
Person-centred care	
The care provider provides care that meets the current care needs of the patient.	1. The healthcare provider has clear inclusion and exclusion criteria for patients established for the application of telemonitoring. Expertise, skill, and motivation for performing telemonitoring are at least part of this. 2. The care provider has demonstrably ensured that a care provider performed an intake interview with the patient prior to the treatment/telemonitoring. At least the following is discussed: - Determining care needs; - Drawing up a treatment/care plan that fits the needs; - Determining whether telemonitoring is an option given the inclusion and exclusion criteria; - Informing the patient about the care process 3. The healthcare provider shall establish ranges of physiological parameters (if necessary per individual patient).
The healthcare provider involves the patient intensively in the development and implementation of the treatment plan.	1. The primary care practitioner ensures that the patient is informed in such a way that the patient can make a considered choice about participating in telemonitoring. 2. The primary care practitioner checks whether the patient explicitly agrees to the treatment plan (informed consent) and records this.
The healthcare provider makes clear for each patient where and with whom he or she can make contact during the care trajectory.	The primary care provider ensures that it is always clear for the patient: - Who bears the ultimate responsibility - Who is charged with the coordination of the care - Who is the point of contact in case of questions
The healthcare provider ensures that the patient understands and follows the instructions for telemonitoring and follows them.	The care provider evaluates after intake and thereafter regularly whether patients have received sufficient explanations to understand and use the telemonitoring.
Management of the organisation	
The healthcare provider has a protocol for telemonitoring.	The care provider has a protocol for telemonitoring, which include: - the objectives of telemonitoring; - the tasks, powers and responsibilities of those involved; - the quality requirements for the processes; - the skills of the care providers.
If the healthcare provider is to provide the telemonitoring in a partnership with other healthcare providers, he will make clear	1. The healthcare provider has demonstrably clear agreements with other healthcare providers involved about the division of tasks and responsibilities for the care provision. 2. The healthcare provider can demonstrate that where necessary for the provision of care consultation and/or evaluation takes place with the other care providers involved.



agreements on the division of tasks and responsibilities for the provision of care.

The healthcare provider ensures the systematic monitoring, control, and improvement of the quality of the telemonitoring.

1. The healthcare provider evaluates the process and the outcomes of telemonitoring in relation to the set goals.
2. The care provider adjusts the working method if the quality objectives are not met.

Recording and sharing of information

The healthcare provider shall ensure that the quality of information in telemonitoring is sufficient to achieve the set objectives.

1. The healthcare provider will ensure that the patient can correctly and reliably collect the telemonitoring data and pass them on to the care providers involved in the treatment.
2. The healthcare provider shall ensure that the data required for the treatment are sufficiently accessible to the care providers involved in the treatment and if necessary available in the electronic patient file.

If the healthcare provider is to provide the telemonitoring in a partnership with other healthcare providers, then the healthcare provider will coordinate the care with the relevant care providers in the partnership and exchanges relevant information with them.

1. In the event of treatment by several care providers there is a joint treatment plan.
2. In case of treatment by multiple care providers/healthcare providers, there is an integrated patient file that can be accessed by all healthcare providers involved and supplemented, or - if there is none - at least all involved care providers have access to the relevant information from the file.

The patient can exercise his/her rights about the patient file.

1. The patient can inspect the file (also electronic) and can obtain an (electronic) copy of it.
2. The healthcare provider asks the patient for permission to the exchange of data if this is required.
3. The healthcare providers inform the patient about the information they exchange with other healthcare providers.

Safety

The healthcare provider shall ensure the safe introduction of new interventions, such as telemonitoring.

1. The executive board and the staff board are aware of the telemonitoring and have given permission.
2. The healthcare provider conducts an appropriate prospective risk assessment and considers in what way the risks can be reduced or can be reduced or eliminated.
3. The healthcare provider establishes that the care providers are competent and skilled are, for example through mandatory training courses.

The healthcare provider ensures that the equipment and software for telemonitoring function properly.

1. The healthcare provider shall ensure that equipment, software, and technical infrastructure meet and continue to meet the requirements that are necessary for performing the telemonitoring.
2. The healthcare provider shall implement procedures to ensure the continuity of telemonitoring.

The healthcare provider shall ensure appropriate information security around telemonitoring.

- The care provider provides sufficient measures in the field of information security in line with EN 7510. This means at least that:
- the healthcare provider applies 2-factor authentication for the applications used in telemonitoring;
 - the healthcare provider ensures appropriate authorisations;
 - the healthcare provider ensures control of audit logs;
 - the healthcare provider ensures appropriate protection of information in electronic messages;

**Table 2 – Guidance for the evaluation of digital applications, algorithms, and artificial intelligence 'Kenniscentrum Digitale Zorg Nederland'**

Evaluated aspect	Source of information
0. General information about the application and the assessor	
0.1 Application (trade name)	CE Declaration of Conformity
0.2 supplier	CE Declaration of Conformity
0.3 Developer	CE Declaration of Conformity
0.4 Type of application / algorithm (robotics, image, speech, text, prediction, chatbot, Augmented Reality, Virtual Reality).	CE Technical File
0.5 Field of care: prevention, triage, diagnostics, treatment (physical, care at distance, virtual care), other.	CE Clinical Evaluation Report
0.6 Brief description of the application (what does it do? What type of care does it contribute to? What is the health claim?).	CE Clinical Evaluation Report
0.7 Stage of product development (development), validation, implementation, start-up/scale-up.	supplier
0.8 Number of current users per type (e.g. health professionals, patients) and by institute (names)	supplier
0.9 Which documents have been submitted for the assessment and to which parts of the evaluation do they refer (add the numbers of the evaluation number in the title of the document)?	supplier
1. Risk assessment	
1.1 Do the users or target group belong to one of the following groups: children, elderly, low literacy?	supplier
1.2 If the application or algorithm does not work as described, can the consequence for the user be mortality or severe morbidity? To which evidence does this refer (Medical Device Regulation (MDR))?	CE Clinical Evaluation Report -MDR
1.3 Does the application or algorithm independently diagnose or give medical advice to the patient? (Clarification: in the end the health carer is responsible for the use of an application or algorithm for a patient).	CE Technical File
1.4 Where in the application and in how far is a degree of uncertainty possible? Examples: input data, decision rules, AI, interpretation, output, medical evidence	CE Clinical Evaluation Report
1.5 Did the ethical perspective play an explicit role in the development of the application? Why or why not?	supplier
1.6 Did the organisation perform a prospective risk inventory exploring risk and management strategies? If yes, please add. If no, why?	supplier
2. End user	
2.1 Does the application demonstrably offer the functionality that the patient expects, if so, consult evidence/reviews? If there were negative reviews, how did you deal with them?	supplier
2.2 Does the application demonstrably offer the functionality that the healthcare provider expects, if so, please consult evidence/evidence/reviews? If there were negative reviews: how did you deal with this?	supplier
2.3 To what extent were end users (patient/family/care provider) involved in the development of the application?	supplier
2.4 Does the supplier expect that all potential users can install and use the application independently?	supplier
2.5 Integration possibilities: For which purposes has the application been made interoperable and how has interoperability been designed?	supplier
2.6 How is the instruction for the users of the application organised?	supplier



2.7 Is the application easy to use for the above target groups? What is the evidence of this?	supplier
2.8 Can the application or the algorithm be used (partly) offline?	supplier
2.9 Is it possible to contact the provider directly and how is this organised and/or is a complaints settlement procedure offered?	supplier
2.10 Via which devices and which operating systems is the application accessible?	Supplier
2.11 What is the procedure (including frequency) for maintenance of the software? Can the application continue to be used during maintenance	supplier

3. Algorithms and artificial intelligence

3.1 Demonstrate that test results are reproducible for all previously mentioned target groups?	CE Clinical Evaluation Report and/or advisory reports (based on state of the art science and practice) Knowledge organisations
3.2 Is the quality of the data used optimal? Please justify.	CE Clinical Evaluation Report; Possibly NDA is possible for assessment of the algorithm Prospective risk inventory (PRI)
3.3 How reliable is the algorithm, also in comparison with other algorithms or care as usual?	CE Clinical Evaluation Report; Possibly NDA is possible for assessment of the algorithm Prospective risk inventory (PRI)
3.4 What type of risk analysis has been performed to identify a potential negative impact?	CE Clinical Evaluation Report; Possibly NDA is possible for assessment of the algorithm Prospective risk inventory (PRI)
3.5 What is the intended use of the application or the algorithm and is the risk acceptable in the light of the intended use?	CE Clinical Evaluation Report
3.6 Is a process in place to detect, analyse and correct erroneous advice and decisions?	supplier
3.7 Has medical knowledge (e.g. from medical doctors) been used in the design of the algorithm?	supplier
3.8 Which standards and/or guidelines does the outcome relate to?	supplier
3.9 Can the generated advice or decisions be traced and understood by healthcare professionals?	supplier
3.10 Is the generated advice or decision approved by a healthcare professional? And can it be explained how this translates into practice?	supplier
3.11 Has it been determined whether the algorithm could generate an unwanted increase or decrease in care use that is undesirable for the patient/care provider? If so, to what extent?	supplier
3.12 Is the European Commission's checklist for reliable artificial intelligence used?	supplier

4. Validation

4.1a Has the algorithm or application been scientifically validated? Are there publications in reputable journals (impact factor)?	supplier
4.1b If applicable, how was the split made between train, test, and validation Data?	supplier
4.2 What level of evidence was obtained in the validated target group(s) as an outcome?	CE Clinical Evaluation Report
4.3 What is the PROBAST (Prediction model Risk Of Bias ASsessment Tool) rating and/or Transparent Reporting of a multivariable prediction model of Individual Prognosis Or Diagnosis (TRIPOD) evaluation?	Supplier and/or consortium (e.g. NFU or other knowledge centre)
4.4 Are the test results validated for the target population?	supplier
4.5 Is the application or algorithm endorsed by a scientific professional association?	supplier

5. Quality & affordability of care



5.1 How does the application contribute to the quality of care?	Supplier, MDR, CE
5.2 How does the application contribute to efficient and sustainable replacement of care? How do you demonstrate this?	Supplier, consider cost-effectiveness study or cost analysis of a business case
5.3a What are the inclusion and exclusion criteria? Are there clear start and stop criteria for included patients and are they verifiably applied by the healthcare provider?	supplier
5.3b Are thresholds applied for parameters at which alarm bells go off?	supplier
5.4 In what way does the care (via the app/algorithm) comply with the state of science and practice?	supplier
5.5 How does the application contribute to health gains?	supplier
6. Data and security aspects	
6.1 Is the data stored encrypted (if so, at what level disk/database/application)?	Supplier and ISO/NEN
6.2 Is data transport encrypted?	Supplier
6.3 Is the application only accessible with multi factor authentication? If yes, which factors? If not, what is the reason for not doing so?	Supplier
6.4 In which country is the server where the data is stored?	Supplier
6.5 Is there any transfer of data to third countries within the meaning of the AVG (whereby transfer is also understood to mean providing access to)?	Supplier and DPIA
6.6 Is the data on the device and/or in the database separated from other applications/clients?	supplier
6.7 Is the patient asked to provide access to data on the device? What is the disclaimer of the data? How is the data processed?	Supplier
6.8 Is the data only accessible to the user and/or after permission also to the care provider?	Supplier and/or investigator file if research
6.9 Are tests conducted with anonymous data?	supplier
6.10 How is access to the data protected with additional measures for administrators?	supplier
6.11 Is the supplier's security policy based on a generally accepted standard (e.g. ISO 2700x)?	supplier
6.12 With what regularity is a penetration test performed on the application? And what has been done with the most important findings?	Supplier and Penetration test (Pentest) report
6.13 For how long is data storage guaranteed if the provider (manufacturer/supplier/provider) disappears?	supplier
6.14 Does the supplier provide a TPM (e.g. ISO, ISEA, SOC2)?	supplier
6.15 Has a privacy impact assessment been made? (Can this be submitted for inspection)?	supplier
6.16 Which personal data are processed?	supplier
6.17 Who is controller, who is processor?	supplier
6.18 Does the processor make use of sub-processors?	supplier
6.19 Is there a clearly readable privacy notice?	supplier
6.20 At what point is the data subject made aware of the above notice?	supplier



6.21 Is consent requested for data collection? And if so, how can this consent be withdrawn?	supplier
6.22 Is consent asked for the use of data by third parties?	supplier
6.23 Is consent asked for the use, modification, deletion of data entered or issued?	supplier
6.24 If consent is not sought for the above purposes, what is the basis of the processing?	supplier
6.25 How long will personal data be kept?	supplier
6.26 For what other purposes is data used other than for the operation of the application? (E.g. development purposes)	supplier

7. General terms and conditions and other laws and regulations

7.1 Please submit the General Terms and Conditions for inspection.	General conditions
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8. Certification

8.1 Are the application and any connected devices CE certified and under which MDR class? If so, when, and if not, why not?	CE Declaration of Conformity
8.2 Is the device also certified outside Europe?	supplier
8.3 Is there a quality assurance system at company level?	supplier

9. Financing

9.1 What is the revenue model behind the application?	Supplier; business case
9.2 Is there a claim title? If so, which one?	
9.3 Is/are alternative form(s) of financing possible for the deployment of the application in the intended care pathway?	

10. Organisational impact

10.1 What will the healthcare provider using the application have to change in its processes, culture, training, and organisation of work?	Supplier; Implementation plan or impact analysis
10.2 What aspects play a role in assessing whether the healthcare provider can successfully implement the changes mentioned in 10.1?	supplier
10.3 How does the manufacturer support the care provider during implementation?	

11. Platform

11.1 What types of parties use the platform? (Patients, care providers, digital care applications, researchers, insurers,...)	supplier
11.2 How is it determined for each type of party whether they will have access to the platform?	supplier
11.3 Is this admission process transparent for all participants in the platform? Why or why not?	supplier
11.4 Does the platform use a search algorithm to disclose applications to participants?	supplier
11.5 If so, is a taxonomy or ontology used?	supplier
11.6 Is communication between participants on the platform moderated?	supplier
11.7 Does the platform provide generic services, such as data storage, information security, single sign-on, to connected Digital Care applications? Why or why not?	supplier



11.8 Is personal data and special personal data shared with other applications within the platform? Please explain.

supplier

11.9 Is it possible for end users to use multiple applications of the platform simultaneously?

supplier

Table 3 – DMTs used as part of existing care reimbursements - performances

Type of care	Examples
General practitioners	A messenger 'shared' consultation (meekijkconsult) platform is used for practitioners to present a patient's case online. (Siilo 2020) A group of specialists, also linked to the platform, provide written online feedback. Menzis (health insurer) started reimbursement in 2020 for a period of three years. The practitioner pays a monthly user fee which is reimbursed by the health insurer. The aim is to reduce the referrals to specialists by 30%. (Menzis 2020)
Secondary Prevention	For diabetes patients, the MiGuide app offers a mobile lifestyle coach on the aspects diet, exercise, glucose, and relaxation. The patient's practitioner's file is linked to the app. Lifestyle advice is tailored to the personal patient information. No direct communication is available with the practitioner, but the use of the app is shared with the practitioner and can be reviewed at the consultation. The app's advice is based on the Dutch Practitioners guidelines (NHG) and in case of discrepancy between patient info and the guidelines (algorithm), the patient receives a yellow priority message.
Gastroenterologists	MijnIBDcoach is a telemonitoring coach for patients with inflammatory bowel disease and irritable bowel syndrome. The patient's specialist health file is shared through the coach. Treatment advice is given based on the symptoms reported by the patient in the coach app. (Federatie Medisch Specialisten 2021) On the one hand, the alarm is triggered by the algorithms, which can, for example, recognise a negative trend in complaints and symptoms; even before a single complaint/symptom scores outside the bandwidth. The other way causing an alarm are the limit values that are set for some measurements by the care providers; these are thus set individually. Examples are blood pressure values or weight. Other limit values are fixed because they are determined by guidelines; for example, a pain score or a saturation measurement. The aim of MijnIBDcoach is to improve the treatment of patients with chronic inflammatory bowel disease through early detection of signs that may indicate activation of the disease. It has been documented that MijnIBDcoach leads to fewer hospital admissions and fewer outpatient visits with at least the same level of satisfaction in care.



2.2. Summary tables of the scope and evidence requirements by country

Table 4 – Summary countries FULL

Country/framework	Finland/Digi-HTA framework	Germany/DiGA Fastrack framework	France/early access programme for telemonitoring and DMTs with a therapeutic purpose	France - Telemonitoring list	England/ESF for DMTs*	Austria	The Netherlands / Remote monitoring of 6 indications	The Netherlands / Digital Care Evaluation Framework
Organisation/agency	Centre for Health and Technology, The Finnish Coordination Centre for Health Technology Assessment (FinCCHTA) and the University of Oulu's MIPT	Federal Institute for Drugs and Medical Devices (BfArM)	Haute Autorité de santé (HAS)	Haute Autorité de santé (HAS)	NICE	AiHTA	Dutch Healthcare Authority	Knowledge Centre for Digital Care/ Health Insurers
Nature of evaluation	Voluntary	Mandatory if wanting reimbursement	Mandatory	Mandatory	Mandatory	Under development	Mandatory for the overall care pathway	Voluntary
Purpose	HTA (not formally linked to reimbursement decisions)	Reimbursement	Reimbursement	Reimbursement	Reimbursement	To be linked to reimbursement	Evaluation of meaningfulness within a pathway (not linked to reimbursement pathway). Healthcare providers are obliged to set their quality criteria before prescribing reimbursed telemonitoring; these fall under the control of the Health Inspection.	The process leads to a DMT implementation step defining the DMT value which can result in a reimbursement contract with the insurers



Prioritisation	NA	NA	NA	So far, telemonitoring guides drafted for: chronic respiratory insufficiency, chronic cardiac insufficiency, chronic renal insufficiency, diabetes and cardiac implants	NA	Chronic diseases	ICD-10 areas that can be meaningful improved have priority: respiratory illness, cancer, cardiovascular disease, psychological illness, chronic illness	*hybrid general practice including prevention and improvement of referral to 2nd line; *patient-centred chronic care by using telemonitoring; *enabling the elderly to live independently at home for longer using digital solutions; *reducing waiting lists in the 1st line, mental health, district nursing, and long-term care by deploying digital solutions; *digital support of integrated care from 2nd line, general practitioner care, district nursing, and long-term care; *technology that prevents care (prevention for certain indications)
Temporary or permanent listing		Permanent	Temporary (1 year)	3 years	Permanent	Under development	Permanent	Temporary contracts between insurer and healthcare provider
Evaluation tool/form	Checklist for manufacturers and scoring on the basis of responses.	Review and discussions	Evaluation by the CNEDiMTS	Stakeholder discussions/involvement	Evaluation by NICE and consultation of stakeholders	Evaluation and discussions with stakeholders	Evidence systematically evaluated (GRADE) for pathway with systematic review of evidence for the e-health topic; a new evaluation	Guidance questions for manufacturers with submission of documents online with feedback



guide is pending
for innovations

Definition of target product	mHealth, artificial intelligence and robotics	CE-marked devices Main function based on digital technologies Patient-centered (self use in collaborations with a HCP)	DMDs (remote medical monitoring or therapeutic). The software must process the data.	DMT (CE marked) within a pathway. The software must process the data.	Medical apps and software. Standalone or combined with other MDs or diagnostic tests	CE marked DMTs classified as DiGA available in German. Should serve a therapeutic function.	E-health, telemonitoring	Application, algorithm, or artificial intelligence e.g. robotics, image, speech, text, prediction, chatbot, augmented reality, virtual reality
Risk classes (MDR) included	All risk classes considered	Class I - IIa	All	All	All	All	Not specified	All risk classes considered
Classification of DMTs considered	NO	No further differentiation affecting evidence requirements	No categorisation made	No categorisation	Specific categorisation in tiers	Medical purpose considered in its focus	Not specified (but evidence evaluation by medical field)	No differentiation (but questions specific for algorithms and artificial intelligence, and end user at risk populations)
Categories	NA	NA	NA	NA	Tier A: System impact; Tier B: understanding or communicating; Tier C: Interventions	Only therapeutical DMD	NA	NA
Type of evaluation	Nominal. Evaluation on individual DMT	Nominal. Evaluation of individual DMT	Nominal. Evaluation of individual DMT	Generic listing conditional to meeting certain established criteria	Nominal. Evaluation of individual DMD	Nominal. Evaluation of individual DMD	Generic evaluation by medical indication	Nominal individual evaluation



Domains included	Safety Effectiveness Cost Usability and accessibility (for both end-users and healthcare professionals) Data security and protection Interoperability Technical stability	Safety & Suitability for Use, Data Protection, Information Security, Interoperability, Further Quality Requirements Medical benefit or patient relevant structural and procedural improvements	Data protection Interoperability and security Clinical effectiveness (medical benefit to the patient) or the system	Data protection Interoperability and security Clinical effectiveness (medical benefit to the patient) or the system	Clinical Effectiveness Economic Impact DTAC: Clinical safety Data protection Technical assurance Interoperability Usability and accessibility	Data protection Interoperability and security Clinical effectiveness (medical benefit to the patient) or the system	Safety Effectiveness by applying GRADE Cost Affordability and accessibility Quality of care / useful care of a care path: based on knowledge, application in practice, outcomes of care, effectiveness, cost-effectiveness, necessity, feasibility, and consistency	Risk assessment of the DMT Data and security aspects Usability and accessibility Interoperability for the end user Maintenance for the end user CE certification app and connected device Quality assurance system Organisational impact for the healthcare provider using the application (change in its processes, culture, training, and organisation of work) and how this should be assessed and supported by the manufacturer.
Evidence requirements - clinical	Decided on a case by case basis	Proof of medical benefit for patients or patient-relevant improvement of structure and processes. Study specific requirements differ for permanent listing versus temporary reimbursement (1 yr listing).	It should be presumed innovative in terms of: • clinical benefit (« bénéfice clinique ») or • improvement in organisation of care, based on the first data available and taking into account	For DMD in the 5 indications with reference guides, the latter specify the criteria the DMD need to comply with. No specific evaluation is necessary on their effectiveness or organizational impact.	Proof that using the DMT impacts on clinical management of the relevant condition or that it provides reliable test results that can be used to impact clinical management	Follows the evidence requirements of NICE (see ESF) for clinical and economic evidence. For other matters uses the DiGI-HTA and the MMA checklists	Decided on a case by case basis with a GRADE process.	Decided on a case by case basis



relevant
comparators

Types of studies	If similar products already in the market for which RCTs exist, these are also considered (Digi-similar RCTs). Effectiveness needs to be proven by studies of good quality. No specific requirements for RCTs exist. This is decided on a case by case basis and for e.g. may not be the same for a class I or class III DMT	<u>For permanent listing:</u> RCT or (if well justified) observational analytic (prospective or retrospective comparison). Stat. and clinc signif results required. <u>For temporary listing:</u> Intermediate results of RCT, results of pilot RCT or non-randomised comparative data (historical control group or intra-individual comparison). A trend for stat or clin sig. required.	Not specified. Considered on a case by case basis	Not specified	Tier C: Study design should be appropriate for the intended purpose of the DMT. RCTs would be preferable where this study design is appropriate. High quality, comparative real-world study designs may also be acceptable .	As per NICE framework	The criterion 'the state-of-the-art of science and clinical practice' considers the relative effectiveness of the new diagnosis or treatment as compared to the current standard. Aspects that are specified are: the comparator that was used for the evaluation of the intervention or treatment, the target group, the outcomes, and if the relative effect is large enough to be clinically relevant. The standard principles of evidence-based	Decided on a case by case basis
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medicine are applied in this process e.g. GRADE recommendations. The evidence is reviewed systematically in the context of this process.

Use of Real World Data

RWE has started being considered

Not mandatory but possible to use RWD to show the positive effect of the application. No specific guidelines on how to use it exist to this date

Not specified

NA

Required to prove evidence that the claimed benefits can be realised in practice

As per NICE framework

Not specified

Not specified



Evidence requirements - cost	Scoring based mainly on comparisons with standard practice (eg without the DMT). CE analysis not required. Mostly based on pricing and general costing questions	Not required as part of the fast track - free pricing for a year then pricing negotiations	Not part of the CNEDiMTS evaluation	Not required as part of the evaluation by HAS	For all: budget impact analysis For DMTs with higher financial risk: Cost-effectiveness analysis	As per NICE framework	Not specified	Quality & affordability of care must be assessed by: • how the application contributes to the quality of care and to efficient and sustainable replacement of care; • the way care (via the app/algorithm) complies with the state of science and practice; • how the application contributes to health gains; • and possibility of alternative form(s) of financing.
Specific requirements for Machine Learning algorithms - Artificial intelligence	A specific section with questions is dedicated to AI while a further section covers specific questions for robotics	No specific requirements	Specific requirements established for AI	Specific requirements established for AI	Not specified	Not specified	Not specified	It should be determined whether the algorithm could generate an unwanted increase or decrease in care use that is undesirable for the patient/care provider.

Table 5 – Summary countries Short Nominal

Frameworks for the reimbursement of DMTs - nominal evaluation						
Country/framework	Finland/Digi-HTA framework	Germany/DiGA Fastrack framework	France/early access programme for telemonitoring and DMTs with a therapeutic purpose	England/ESF for DMTs	Austria	The Netherlands / Digital Care Evaluation Framework



Organisation/agency	Centre for Health and Technology, FinCCHTA and University of Oulu's MIPT	Federal Institute for Drugs and Medical Devices (BfArM)	Haute Autorité de santé (HAS)	NICE	AiHTA	Knowledge Centre for Digital Care/ Health Insurers
Nature of evaluation	Voluntary	Mandatory for reimbursement	Mandatory	Mandatory	Under development	Voluntary
Purpose	HTA (not formally linked to reimbursement)	Reimbursement	Reimbursement	Reimbursement	To be linked to reimbursement	Possible reimbursement contract with insurers
Prioritisation	NA	NA	NA	NA	Chronic diseases	6 different fields: eg GP including prevention and referral to 2nd line; Telemonitoring for patient-centred chronic care; ...
Temporary or permanent listing	NA	Permanent	Temporary (1 year)	Permanent	Under development	Temporary contracts between insurer and healthcare provider
Evaluation tool/form	Checklist and scoring	Review and discussions	Evaluation by the CNEDiMTS	Evaluation by NICE and consultation of stakeholders	Evaluation and discussions with stakeholders	Guidance questions for manufacturers with feedback
Target	mHealth, AI and robotics	CE-marked DMTs; main function based on DMTs; patient-centered (self use)	DMDs (remote medical monitoring or therapeutic)	Medical apps and software. Standalone or combined with other MDs or diagnostic tests	CE marked DMTs classified as DiGA available in German. Should serve a therapeutic function.	App, algorithm, or AI e.g. robotics, image, speech, text, prediction, chatbot,...
Risk classes	All	Class I - IIa	All	All	All	All risk classes considered
Classification	NO	No further differentiation affecting evidence requirements	No categorisation made	Specific categorisation in tiers	Medica purpose considered in its focus	No differentiation (but questions specific for algorithms and AI)
Categories	NA	NA	NA	Tier A: System impact; Tier B: understanding or communicating; Tier C: Interventions	Only therapeutical DMD	NA
Type of evaluation	Nominal. Evaluation on individual DMT	Evaluation of individual DMTs	Nominal. Evaluation of individual DMT	Nominal. Evaluation of individual DMD	Nominal. Evaluation of individual DMD	Nominal. Evaluation of individual DMD
Domains included	Safety; effectiveness; cost; usability and accessibility; data security and protection ; interoperability; technical stability	Safety & suitability for Use, data Protection, security, interoperability, quality; effectiveness/efficiency	Data protection; interoperability and security; clinical effectiveness (medical benefit to the patient) or the system	Effectiveness; economic Impact; DTAC; safety; data protection; technical assurance ; interoperability usability and accessibility	Data protection; interoperability and security; effectiveness (medical benefit to the patient) or the system	Risk assessment of the DMT; data and security aspects; usability and accessibility; interoperability; maintenance; CE certification; quality



						assurance system; organisational impact.
Evidence requirements - clinical	Decided on a case by case basis	Proof of medical benefit or patient-relevant improvement of structure and processes. Study specific requirements differ for permanent listing and temporary reimbursement	Must be presumed innovative in terms of: clinical benefit or improvement in organisation of care, based on 1st data available	Proof of positive impact on clinical management	Follows evidence requirements of NICE (see ESF) for clinical evidence. For other matters uses DiGI-HTA and the MMA (Moshi et al.) checklists	Decided on a case by case basis
Types of studies	If similar products for which RCTs exist, these are considered (Digi-similar RCTs). Effectiveness to be proven by studies of good quality but decided on a case by case basis (not be the same for a class I or class III DMTs)	<u>For permanent listing:</u> RCT or (if well justified) observational analytic (prospective or retrospective comparison). <u>For temporary listing:</u> Intermediate results of RCT, results of pilot RCT or non-randomised comparative data	Not specified. Considered on a case by case basis	Tier C: should be appropriate for the intended purpose of the DMT. RCTs preferable where appropriate. High quality, comparative RWD studies may also be acceptable	As per NICE framework	Decided on a case by case basis
Use of RWD	RWE considered	Not mandatory but possible to use RWD	Not specified	Required to prove evidence that the claimed benefits can be realised in practice	As per NICE framework	Not specified
Evidence requirements - cost	Mostly based on pricing and general costing questions	Not required as part of the fast track	Not part of the CNEDiMTS evaluation	For all: budget impact analysis For DMTs with higher financial risk: Cost-effectiveness analysis	As per NICE framework	Quality & affordability of care must be assessed
Requirements for Machine Learning algorithms - AI	Specific sections dedicated to AI and robotics	No specific requirements	Specific requirements established for AI	Not specified	Not specified	To determine if the algorithm could generate an unwanted increase/decrease in care use

Table 6 – Summary countries_Short generic

Country/framework	France - Telemonitoring list	The Netherlands / Remote monitoring in 6 indications
Organisation/agency	Haute Autorité de santé (HAS)	Dutch Healthcare Authority
Nature of evaluation	Mandatory	Mandatory for the overall care pathway
Purpose	Reimbursement	Possible reimbursement. Healthcare providers set quality criteria before prescribing



Prioritisation	Guides for: chronic respiratory insufficiency, chronic cardiac insufficiency, chronic renal insufficiency, diabetes and cardiac implants	ICD-10 priority areas: respiratory illness, cancer, cardiovascular disease, psychological illness, chronic illness
Temporary or permanent listing	3 years	Permanent
Evaluation tool/form	Stakeholder discussions/involvement	(Generic) evidence systematically evaluated (GRADE) for full pathway with SR review for the e-health topic
Definition of target product	DMT (CE marked) within a pathway. The software must process the data.	E-health, telemonitoring
Risk classes (MDR) included	All	Not specified
Classification of DMTs considered	No categorisation	Not specified (but evidence evaluation by medical field)
Categories	NA	NA
Type of evaluation	Generic listing conditional to meeting established criteria	Generic evaluation by medical indication
Domains included	Data protection; interoperability and security, effectiveness (medical benefit to the patient) or the system	Safety; (generic) effectiveness; cost affordability and accessibility ; quality of care: based on knowledge, application in practice, outcomes of care, effectiveness, CEs, need, feasibility, and consistency
Evidence requirements - clinical	For DMD in the 5 indications with reference guides, criteria the DMD needs to comply with. No DMD specific evaluation is necessary	Decided on a case by case basis
Types of studies	Not specified	Relative effectiveness of the (generic) remote monitoring compared to standard. Evidence reviewed systematically in the context of this process.
Use of Real World Data	NA	Not specified
Evidence requirements - cost	Not required as part of the evaluation by HAS	Not specified
Specific requirements for Machine Learning algorithms - Artificial intelligence	Specific requirents established for AI	Not specified



2.3. MMA MODULE FOR HEALTH TECHNOLOGY ASSESSMENT

Table 7 – A module which can be used in addition to existing core HTA domains to adapt HTA and/or reimbursement evaluation frameworks to assess Medical Mobile Applications*

HTA domain	HTA domain status	MMA technology-specific considerations	
		Challenge posed by MMA	MMA specific modifications and adaptation(s)
Safety		The risk of misinformation	- How the MMA output (i.e. information) affects clinical decision making regarding management of a patient's condition
Cost-Effectiveness (in fee-for-service model)		Technological evolution	- Considerations of applicability of the system, platform, licensing, attachable hardware, and versions of the MMA to those that would be used in the health system - Unit costs including MMA costs and in-app purchases
Organisational aspects		Digital health literacy	- The training/education (i.e. digital literacy) which may be needed for the user(s) (i.e. medical practitioners, patients, caregivers) to effectively utilise the MMA. Examples include: • Continual professional development (CPD) courses for medical practitioner(s) to effectively learn how to utilise and recommend MMAs in clinical practice • Education that patient(s) have to undergo to effectively learn how to utilise MMAs
		Responsibility	- Accreditation that may be needed for professionals (i.e. medical practitioners, allied health workers, technicians) to prescribe and/or use the MMA
		Connectivity	- The MMA interaction with current health informatics systems (i.e. hospitals and surgeries). Examples of health informatics systems include, but are not limited to, <i>PROCURA</i> and <i>Enterprise patient administration system (EPAS)</i>
		Technological evolution	- How adopting the MMA could alter the current utilisation of services (i.e. workload, workforce, compliance, etc.) - How adopting the MMA will change treatment location (i.e. home-based, rural, remote, hospital, clinic, etc.)
		Patient privacy and confidentiality	- The presence of a privacy policy - The contents of a privacy policy
Ethical aspects		Equity concerns	- Considerations include user disability (how could users' with blindness use the MMA), language (users' who have English as a second language), age, literacy, socio-economic status, etc.
		Access concerns	Considerations include the cost of platform, in-app purchases, cost of MMA, geographical location, internet availability etc.
		Technological evolution	Any possible conflicts of interest (i.e. developer or owner affiliation, sources funding, third-party sponsorship, etc.)
Legal aspects		Responsibility	- Litigation risks to the relevant person(s) associated with the use or recommendation of the MMA for healthcare practitioners (i.e. GPs, allied health workers, etc.) - How insurance(s) (i.e. professional indemnity, life, health, income) for all stakeholders (i.e. patients, medical professionals, developers) could be affected through use or recommendation of the MMA - How possible professional registrations could be affected through the use or recommendation of the MMA (e.g. for medical practitioners with AHPRA) - Clarify which party owns the data related to the MMA (i.e. patient, third party, medical practitioners) - Clarify around which party (i.e. manufacturer, medical practitioner who prescribed it) is responsible for the medical advice provided by the MMA - Clarify around which party (i.e. manufacturer, medical practitioner, app developer) is responsible for monitoring and reviewing the patient data entered into the MMA
		Reappraisal	- Post-market data that requires a full review of the effectiveness and safety of an MMA. These are performance data that alter the effective measures of the MMA (i.e. inferior or superior to the original measures stated in the original HTA) and/or which change the harms posed by the MMA (i.e. inferior or superior to the original measures stated in the original HTA) - How the manufacturer plans to monitor the MMA's performance data (i.e. data includes user feedback, complaints, and adverse events, real-world data, etc.) - How the data collection implemented has the least user burdensome approach to collect the MMA's performance data - How the post-market data could be used to enable or disable new MMA functionalities (i.e. addition or removal of functionalities stated in the original submission, etc.) - How post-market data could affect the MMA's cost-effectiveness, safety, effectiveness - How post-market data could affect the ethical, legal, and/or organisational concerns associated with the MMA
Post-market monitoring		Reappraisal	- Post-market data that requires a full review of the effectiveness and safety of an MMA. These are performance data that alter the effective measures of the MMA (i.e. inferior or superior to the original measures stated in the original HTA) and/or which change the harms posed by the MMA (i.e. inferior or superior to the original measures stated in the original HTA) - How the manufacturer plans to monitor the MMA's performance data (i.e. data includes user feedback, complaints, and adverse events, real-world data, etc.) - How the data collection implemented has the least user burdensome approach to collect the MMA's performance data - How the post-market data could be used to enable or disable new MMA functionalities (i.e. addition or removal of functionalities stated in the original submission, etc.) - How post-market data could affect the MMA's cost-effectiveness, safety, effectiveness - How post-market data could affect the ethical, legal, and/or organisational concerns associated with the MMA

HTA domain	HTA domain status	MMA technology-specific considerations	
		Challenge posed by MMA	MMA specific modifications and adaptation(s)
Description and technical characteristics	Mandatory	Operating system(s) for MMA	- Operating systems of the MMA (i.e. Android, iOS, etc.)
		Operating platform(s) for MMA	- Operating platforms of the MMA (i.e. smartphone, tablet, smartwatch)
Current use of the technology		Rationale for use	- The intended purpose of the MMA (i.e. diagnose, treat, inform clinical management, clinical management) - The healthcare condition or situation that the MMA addresses - MMA input (i.e. image, physiological status, symptoms, etc.) - MMA algorithm (i.e. equations, analysis engine model logic, algorithm, etc.) - MMA output (i.e. inform, treat, diagnose)
		Potential software changes (i.e. updates)	- Post-market software changes, that do not require the re-evaluation of an MMA and are corrective, preventive, adaptive, and/or perfective (see <i>Effectiveness</i> for more information) - Post-market software changes that do require a re-evaluation of the effectiveness and safety of an MMA and which enable or disable new MMA functions (see <i>Effectiveness</i> for more information)
Effectiveness		Accuracy (i.e. constant error)	- Closeness of the output to the true value to the MMA's output - Accuracy measures the effect of software errors on the MMA output - Example: In psychometrics, accuracy is the degree to which test scores are supported by evidence and theory.
		Configuration	- The MMA's ability to withstand user configuration in an unintended way (i.e. results of <i>fuzzing</i> or <i>fuzz testing</i>) - Limitations of the MMA (i.e. assumptions, data quality, algorithms)
		Communication and display	- The design of the MMA user interface (i.e. level of complexity, type of platform, how information is displayed, etc.) - The appropriateness of the MMA interface as a means of information display (i.e. language translation, units displayed, clarity, etc.) - The MMA's ability to communicate the relevant information (i.e. data quality, network availability, correct installation, etc.)
		Cybersecurity and connectivity	- Formalised and safe methods have been implemented to convert, transmit, and/or store MMA data (i.e. results of <i>fuzzing</i> or <i>fuzz testing</i>) - Users can safely implement information security updates - System supports ensure protection of MMA system information - MMA software adheres to robust programming principles (i.e. paranoia, stupidity, dangerous implements, cannot happen) - Balances the availability of timely information and against privacy and security (i.e. results of <i>fuzzing</i> or <i>fuzz testing</i>) - How MMA integrates with other software (i.e. results of <i>fuzzing</i> or <i>fuzz testing</i>) - The need for MMA security software to be updated so that it can be used alongside other systems, applications or in operating environments (i.e. results of <i>fuzzing</i> or <i>fuzz testing</i>)
		Potential software changes (i.e. updates)	- Adaptive software changes (i.e. maintains software with dynamic environment) - Perfective software changes (i.e. recoding to improve performance) - Corrective software changes (i.e. corrects problems) - Preventive software changes (i.e. corrects latent faults before they cause operational problems)
		Precision (i.e. variable error)	- Under unchanged conditions, the degree to which the recurrent measurements input into the MMA generates the same output (e.g. reproducibility, consistency). - Example: in psychology precision is degree in which two or more of measurement of the same tool consistently arrive at the same result.
Analytical validity			- MMAs ability to reliably and accurately produce the intentional output from the input data - The algorithm used by the MMA is a recognised standard (the current standard of care or described in the literature (i.e. insulin dosing)) - MMA accuracy is relative to reference standard (i.e. <i>International normalisation ratio (INR)</i>) - MMA comparable to another software or device that has an association between the software output and a health outcome



HTA domain	HTA domain status	MMA technology-specific considerations	
		Challenge posed by MMA	MMA specific modifications and adaptation(s)
Social aspects	Optional	None	- How the use of the MMA may affect the patients' caregiver(s), including relationships with medical professionals - How the use of the MMA may affect the users' relationships (i.e. family dynamics, friends, and other relevant social relations) - How the MMA may benefit patient autonomy

APHRA, Australian Practitioner Regulation Agency; GP, General practitioner; HTA, Health technology assessment; MMA, Mobile medical applications.



3. IDENTIFIED EXAMPLES OF DMT EVALUATED IN OTHER COUNTRIES

The 62 DMTs that were initially selected by the study team are:

- 38 DMTs reimbursed in Germany under the DiGAs status:

CANKADO PRO-React Onco ; Cara Care für Reizdarm ; companion patella powered by medi - proved by Dt. Kniegesellschaft ; deprexis (also reimbursed in FR) ; Elevida ; Endo-App ; HelloBetter Diabetes und Depression ; HelloBetter Panik ; HelloBetter ratiopharm chronischer Schmerz ; HelloBetter Stress und Burnout ; HelloBetter ; Vaginismus Plus ; Invirto- Die Therapie gegen Angst ; Kalmeda ; Kranus Edera ; Mawendo ; Meine Tinnitus App - Das digitale Tinnitus Counseling ; Mindable: Panikstörung und Agoraphobie ; neolexon Aphasie ; NichtraucherHelden-App ; Novego: Depressionen bewältigen ; Optimune ; Oviva Direkt für Adipositas ; PINK! Coach ; re.flex ; Selfapys Online-Kurs bei Depression ; Selfapys Online-Kurs bei Generalisierter Angststörung ; sinCephalea – Migräneprophylaxe ; somnio ; velibra ; Vitadio ; Vivira ; Vorvida ; zanadio ; ESYSTA App & Portal – Digitales Diabetesmanagement ; M-sense Migräne ; Mika ; Rehappy ; Selfapys Online-Kurs bei Panikstörung ;

- 24 DMTs in countries other than Germany or covered by some sickness funds in Germany (not evaluated as part of the fast track for DiGAs):

Sleepio (UK) ; Superbrains (NL) ; Zio XT (UK) ; Decode (UK) ; MyCOPD (UK) ; Kaia (DE not as DiGA) ; Telemonitoring for COPD (NL) ; Moovcare Poumon (FR) ; Skin vision (NL, UK, DE not as DiGA) ; Kaiku (FIN) ; DGLB1 (FR) ; DiabLive (DE) ; MiGuide (NL) ; Mysgr (DE not as DiGA) ; MijnIBDcoach (NL) ; Evondos Dosing robot (FIN) ; Indego Exoskeleton (FIN) ; Lokomat (FIN) ; Hip airbag (NL) ; Suvanto Care (FIN) ; Unipercare (FIN) ; Siilo Messenger (NL) ; Zorgrobot Tessa (NL) ; ADA (DE not as DiGA)

4. QUESTIONNAIRE USED FOR THE STAKEHOLDERS CONSULTATION

PART 1: Scope of a future Belgian Framework

Please note that the focus of this KCE survey is limited to

Digital medical technologies (DMTs) categorised as medical devices (MDs), such as apps, web browser-based (and other software-based) solutions, used with or without sensors or other non-invasive wearables.

AND

Used as support to diagnose, (tele)monitor, treat, or alleviate disease, injury, or disability, employing their specific digital functions.

AND

Used directly by patients, in consultation with healthcare professionals or by capturing patients' data to be shared with healthcare professionals.

Excluded:

- Medical devices for exclusive use by healthcare professionals (e.g. electronic prescribing systems that provide patient-level advice on prescribing)
- Robots
- Digital technology for exclusive use by patients, without any involvement of a healthcare professional or medical follow-up
- Apps used for primary prevention (e.g. apps for weight loss, monitoring fitness, well-being) or not categorised as MD (including diary-type of apps without alert functions or any data processing).

1. Do you agree with this focus?



Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your answer

- If you disagree, please list any aspects that in your view, should be excluded, or any additional aspects that should be considered.

2. In your view, should a new framework **focus initially on certain types of DMTs** before including others (e.g. diagnostic, monitoring, therapeutic...)?

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your answer

3. Should a new framework **focus initially on high-burden diseases or unmet-need fields** and then progressively consider the inclusion of others?

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your answer

E.g. In France telemonitoring guides have been drafted for chronic respiratory insufficiency, chronic cardiac insufficiency, chronic renal insufficiency, diabetes, and a 5th guide is in preparation for cardiac implants

In the Netherlands, reimbursement (so-called “facultatieve prestaties”) is possible for 6 indications: cardiac arrhythmia, hypertension, heart failure, chest pain, chronic respiratory insufficiency, and asthma.

In the Netherlands, the Knowledge centre prioritises assessments of those DMTs for health topics with a high burden of disease, when there is a limited or anticipated shortage of healthcare personnel, and care with increasing expenses.

4. Should the framework **focus initially** (or mainly) on **chronic illnesses**?

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your answer.

E.g. In Austria, (framework under development) the focus is limited in the first instance to “therapeutic” DMTs for chronic disease.

5. Do you consider the **aspects** listed in the bullets below to be **important** for a future framework?

- **Risk category** (as set at EU level) – Note: you may consult our appendix for a definition of EU risk categories

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your answer

- **Medical purpose**: secondary prevention, diagnosis, therapy, monitoring, ...

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your answer

- **Inclusion (or not) of AI** (artificial intelligence) **algorithms**:

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your answer

- **Indication (or type of indication) for use**. E.g. prioritisation of certain illnesses with growing incidence or high mortality or morbidity such as heart disease, diabetes, or prioritisation of chronic versus acute illnesses.

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your answer

- What **other** crucial or important aspects should be considered; please specify:



6. Should a new **framework** be **limited** to **DMTs** likely to present a **low risk to users (as set at EU level)**, with high-risk DMTs following the traditional MD evaluation procedure?

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your answer

Eg. In Germany, the fast-track system is limited to DMTs CE-marked as Class 1 and 2a low risk medical devices (add link to the definition of the categories included at the end of this document).

7. Should **diagnostic tools** to be used by patients in consultation with, and prescribed by healthcare professionals be **included** in the system?

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your answer

8. The **definition** currently used **by the National Institute for Health and Disability Insurance (RIZIV-INAMI)** focuses on technology having fulfilled the conditions for level M2 of the pyramid and “*allowing a healthcare provider to diagnose a patient remotely (with transfer of data in real time), apply a therapy or monitor it through a MD designed for use by patients in their own environment*”.

- 8.a This definition **excludes DMTs to be used exclusively by patients**. Do you agree with this proposition?

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your answer

E.g. The German DiGA fast-track framework focuses on DMTs used autonomously by the patient or by the patient together with the healthcare professional (the latter only when the input of the physician has a small influence on the result. Results should come mainly from the digital functions).

- 8.b The definition currently used by RIZIV-INAMI also **excludes technology without transfer of data in real time**. Do you agree with this proposition?

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your answer

Part 2: Evidence requirements – clinical and operational

9. Should the **framework** for evaluating **monitoring DMTs** differ in its evidence requirements / procedures from the **system** for evaluating **DMTs with other** medical purposes? (e.g. a therapeutic app guiding the need to inject - and the amount of- insulin, compared to a heart rate monitoring app, with the purpose to produce a report to be discussed with the treating physician).

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your response.

- If agree (strongly agree or somehow agree), how should it differ?

10. Is your previous response **valid** for both **monitoring DMT apps** aimed at **referring a patient to a healthcare professional** (e.g. an app monitoring pre-cancerous lesions), and **monitoring DMTs interacting** with the patient treatment (e. g. an app linked to an **implanted cardiac device or to diabetes pump**)?

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your response.

11. Should the evidence requirements for evaluating **DMTs** which incorporate an **artificial intelligence (AI) component** (machine learning (ML) algorithms) **differ** to that of DMTs **without AI/ML**?

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond



Please justify your response.

- If you strongly agree or somehow agree, how should it differ?

E.g. In France DMTs both with and without an AI/ML component are considered for reimbursement. However, the Haute Autorité de Santé (HAS) drafted a table with the additional elements that need to be described for MDs using automatic learning (AI): the role of each concerned functionality, the characteristics of the exploited data, the obtained results, and the functioning modalities of the algorithm.

12. Should there be some further framework specific **sub-division in evidence requirements according to the risk** the DMTs may pose to patients, and not just limited to CE-marked risk class?

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your answer

13. In your opinion, should a new Belgian framework focus its evidence requirements not just on **medical benefits** (morbidity, mortality, or quality-of-life - endpoint categories comparable to those used in the benefit assessment of pharmaceuticals) but also consider **improvement of structure, processes or organization** (e.g. coordination of treatment procedures, alignment of treatment with guidelines, adherence...) as per the German DiGA or the French systems?

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your answer

- If agree, under what circumstances and for which DMTs should these structural/organisational outcomes be considered?

14. In your opinion, should a new Belgian framework also **consider** benefits such as **patient satisfaction, empowerment, education, distress**,...?

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your answer

- If agree, under what circumstances and for which DMTs should these soft patient benefits be considered? (eg an app for diabetes patients measuring distress as outcome).

15. Would proving a decrease in consumption of medical resources (e.g. via a reduced number of consultations or hospitalisations) be enough to be considered for reimbursement in the case of DMTs focusing purely on **monitoring “stable” chronic conditions**, based on **international clinically validated questionnaires** or tools, (eg with red flags/alerts only when certain measurement/responses indicate a problem, and not using AI algorithms)?

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

- If agree, how should such **decrease in consumption be proven?** (eg. pilot study, pre/post study, prospective observational studies, retrospective case studies or case series, ...other)
- If disagree, what **additional evidence** should be considered?

Part 3: Evidence requirements - Economic

16. In your view, should **cost-effectiveness** (measuring the incremental costs per QALY or LYG) be kept as criterion for the reimbursement of **all DMTs** (in addition to budget impact)?

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your answer

- If disagree, Should **simple costing studies** (looking at costs separately from clinical gains) be accepted in some cases (in addition to budget impact)?

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your answer

- If agree, in which cases?



Eg. In the English framework, DMTs in Tier C category expected to be cost-saving are subject to cost-consequences evidence requirements (studies looking at costs separately from clinical outcomes), as opposed to cost-effectiveness (which is only requested for cost additive DMTs).

Part 4: Evidence requirements – other aspects

17. In your view, are the current requirements to attain level M2 of the pyramid **sufficient to guarantee privacy of data and data protection**?

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your answer

- If disagree, please specify which further requirements you believe would be needed.

Part 5: Other important aspects linked to the reimbursement of DMTs

18. Should a **temporary reimbursement** category for DMTs be considered for **promising apps** for which not enough evidence exists, but for which evidence development is ongoing and can be completed within a limited time (e.g. 1 year as per the German DiGA system)?

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

- If agree, how would you **define a “promising DMT”**?
 - On the basis of **what data/evidence** should this be decided?
Please give one or two examples.
 - If disagree, why shouldn't a temporary reimbursement category be considered?

19. **Reporting of changes:** in most of the existing frameworks, (e.g. the German DiGA framework), there is an obligation to report significant changes in an app, after which a re-evaluation may be done, which can have an impact on the reimbursement status. **What types of changes** would you consider “significant” and therefore subject to a re-evaluation? Please justify your response and give one or two examples.

20. Should **reimbursement** be **considered** only **after a certain period** of use (e.g. after 1 week or 1 month), to limit reimbursement to those who use it and see a value in its use?

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

- If agree, what practical problems do you believe such implementation may bring?
- How could the previously mentioned practical problems be overcome?

21. In case of DMTs, to be used over a long-term period (not a single use DMT), should **reimbursement** be granted **at different points in time** instead of granting a single payment, in order to allow stopping reimbursement when patients stop using the app/DMT?

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your answer

22. In the NICE UK system, the DMT manufacturers must demonstrate **commitment to ongoing data collection** to show usage of the DMT in the target population as well as user outcomes (if relevant) or user satisfaction (using non-patient identifiable information) to show the ongoing value of the DMT. Should such **ongoing data collection** also be a **prerequisite** for reimbursement in Belgium?

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your answer

23. For the **evaluation of implants and medical devices** for reimbursement in **Belgium**, the time for **completion** of the procedure is set at **285 days** overall. Do you think this time should be different for the evaluation of DMTs?

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your response



Note: differences in the current frameworks for the evaluation of DMTs exists (e.g. evaluation via the German fast-track procedure needs to be completed within 90 days; in France temporary coverage for innovative MDs is decided 45 days, same delay as the fast track system for telemonitoring).

Part 6: European frameworks Pros and Cons - evidence requirements
– Note: please consult the summary table provided in the appendix for some basic information on requirements in the EU countries studies

24. Do you consider the **evidence requirements** set up in the **UK NICE Evidence Standards Framework for DMTs** as **appropriate for consideration** in a new framework in Belgium?

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your response

25. Do you consider the **evidence requirements** set up in the **French (dual) Telemonitoring list system** as **appropriate for consideration** in a new framework in Belgium?

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your response

26. Do you consider the **evidence requirements** set up in the **French (dual) fast-track system for telemonitoring and DMTs** as **appropriate for consideration** in a new framework in Belgium?

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your response

27. Do you consider the **evidence requirements** set up in the **German fast track DiGA system** as **appropriate for consideration** in a new framework in Belgium?

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your response

28. Do you consider the **evidence requirements** set up in the **Dutch framework for DMTs** as **appropriate for consideration** in a new framework in Belgium?

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your response

29. Do you consider the **evidence requirements** set up in the **Finnish Diga-HTA system** as **appropriate for consideration** in a new framework in Belgium?

Strongly agree, somehow agree, somehow disagree, strongly disagree, not qualified to respond

Please justify your response

30. How could **the appropriateness** of the **evidence** requirements linked to one of more of these frameworks be increased?

- NICE Evidence Standards Framework for digital health technologies

- French (dual) evaluation framework - Telemonitoring list

- French (dual) evaluation framework - Fast access to telemonitoring and DMTs

- German fast track DiGA system

- Dutch framework



- Finnish Diga-HTA system

Part 7: European frameworks Pros and Cons - General implementation/adoption of systems **Note: please consult the summary table provided in the appendix for some basic information on requirements in the EU countries studies**

31. If the following frameworks were to be implemented in Belgium, what would be the **main advantages** and **disadvantages/barriers** they would pose?

- NICE Evidence Standards Framework for digital health technologies
 - Advantages _____
 - Disadvantages _____
- French (dual) evaluation framework - **Telemonitoring list**
 - Advantages _____
 - Disadvantages _____
- French (dual) evaluation framework - **Fast access** to telemonitoring and DMT
 - Advantages _____
 - Disadvantages _____
- German fast track DiGA system
 - Advantages _____
 - Disadvantages _____
- Dutch framework

- Advantages _____

- Disadvantages _____

- Finnish Diga-HTA system
 - Advantages _____
 - Disadvantages _____
- Austrian (under development) framework
 - Advantages _____
 - Disadvantages _____

32. In your view, which if any are the most **important gaps** in the **summarised systems** (please consult the summary table on European frameworks to identify the possible gaps) that should be considered in the development of a new framework for Belgium?

33. Are there any important aspects you believe have been missed in this survey? If so, which ones and why do you think they are important?

34. You have reached the end of the survey. Would you like to add any information or opinion that you think could be helpful for this research project?



5. EU LEGAL FRAMEWORK REGARDING MEDICAL DEVICES

The Medical Device Regulation (MDR)^d, alongside the In Vitro Diagnostic Device Regulation (IVDR)^e, provides a harmonised regulatory framework to ensure the safety and performance of devices in the EU. The MDR is fully applicable since 26 May 2021 and the IVDR since 26 May 2022, following the transition periods. Unlike directives, regulations do not need to be transposed into national law. Therefore the MDR and the IVDR limit discrepancies in interpretation across the EU market. Compared to the former Medical Devices Directive and the In Vitro Medical Devices Directive, the MDR and the IVDR bring elevated clinical requirements, re-classified and up-classified devices and a changing role of notified bodies. In the UK, Medical Device Regulations applicable to the Great Britain market are planned to come into force by July 2024.^f Till then, transitional arrangements outline the recognition of CE marked medical devices placed on the Great Britain market.

5.1. Qualification and classification of apps and the components of the system they are part of

In the following sections we will elaborate on the qualification of the different components of the system (consisting of a wearable (and the software driving it), a processing unit and an app) in order to determine whether they fall within the field of applications of the MDR/IVDR. Another important step is the determination of the correct classification of the different parts in the

system, as this will determine which requirements need to be fulfilled for MDR/IVDR compliance.

5.1.1. Qualification of wearables

There is no legal definition of “wearables” in the EU legislation, but the European Commission proposed a definition of smart wearables in its “Smart Wearables Reflection and Orientation Paper”.^g *The paper states that “smart wearables are body-borne computational and sensory devices which can sense the person who wears them and/or their environment. Wearables can communicate either directly through embedded wireless connectivity or through another device (e.g. a smartphone). (...) Smart wearables may have control, communication, storage, and actuation capabilities.”*

The International Electrotechnical Committee (IEC)^h Standardisation Management Board Strategic Group 10 on Wearables has ongoing efforts to clarify the terminology and obtain an agreed understanding of Wearable Smart Devices. It distinguishes between the following categories of smart wearables: near-body electronics, on-body electronics, in-body electronics, and electronic textiles. Also, the Moving Pictures Expert Group (MPEG), a working group of ISO/IEC, explores new standardisation needs for wearables. They have developed a conceptual model for wearables (See Figure 3).

According to the MPEG definitionⁱ, a wearable may contain several types of sensors, integrated as a system on a module. The sensors sense physiological phenomena from the user or from surrounding environment. The wearable processes this information and acts (e.g. display some visual

^d Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117, 5.5.2017, p. 1–175

^e Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, OJ L 117, 5.5.2017, p. 176–332

^f <https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices-and-extension-of-standstill-period/implementation-of-the-future-regulations>.

^g <https://digital-strategy.ec.europa.eu/en/news/european-commission-seeks-input-reflection-and-orientation-paper-smart-wearables>.

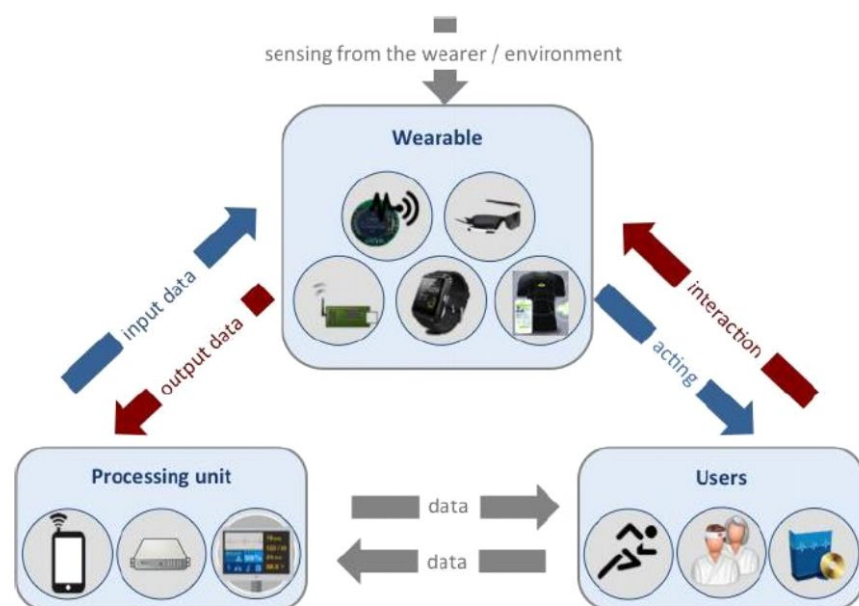
^h <https://www.iec.ch/homepage>.

ⁱ <https://mpeg.chiariglione.org/standards/mpeg-iomt/iomt-architecture-0>.



content, play some audio content, send an alert, provide force feedbacks) on the user. The user can interact with the wearable by a set of commands and may do so via the processing unit.

Figure 3 – Conceptual model for wearables



The decisive criteria to determine whether a wearable constitutes a medical device or an in vitro diagnostic medical device, is to establish whether it is **intended** to be used for one of the medical purposes in art. 2(1) MDR/2(2) IVDR (see Box 1).

Box 1 – Definition of “medical device”

“**Medical device**” means any instrument, apparatus, appliance, software, implant, reagent, material, or other article **intended by the manufacturer** to be used, **alone or in combination**, for human beings for one or more of the following specific **medical purposes**:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.



'In vitro diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, **intended by the manufacturer** to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:

- (a) concerning a physiological or pathological process or state;
- (b) concerning congenital physical or mental impairments;
- (c) concerning the predisposition to a medical condition or a disease;
- (d) to determine the safety and compatibility with potential recipients;
- (e) to predict treatment response or reactions;
- (f) to define or monitoring therapeutic measures.

Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices;

Primarily, the **intention of the manufacturer** plays a decisive role for the qualification of a wearable as a medical device. Therefore, how the manufacturer advertises and describes the product may have an important impact on the classification as a medical device. A bracelet monitoring the heart rate used for the investigation of a physiological process can be qualified as a medical device, as it serves a medical purpose whereas if the heart rate monitoring is intended, for instance, for the user's own information during physical exercise — it may not be subject to the medical devices rules.^j **Examples of wearables in health care classifying as medical devices are blood pressure monitors, continuous glucose monitoring,**

defibrillators, drug delivery products, ECG Monitors, Hearing Aids, Insulin Pumps, etc.^k

Wearables will often **not operate alone** but as part of a system, accompanied by a processing unit (smartphone, computer, etc.) or a software (e.g. an app). In that regard, the concept of **"accessory"** under the medical devices regulations is relevant. An accessory for a medical device is defined as *"an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s)"* *"an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device"* (Article 2 (2) MDR/2 (4) IVDR).

The question whether a product is a device in its own right or rather accessory to one another merely depends on the functionalities and on the intention of the manufacturer. Again, the description of the manufacturer will have a primordial importance. Manufacturers must describe in the technical documentation accessories of a medical device which are intended to be used in combination with it they must include in the instructions for use information allowing the selection of the corresponding software and accessories.^l

^j p. 16 MEDDEV 2.1/6 Guidelines on classification of standalone software https://www.medical-device-regulation.eu/wp-content/uploads/2019/05/2_1_6_072016_en.pdf

^k Lu L, Zhang J, Xie Y, Gao F, Xu S, Wu X, Ye Z. Wearable Health Devices in Health Care: Narrative Systematic Review. JMIR Mhealth Uhealth. 2020 Nov 9;8(11):e18907. doi: 10.2196/18907. PMID: 33164904; PMCID: PMC7683248.

^l Article 32.2(c), Annex I, Chapter III Section 23.4(f), Annex II Section 1.1(h) MDR.



5.1.2. Classification of wearable

Once a product qualifies as a medical device, the manufacturer must determine its classification in order to identify the applicable conformity assessment procedure evaluating the compliance with the general safety and performance requirements under the medical devices regulations. In order to set the risk class, a set of criteria that can be combined in various ways is used, e.g. duration of contact with the body, degree of invasiveness, local vs. systemic effect, potential toxicity, the part of the body affected by the use of the device and if the device depends on a source of energy.^m

Classification is carried out in accordance with Annex VIII of the MDR/IVDR. Medical devices are divided into classes I, IIa, IIb and III, taking into account their intended purpose and their inherent risks. Under the IVDR classification system, IVD devices are grouped by risk, similarly to how other medical devices are grouped under the MDR. However, because in vitro devices are used with biological material that has been removed from the body, they may also pose a risk to public health due to transmissible agents within the biological material. As a result, IVDR classification also takes public health risk into account.

Box 2 – Risk classes medical devices

The **MDR** establishes four risk classes:

Class I - generally regarded as low risk

Class IIa - generally regarded as medium risk

Class IIb - generally regarded as medium risk

Class III - generally regarded as high risk

The **IVDR** establishes four risk classes based on both patient and public health risk:

Class A - Low patient and public health risk.

Class B - Moderate patient risk and/or low public health risk.

Class C - High patient risk and/or moderate public health risk.

Class D - High patient risk and high public health risk

If the device in question is intended to be used in combination with another device (for instance with an app qualifying as medical device), the classification rules shall apply separately to each of the devices.ⁿ Accessories for a medical device shall be classified in their own right separately from the device with which they are used.^o The risk class of the accessory can thus be different than the medical device it is linked to.

^m P. 4 https://health.ec.europa.eu/system/files/2021-10/mdcg_2021-24_en_0.pdf

ⁿ Annex VIII, chapter II implementation rule 3.2 MDR/ Annex VIII, 1.2 IVDR.

^o Annex VIII, chapter II implementation rule 3.2 MDR/ Annex VIII, 1.3 IVDR.



5.1.3. Qualification of software

Software is not defined by the medical devices regulations, but the notion is clarified by a Medical Device Coordination Group Guidance document on Qualification and Classification of software in the MDR and the IVDR^p, where it is defined as “a set of instructions that processes input data and creates output data”. An example of input data are data received from/transmitted by devices. Any data produced by a software can be considered as an output data. Output data examples are screen display data such as layout with number, characters, picture, graphics, etc.

The basic rule for software in general, as set out in Recital 19 MDR^q is that *“software in its own right, when specifically **intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device (see Box 1 - Definition of “medical device”), qualifies as a medical device, while software for general purposes, even when used in a healthcare setting, or software intended for life-style and well-being purposes is not a medical device. The qualification criteria are unaffected by the software’s location or the type of interconnection between the software and a device.”*** The latter implies that the criteria apply to software (such as apps), whether used on a mobile phone, in the cloud, or on other platforms.

The Medical devices regulations do not provide for much detail on the qualification of software applications. Yet, a number of guidance documents

such as the above mentioned most recent guidance^r endorsed by the Medical Device Coordination group (hereafter MDCG guidance), the MEDDEV 2.1/6 guidance^s (drafted in light of the ‘old’ regulatory framework based on Directive 93/42/EEC and Directive 98/79/EC) of the EU Commission and the Medicines and Healthcare products Regulatory Agency (MHRA) guidance “Medical device stand-alone software including apps”^t provide for more interpretation related to the qualification of software and in particular apps. Although these guidance documents are not legally binding, they provide a very solid framework to fulfill the requirements set out in the MDR/IVDR.

1. For the **qualification of an app**, the MDCG guidance first determines whether the app falls within the general scope of the MDR/IVDR.

as **Medical Device Software** (“MDSW”)^u defined by the MDCG as “software that is intended to be used, alone or in combination, for a purpose as specified in the definition of a medical device in the medical devices regulation or in vitro diagnostic medical devices regulation”,

^p p. 5 MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR, https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2019_11_guidance_qualification_classification_software_en_0.pdf

^q See similar disposition recital 17 IVDR.

^r MDCG (2019) Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2019_11_guidance_qualification_classification_software_en_0.pdf.

^s European Commission (2016) MEDDEV 2.1/6 (2016) <https://ec.europa.eu/docsroom/documents/17921/attachments/1/translations>

^t MHRA (2021) Guidance: Medical device stand-alone software including apps (including IVDMDs). https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/957090/Software_flow_chart_Ed_1-07b-UKCA_002_FINAL.pdf

^u An example of an independent medical device software is a smartwatch app, which is intended to send alarm notifications to the user and/or health practitioner when it recognises irregular heartbeats for the purpose of detecting cardiac arrhythmia.



as an **accessory to a medical device**^v which is defined in the MDR^w as “an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s)”

or as **software driving or influencing the use of a (hardware) medical device**, which is defined in the MDCG guidance by “Software which is intended to drive or influence the use of a (hardware) medical device and does *not* have or perform a medical purpose *on its own*, nor does it create information on *its own* for one or more of the medical purposes described in the definition of a medical device or an in vitro diagnostic medical device. This software can, but is not limited to:

- (a) operate, modify the state of, or control the device either through an interface (e.g., software, hardware) or via the operator of this device
- (b) or supply output related to the (hardware) functioning of that device.”

Software that is driving or influencing the use of a medical device is covered by the medical devices regulations (MDR or IVDR) either as part/component of a medical device^x or as an accessory for a medical device. Components of a medical device are a part of the medical device itself which goes through the certification process. Accessories are also subject to all medical devices regulatory requirements. If the software drives or influences a (hardware) medical device and also has a medical purpose, then it is qualified as a MDSW. An example is software intended to measure and transmit blood

glucose levels, calculate insulin dose required and drive the insulin pump to administer the calculated dosage (closed loop insulin delivery system).^y

The qualification process is facilitated by decision trees (that have been merged in an infographic – see Figure 4), listing a **number of key characteristics that determine whether the app is eligible for MDSW qualification. As such, apps that do not perform an action on data, or perform an action limited to storage, archival, communication, simple search, or lossless compression, do not qualify as MDSW. Also, apps that are not for the benefit of individual patients will not qualify as MDSW either.** This excludes i.a. apps intended to aggregate population data, provide generic diagnostic or treatment pathways (not patient specific), serve as scientific literature, templates, models, etc.

To ultimately qualify as MDSW, the app must **be intended** by the developer to be used, alone or in combination, for one of the **medical purposes** listed in Art. 2(1) MDR/2(2) IVDR (see Box 1). **Apps for general purposes (e.g. email systems, video communication systems, paging, etc. ...^z), even when used in a healthcare setting, or for life-style and well-being purposes are excluded (recital 19 MDR/17 IVDR). A task such as e-mailing, web- or voice messaging, data parsing, word processing, and back-up is by itself not considered as having a medical purpose.** Moreover, the operating system or the virtual environment does not impact the qualification criteria. It must also be stressed that the risk of harm that a software may cause to the users of the software, including a possible malfunction is not a criterion to classify as a medical device.^{aa} **Software intended for non-medical purposes** (excluding MDR Annex XVI devices), **such as invoicing or staff planning, does not qualify as a medical**

^v An example of an accessory to a medical device is an app that is used in conjunction with a lens that is used to capture images of potential skin tumours with a mobile phone. p. 24
<https://www.rivm.nl/bibliotheek/rapporten/2018-0083.pdf>.

^w For the definition in the IVRD see art. 2 (4).

^x Article 23(2) MDR/art. 20(2) IVDR.

^y p. 7 MDCG Guidance on Qualification and Classification of Software in Regulation EU 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR.

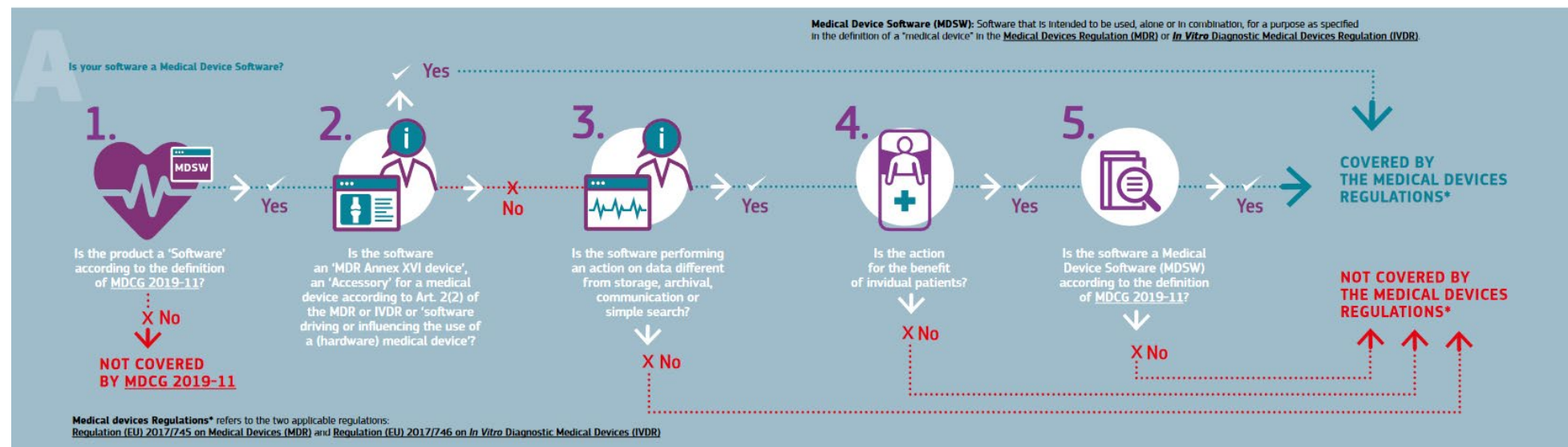
^z p. 20 MDCG Guidance on Qualification and Classification of Software in Regulation EU 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR.

^{aa} P. 7 MDCG Guidance on Qualification and Classification of Software in Regulation EU 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR.

device software and does not fall under the MDR.^{bb} The purpose is determined by what the manufacturer states in the device's labelling, instructions for use, and any promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation (Art. 2(12)

MDR and IVDR). For apps, relevant will for instance be the app store description, the category in which it is offered for sale, the adverts, the landing page, and the developer's social media channels.^{cc}

Figure 4 – ‘Is your software a medical device software’



Source: https://health.ec.europa.eu/system/files/2021-03/md_mdcg_2021_mdsw_en_0.pdf

^{bb} p. 6 MDCG Guidance on Qualification and Classification of Software in Regulation EU 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR.

^{cc} p. 11 MHRA (2021) Guidance: Medical device stand-alone software including apps (including IVDMs).
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/957090/Software_flow_chart_Ed_1-07b-UKCA_002_FINAL.pdf.



5.1.4. Classification of software

Software must be classified according to the EU MDR classification into one of the four risk classes (see Box 3). Decisive elements for classification are the **intended use**, the **significance of the information that is provided by the software** and the **potential impact of an (incorrect) decision made using information from the MDSW** and the **state of the healthcare situation or patient condition (critical-serious-non-serious)** are important.^{dd}

Box 3 – Risk classes software

- Medical device software that has **its own intended medical purpose**, is subject to classification Rule 11 (Annex VIII) of the MDR. These classification state that:
- *Software intended to provide information which is used to take decisions with **diagnosis or therapeutic purposes** is classified as **class IIa**, except if such decisions have an impact that may cause: Death or an irreversible deterioration of a person's state of health, in which case it is in **class III**; or • Serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as **class IIb**.*

- *Software intended to **monitor physiological processes** is classified as **class IIa**, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as **class IIb**. All other software are classified as **class I**.*
- **Software which drives a device or influences the use of a device, will fall within the same class as that device.^{ee} If the software is independent of any other device, it will be classified in its own right.** If the software drives or influences a (hardware) medical device **and** also has a medical purpose, it is classified on its own. However, the risk class shall not be lower than the risk class of the hardware medical device. Moreover, if several rules, or if, within the same rule, several sub-rules, apply to the same device based on the device's intended purpose, the strictest rule and sub-rule resulting in higher classification apply.^{ff}
- **For active devices (including software) that are intended for controlling, monitoring or directly influencing the performance of active**
- **implantable devices** rule 9 foresees that they are classified as **class III**.

MDCG Guidance on Qualification and Classification of Software in Regulation provides some illustrative examples (see Table 8)

^{dd} p. 26 MDCG Guidance on Qualification and Classification of Software in Regulation EU 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR.

^{ee} Rule 3.3 Annex VIII MDR.

^{ff} Rule 3.5 Annex VIII MDR.



Table 8 – Examples of software per risk class

Class	Rule 11	Examples
IIa	Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:	- MDSW intended to rank therapeutic suggestions for a health care professional based on patient history, imaging test results, and patient characteristics, for example, MDSW that lists and ranks all available chemotherapy options for BRCA-positive individuals. - Cognitive therapy MDSW where a specialist determines the necessary cognitive therapy based on the outcome provided by the MDSW.
III	— death or an irreversible deterioration of a person's state of health ¹ , in which case it is in class III; or	MDSW intended to perform diagnosis by means of image analysis for making treatment decisions in patients with acute stroke.
I Ib	— a serious deterioration of a person's state of health ¹ or a surgical intervention, in which case it is classified as class I Ib.	- A mobile app intended to analyse a user's heartbeat, detect abnormalities and inform a physician accordingly. - MDSW intended for diagnosing depression based on a score resulting from inputted data on patient symptoms (e.g. anxiety, sleep patterns, stress etc.).
IIa	Software intended to monitor physiological processes is classified as class IIa,	- MDSW intended to monitor physiological processes that are not considered to be vital. - Devices intended to be used to obtain readings of vital physiological signals in routine check-ups including monitoring at home.
I Ib	except if it is intended for monitoring of vital physiological parameters ³ , where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class I Ib.	Medical devices including MDSW intended to be used for continuous surveillance of vital physiological processes in anaesthesia, intensive care or emergency care.
I	All other software is classified as class I.	MDSW app intended to support conception by calculating the user's fertility status based on a validated statistical algorithm. The user inputs health data including basal body temperature



In determining the proper classification of MDSW under the IVDR, the manufacturer shall consider all classification and implementing rules of Annex VIII of the IVDR.⁹⁹

In the UK, future Medical Devices Regulations, applicable to the Great Britain market are planned to come into force by July 2024. In the meantime a £1.8 million funding boost has been given by a charity research foundation to the Medicines and Healthcare products Regulatory Agency (MHRA) and the National Institute for Health and Care Excellence (NICE) to explore and provide guidance for appropriate, risk-proportionate regulation of digital mental health tools. Currently, there are challenges around the regulation of digital mental health tools, such as clarity around whether they are medical devices and if so, which risk classification they fall into.^{hh}

5.1.5. Qualification of non-medical components

Whereas the apps (and other software with a medical purpose) and wearables may be classified as medical devices (cfr. supra), clearly non-medical components, such as smartphones or connectivity adapters are not categorised as medical devices since they have no medical purpose. Hence, they will not fall into the scope of the medical devices regulations, although the medical devices regulations require that (medical) devices that are intended to be operated together with other devices or products need to be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.ⁱⁱ Nevertheless, they may fall under other EU legislation. For instance, mobile phones and all other Wi-Fi, Bluetooth, LTE, 5G, GPS and other radio-electric enabled devices sold in the European Union fall under the radio equipment directive 2014/53/EU.^{jj} This directive ensures a single market for radio equipment by setting essential

requirements for safety and health, electromagnetic compatibility, and the efficient use of the radio spectrum. It also provides the basis for further regulation governing some additional aspects. These include technical features for the protection of privacy, personal data and against fraud. Furthermore, additional aspects cover interoperability, access to emergency services, and compliance regarding the combination of radio equipment and software. Just like medical devices, these devices must also meet the requirements of the respective directive and can, after going through an evaluation process, be CE marked.

5.2. General safety and performance requirements for medical devices

Both the MDR and the IVDR outline General Safety and Performance Requirements (GSPRs) for medical device designers and manufacturers. As the requirements in both regulations are quite similar and the aim of this report is not to go into an in depth comparison between the MDR and the IVDR requirements, we will, in the following, zoom in to the requirements included in the MDR. Annex I under the MDR, General Safety and Performance Requirements, outlines some broad requirements that every manufacturer of medical devices selling their products in the European Union must comply with, regardless of the type and class of products. The general safety and performance requirements include 3 major chapters:

- General Requirements
- Requirements regarding design and manufacture
- Requirements regarding the information supplied with the device

⁹⁹ Guidance on the application of the IVD classification and implementing rules can be found at https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en.

^{hh} <https://medtech.pharmaintelligence.informa.com/MT145932/UKs-MHRA-Gets-18-Million-Charity-Boost-To-Develop-Mental-Health-App-Regulation>.

ⁱⁱ Annex I, chapter II, 14.5 MDR.

^{jj} Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC Text with EEA relevance, OJ L 153, 22.5.2014, p. 62–106.



According to the **general requirements**, manufacturers need to:

- Eliminate or reduce risks as far as possible, take protection measures in relation to risks that cannot be eliminated, provide information for safety and, where appropriate, training to users;
- Inform users of any residual risks;
- eliminate or reduce risks related to use error;
- ensure that the characteristics and performance shall not be adversely affected during the lifetime of the device;
- ensure that the characteristics and performance are not adversely affected during transport and storage;
- All known and foreseeable risks shall be acceptable when weighed against the evaluated benefits to the patient and/or user.

With regard to the **design and manufacture** related requirements, manufacturers need to carefully read and understand each requirement since only some of them will apply to a particular device. There are several dispositions that may apply to particular types of apps, depending on the functionalities and used, e.g. remote patient monitoring app, diagnostic tests app for secondary prevention or treatment, chronic disease monitoring,...

For devices with a diagnostic or measuring function for instance, it is foreseen that they shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purposed, based on appropriate scientific and technical methods. The limits of accuracy needs to be indicated by the manufacturer (Annex I 15.1 MDR). Devices that incorporate software or are software themselves, must be designed to ensure repeatability, reliability and performance in line with their intended use (Annex I, 17.1 MDR) and they must be developed and manufactured in accordance with the state of the art taking into account the principles of development of cycle, risk management, information security verification and validation (Annex I, 17.2 MDR). Furthermore, manufacturers are held to set out minimum requirements, concerning hardware, IT networks characteristics and IT security measures, including protection

against unauthorized access, necessary to run the software as intended (Annex I, 17.4 MDR). For devices intended to monitor one or more clinical parameters of a patient, the manufacturer must foresee appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health (Annex I, 18.4 MDR). Manufacturer also need to take measures to protect against risks posed by medical devices intended by the manufacturer for *use by lay persons*, as is the case for apps used by patients. They must be manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can be reasonably anticipated in the layperson's technique and environment. The information and instructions must be easy for the lay person to understand and apply (Annex I, 22.1 MDR). Furthermore, devices for the use by lay persons shall be designed and manufactured in such a way as to ensure that the device can be used safely and accurately by the intended users at all stages of the procedure if necessary after appropriate training and/or information. Manufacturers should also reduce as far as possible the risk of error by the intended user in the handling of the device and the interpretation of the results (Annex I, 22.2 MDR).

The requirements regarding the **information supplied with the device** include:

- General requirements regarding the information supplied by the manufacturer,
- Information on the label,
- Information on the packaging which maintains the sterile condition of a device,
- Information in the instructions for use.



5.3. Clinical Evaluation

The MDR requires the confirmation of conformity with relevant general safety and performance requirements under the normal conditions of the intended use of the device and an acceptable risk - clinical benefit ratio. The MDR specifies that clinical benefit^{kk} means the positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient -relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health. **In the context of apps, this means that the manufacturer will need to provide evidence of the performance and safety of accessing and using the collected data for the different possible medical purposes of the app.** Confirmation of this conformity shall be based on **clinical evaluation** (assessment) of the clinical data pertaining to the device and which shall include “consideration of currently available alternative treatment options for that purpose, if any” (article 61 (3) MDR). The manufacturer shall specify and justify the level of clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose (art. 61 (1) MDR). A clinical evaluation does not mean a clinical trial but refers to a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer. The clinical evaluation aims to assess the residual risks that remain after the manufacturer has implemented all available risk mitigation methods and then decide whether the anticipated

clinical benefits of the device under consideration outweigh its risks. This clinical evaluation shall follow a defined and methodologically sound procedure based on a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device, a critical evaluation of the results of all available clinical investigations. In addition, a clinical evaluation shall consider currently available alternative treatment options for that purpose, if any. After placing the device on the market, the clinical evaluation must be updated. A clinical evaluation does not necessarily mean that clinical investigations (trials) have to be performed for all devices or that these clinical investigations must have a specific study design. Clinical investigations are required for implantable and Class III medical devices (MDR Article 61.4).^{ll} Clinical investigations shall be performed on the basis of an appropriate plan of investigation reflecting the latest scientific and technical knowledge and defined in such a way as to confirm or refute the manufacturer's claims regarding the safety, performance and aspects relating to benefit-risk of devices as referred to in Article 62(1). The rationale for the design and chosen statistical methodology shall be presented. The endpoints shall be determined and assessed using scientifically valid methodologies. The primary endpoint shall be appropriate to the device and clinically relevant (annex XV of the MDR).

MDCG Guidance on clinical evaluation of medical devices software

The MDCG endorsed a Guidance on Clinical Evaluation of Medical Device Software^{mm}, providing important guidance to manufacturers trying to collect **clinical evidence** for their **MDSW**. As such the manufacturer shall produce

^{kkkk} Art. 2 (53) MDR.

^{ll} However, clinical investigations are not required for a class III device which have been lawfully placed on the market in accordance with Directive 90/385/EEC or Directive 93/42/EEC and for which the clinical evaluation is based on “sufficient clinical data”. A clinical investigation is also not required when the applicant modifies its own devices or when the applicant claims that a new medical device is equivalent to an existing device from another manufacturer.

^{mm} MDCG Guidance on Clinical Evaluation (MDR) / Performance Evaluation (IVDR) of Medical Device Software
https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2020_1_guidance_clinic_eva_md_software_en_0.pdf.



clinical evidence to demonstrate the **safety and the clinical benefits** claimed for the device. Software that is intended to drive or influence a medical device is outside the scope of this guidance. The text also provides valuable indications on the **level of clinical evidence** that notified bodies will expect from MDSW manufacturers.

In summary the clinical evaluation consists of three components: valid clinical association, technical performance and clinical performance.

As a first step includes the **clinical association or scientific validation**. It should be demonstrated that the outcome of the software device can be associated with the targeted physiological state or clinical condition or clinical parameter.

This can be usually achieved by mean of existing clinical performance data, such as - Professional medical society guidelines, Systematic scientific literature review, clinical investigations/clinical performance studies, published clinical data (e.g. Summary of Safety and Clinical Performance (SSCP) / Summary of Safety and Performance (SSP), or new clinical performance data (Secondary data analysis (Analysis of real-world data) or performing clinical investigation/clinical performance study) iff the existing one is not sufficient.

The second step consists of **demonstrating the technical performance**, i.e. the ability of the MDSW to accurately, reliably and precisely generate the intended output. Typically, verification and validation activities, e.g. unit-level, integration and system testing,...will be used for such demonstration.

The last step is the **clinical performance validation** which refers to the MDSW's ability to yield clinically relevant output in accordance with the intended purpose. The clinical relevance of a MDSW's output is a positive impact

On the health of an individual expressed in terms of measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, prediction of risk, prediction of treatment response(s), or

Related to its function, such as that of screening, monitoring, diagnosis of aid to diagnosis or patients, or

On patient management or public health.

Evidence supporting clinical performance can be generated by testing the MDSW under evaluation, or an equivalent device, in the target population and for the intended use. The applied methodology should be appropriate in light of the device characteristics and intended purpose and may include pre-clinical testing, a clinical investigation or a clinical performance study.

Clinical evaluation or performance evaluation of MDSW must consider the benefit – risk ratio in light of the **“State-Of-The-Art”** related to practice of medicine for diagnosis, treatment or patient management. Developed stage of current technical capability and/or accepted clinical practice in regard to products, processes and patient management, based on the relevant consolidated findings of science, technology and experience. The state-of-the-art embodies what is currently and generally accepted as good practice in technology and medicine. The state-of-the-art does not necessarily imply the most technologically advanced solution; it is sometimes referred to as the “generally acknowledged state-of the-art”.

A detailed list of sources that can be used at each step in the guidance. Furthermore is also provide examples of products with associated demonstrations for each step.



6. EU LEGAL FRAMEWORK REGARDING CYBERSECURITY, INTEROPERABILITY AND PRIVACY

6.1. Cybersecurity requirements

DMTs usually transfer data via specific program interfaces to clouds or physical servers. DMTs also often use Bluetooth or Internet (Wi-Fi or 4G/5G) and rely on external exploitation systems (Apple, Android or other mobile operating systems). This infrastructure increases cybersecurity vulnerabilities.

Therefore, different legal frameworks, at European and national level, aim to ensure cybersecurity by imposing general obligations either on products or on actors.

6.1.1. Cybersecurity aspects in the medical devices Regulations

For DMTs qualifying as medical devices, the MDR and IVDR (see more details above in section 6 of this supplement) require manufacturers (amongst other requirements) to develop and manufacture their products to develop and manufacture their products in accordance with the state of the

artⁿⁿ taking into account the principles of risk management, including information security, as well as to set out minimum requirements concerning IT security measures, including protection against unauthorised access. Manufacturers must also set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended. Any restrictions on use of a medical device linked to other systems or networks vulnerabilities must be indicated on the label and/or in the instructions for use^{oo}.

Cybersecurity aspects should be covered by the CE mark delivered by a Notified Body (if applicable) or self-affixed by the manufacturer but the **MDR and IVDR** do not impose the use of specific harmonized standards^{pp} or require specific certificates regarding cybersecurity. Notified Bodies and manufacturers can use the numerous existing guidelines or standards to guide them but are not obliged to use them.

In 2019, the Medical Device Coordination Group (MDCG - regrouping representatives of the Member States national competent authorities) has issued a **Guidance on cybersecurity** explaining in more detail to the manufacturers the essential requirements with regard to cybersecurity^{qq}. In appendix III of this Guidance, the MDCG mentions, for information only, **about 15 international standards** (mainly **ISO or IEC**^{rr}) without imposing

ⁿⁿ The state-of-the-art embodies what is currently and generally accepted as good practice in technology and medicine. The state-of-the-art does not necessarily imply the most technologically advanced solution.

^{oo} Annex I of the MDR, paragraph 17. See also paragraphs 16.2, 16.3 and 16.4 of Annex I IVDR. The old Directives (Medical Devices Directives) are transitionally still applicable to an important number of devices. In these old Directives cybersecurity requirements were more vague. (See Annex I - section II, 9 AIMDD and article 12 and Annex I – Chapter II – paragraph 12 of the MDD).

^{pp} The European Commission may request the European standardisation bodies (ESBs) to develop 'harmonised standards' in relation to specific aspects in a particular directive or regulation required for CE marking, which when published in the OJEU have the value of official harmonised standards, the compliance with which confers a presumption of conformity with the applicable aspect of the legislation in question. There are General European harmonised standards, for instance regarding sterile devices, but not for cybersecurity: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en

^{qq} <https://ec.europa.eu/docsroom/documents/41863>.

^{rr} These are two international organisations developing standards e.g for medical devices.

or recommending the use of a specific one. This MDCG Guidance also reminds manufacturers that they have to provide clinicians/physicians with the information they need to have meaningful discussion with their patients about the risks and benefits of the device they use, including cybersecurity risks. To provide security information mainly to the healthcare delivery organisations, the Guidance refers to a document called “the Manufacturer

Disclosure Statement for Medical Device Security (“MDS2”), a template that is widely used (not mandatory) by the industry. Despite not being officially legally binding, the MDCG Guidance is likely to be followed relatively strictly because it represents the common interpretation principles agreed between the different national competent authorities of the EU Member States. Many notified bodies are therefore likely to use it.

Figure 5 – Cybersecurity requirements contained in MDR – Annex I

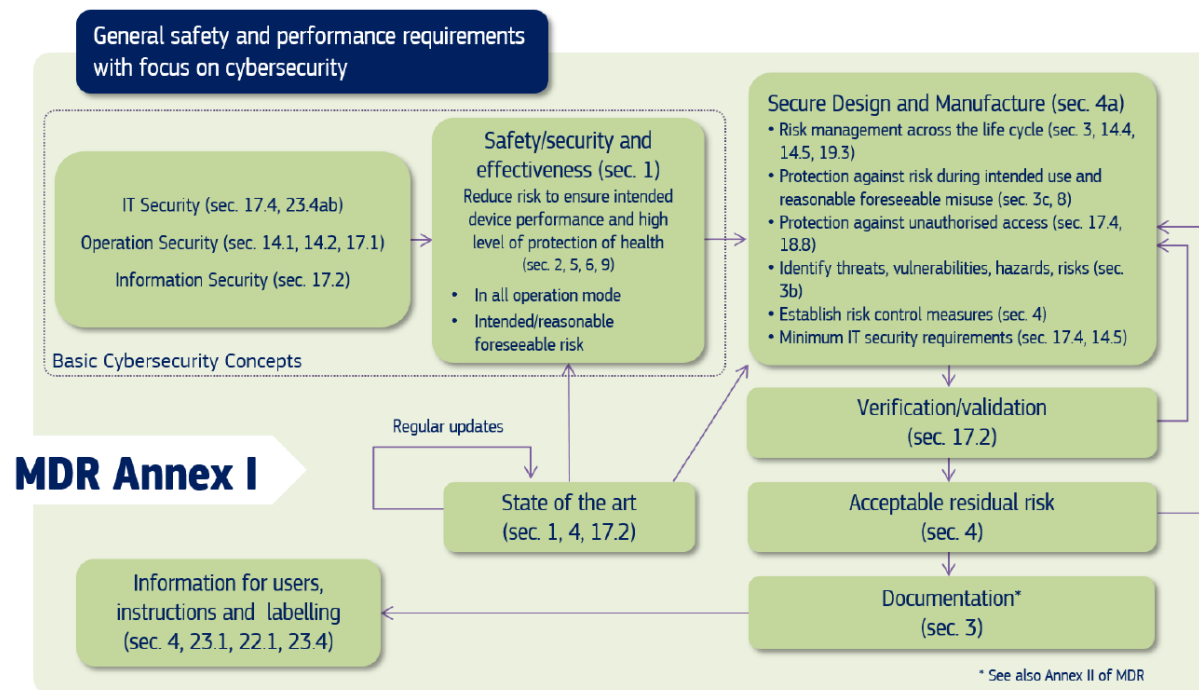


Figure 1: Cybersecurity requirements contained in MDR Annex I

Source: MDCG 2019-16 - Guidance on Cybersecurity for medical devices available at :<https://ec.europa.eu/docsroom/documents/41863>



6.1.2. Initiatives to regulate other digital products

Except for the digital products that are covered by the MDR-IVDR mentioned above, **most of the hardware and software products** are currently **not covered by any specific EU legislation tackling their cybersecurity**. In particular, the current EU legal framework does not address the cybersecurity of non-embedded software, even if cybersecurity attacks increasingly target vulnerabilities in these products.

On 15 September 2022, the European Commission has presented a proposal for a new **Cyber Resilience Act**^{ss} to protect consumers and businesses from products with inadequate security features. This proposal aims to introduce mandatory cybersecurity requirements for products with digital elements, throughout their whole lifecycle. The proposed Regulation will not apply to products with digital elements within the scope of the MDR and IVDR. However, as DMTs are often based on an IT architecture that mixes different elements (medical devices, non-medical software, cloud servers etc.), it could contribute to ensure their cybersecurity.

6.1.3. Cybersecurity obligations for certain public and private organisations (NIS Directives)

The **NIS Directive**^{tt} requires the EU Member States to be appropriately equipped, e.g. via a **Computer Security Incident Response Team (CSIRT)** and a competent national NIS authority.

The NIS law establishes a series of **cybersecurity obligations** for public and private companies, organizations, institutions and governments that offer “essential services” (“ESOs”) as well as for digital service providers. (The “DSPs”).

^{ss} Proposal for a regulation on cybersecurity requirements for products with digital elements, known as the Cyber Resilience Act (COM(2022)454 final).

^{tt} Directive on security of network and information systems. O.J. L194, 19.7.2016.

Operators of essential services must be identified by the national authorities and have to take appropriate security measures and to notify incidents of significant impact to the relevant national authority. Also, key digital service providers (search engines, cloud computing services and online marketplaces) have to comply with these security and notification requirements.

Under the updated European “**NIS-2**” **Directive**^{uu} (when adopted), all health care providers (larger than 50 employees or 10 million euro annual revenue) will be automatically subject to **minimal cybersecurity requirements**.

6.1.4. Standards and certifications

There are **hundreds of standards** that touch upon cybersecurity aspects such as those developed by ISO or IEC (e.g. IEC 62443 or IEC 81001-5-1:2021) and many other organisation such as SESIP, AAMI TIR57 (USA), AAMI TIR97 (USA), AAMI SW96 (USA), UL2900-2. National standards also exist such as the BSZ from BSI (Germany). All these standards can be used to provide evidence of conformity to the cybersecurity (incl. requirements of the MDR and IVDR). At worldwide level, guidelines are also developed by the International Medical Device Regulators Forum (IMDRF). Each country currently decides to make the use of those standards mandatory and to require a certificate of compliance with certain standards.

The EU Cybersecurity Act^{vv} mandates the European Union Agency for Cybersecurity (ENISA) to support Member States in their cybersecurity policies and to support and promote the development and implementation of **EU cybersecurity certification schemes for ICT products, services and**

^{uu} (To be adopted) Proposal for a Directive on measures for a high common level of cybersecurity across the Union (COM/2020/823 final).

^{vv} Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013, O.J.L151 07.06.2019.



processes. This legislation (certification schemes) is still **under construction**.

6.2. Interoperability requirements

There are several definitions and understandings behind the concept of interoperability. There are, usually, different “levels” of interoperability. For instance, the Healthcare Information and Management Systems Society (a US non-profit organisation promoting digital health care) defines the following levels of interoperability^{ww}:

- Foundational (also sometimes called ‘basic’) **interoperability** permits data exchanged from one digital system to another but does not require the receiving system to interpret the data.
- **Structural interoperability** defines the structure or format of data exchange. The Health Level 7 (HL7) series of standards, for example, provides guidance on how messages should be structured.
- **Semantic interoperability** represents the highest level of interoperability. It deals with the content of the messages exchanged among digital systems, not just the messaging format. It takes advantage of both the structuring of the data exchange and the codification of the data including vocabulary so that the receiving information technology systems can interpret the data.

The direct transposition of these levels into interoperability requirements is however complex as the requirements for interoperability also depend on the degree of integration of the IT health environment and the specificities of the DMT.

6.2.1. Interoperability aspects in the Medical Devices Regulation

According to Article 1 (26) of the MDR ‘interoperability’ is the ability of two or more devices, including software, from the same manufacturer or from

different manufacturers, to: (a) exchange information and use the information that has been exchanged for the correct execution of a specified function without changing the content of the data, and/or (b) communicate with each other, and/or (c) work together as intended.

Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe^{xx}.

Interoperability is mentioned in the medical devices legislation. However, is up to the manufacturers decide whether their devices are “*intended to be operated with*” other devices or products. They decide if they want their devices to be interoperable with those placed on the market by other manufacturers or with the devices or systems used by the health care systems (patient record etc.).

Interoperability is also mentioned in recital 68 of the GDPR linking to the data subject right to data portability (see infra section 7.3.4). Recital 68 GDPR indicates that data controllers are encouraged to develop interoperable formats that enable data portability. Up to today, there are no standardized technical requirements for interoperability that are put forward in this regard despite numerous initiatives at the EU level including to create a common electronic health record exchange format^{yy} or the recent proposal for a European Health Data space^{zz}.

^{ww} <https://www.wolterskluwer.com/en/expert-insights/what-is-semantic-interoperability>.

^{xx} Annex I, 14.5 of the MDR.

^{yy} <https://digital-strategy.ec.europa.eu/en/policies/electronic-health-records>.

^{zz} https://ec.europa.eu/commission/presscorner/detail/en/QANDA_22_2712.



6.2.2. European Health Data Space

The European Commission proposed a new Regulation to create a health-specific data sharing framework establishing clear rules, common standards and practices, infrastructures and a governance framework for the use of electronic health data by patients and for research, innovation, policy making, patient safety, statistics or regulatory purposes. It could have an important impact not only on interoperability of DMTs in the future but also on the way and the purposes for which these DMTs process data.

Indeed, the proposal introduces **security criteria for interoperability and security of electronic health record systems and requires manufacturers to certify them**. The proposal also foresees that data processing can only take place in secure processing environments, which need to comply with very high standards of privacy and (cyber)-security and no personal data can be downloaded from such environments. Moreover, the researcher, company or public institution can only access **non-identifiable data** (offering information about the disease, symptoms and medication, without revealing the identity of the individual). It is forbidden for the user to re-identify the data subjects.

Finally, processing electronic health data **for secondary use of data** would **only be possible for specific purposes foreseen in the Regulation**, based on an authorisation issued by a data access body. It will be forbidden to use the data to take decisions detrimental to individuals, or to market health products towards health professionals or patients. The European Data Protection Boards has issued some advice on this draft proposal ^{aaa}. One of the remarks made by the EDPB concerns the attempts at delimiting which data generated by medical devices, wellness applications or other digital health applications shall be made available for secondary uses. According to the EDPB, it is still unclear in the current proposal what kind of data fall under this category and who would assess its validity and quality once inserted by individuals in their own EHR or made directly available by data holders.

^{aaa} https://edps.europa.eu/system/files/2022-07/22-07-12_edpb_edps_joint-opinion_europeanhealthdataspace_en_.pdf.

This proposal has just been submitted and will still have to follow the whole EU legislative process before it will be eventually adopted.

6.2.3. Standards and certifications

Exactly as for cybersecurity, there several interoperability standards applicable to DMTs such as KMEHR (Kind Messages for Electronic Healthcare Record, specifically developed for exchange of information between software of hospital, HCP, etc. in Belgium), HL7 CDA (Clinical Document Architecture developed by HL7), HL7 FHIR (Fast Healthcare Interoperability Resources by HL7), SNOMED-CT (Systematized Nomenclature of Medicine - Clinical Terms), ISOs 14971 (Application of risk management to medical devices), 27001 (Information security management), 62304 (Medical device software - Software life cycle processes), 82304-2 (Health software - Part 2: Health and wellness applications - Quality and reliability).

In 2021, the **ISO-82304-2** (Health software - Part 2: Health and wellness applications - Quality and reliability) ^{bbb} was published. This standard is being validated at European level as a voluntary standard and complements ISO-82304-1 (Health software - Part 1: General requirements for product safety). ISO-82304-2 is partly based on the British standard PAS-277 and is specifically aimed at Mobile Applications with 81 questions. This standard could help to standardise the level of requirement for the quality of mobile health applications at international level and limit the proliferation of different evaluation systems in different countries.

^{bbb} <https://www.iso.org/standard/78182.html>



6.3. Data Protection Regulation

Mobile applications studied under the scope of this report aim to deliver or support health services through digital technologies. However, those applications do not only process personal information about health but often also lifestyle, well-being or behaviour information. In addition, health apps usually also involve a large number of actors: developers, app stores, devices manufacturers, advertisers but also physicians, hospital, insurers etc.

Personal data, and specifically health data, enjoy a specific protection from the European General Data Protection Regulation (hereafter “the GDPR”)^{ccc} which came into effect in May 2018 and repealed the former Directive (hereafter the Personal data Directive)^{ddd}. GDPR is applicable regardless of the technology used for processing and regardless on how the data is stored – in an IT system, through video surveillance, or on paper. In Belgium, this legal framework is completed by a law of 30 July 2018^{eee}. Indeed, the Regulation provides a **margin of appreciation for Member States to specify their own rules for the processing of special categories of personal data (‘sensitive data’)**.

While one of the main goals of the GDPR was to adapt the data protection rules to the new challenges linked to digital technology development^{fff}, **the concrete application of the principles established in the GDPR to DMTs remains highly complex**; given the complexity of the ecosystem of these DMTs (interoperate with several different products and services, they have several purposes, ...), it is very difficult to define the principles to be followed, for example to identify who the (joint) data controller(s) is (are), to detail exhaustively the purposes of the processing or to inform appropriately

the data subjects. This **lack of concrete guidance** is coupled in many countries, including in Belgium, with the **absence of certification bodies** responsible for issuing certificates of compliance with the GDPR.

6.3.1. General GDPR principles applied to apps

6.3.1.1. Territorial scope

DMTs are sometimes owned by companies outside the EU. Moreover, certain apps might rely on services located outside the EU or send data outside the EU.

The EU GDPR has a wide territorial scope. It applies to the processing of personal data in the context of the activities of an establishment of a controller or a processor in the Union, regardless of whether the processing takes place in the Union or not (Art. 3(1)). Furthermore, it may apply even to companies not established in the EU, in cases in which they process the personal data of subjects who are in the EU and the processing activities are related to the targeted monitoring of their behaviour as far as their behaviour takes place within the Union (Articles 3(2)(b) and 4(1)).

Under the GDPR, contractual clauses ensuring appropriate data protection safeguards can be used as a ground for data transfers from the EU to third countries. This includes model contract clauses – so-called standard contractual clauses (SCCs) – that have been “pre-approved” by the European Commission.

With regard to exchange of data specifically with the USA, the European Commission and the US government had signed, in 2016, an adequacy

^{ccc} Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). O.J. L119, 4.5.2016.

^{ddd} Council directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data, O.J. L281/31 1995.

^{eee} Law of 30 July 2018 regarding the protection of natural persons regarding the processing of personal data, M.B.-B.S. 05.09.2018.

^{ggg} Article 29 Working Party Opinion 05/2014 on Anonymisation Techniques https://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/files/2014/wp216_en.pdf



decision on the EU-US Privacy Shield, allowing the free transfer of data to companies certified in the US under the Privacy Shield. In its judgment of 16 July 2020 (Case C-311/18), the Court of Justice of the European Union invalidated this adequacy decision. The EU-US Privacy Shield is therefore no longer a valid mechanism to transfer personal data from the European Union to the United States. At the time of the writing of this report, EU and USA announced the signature of a new agreement in the coming months.

6.3.1.2. Which data are collected?

DMTs can collect an important amounts of data concerning the patient health / well-being status or even habits but also concerning certain devices functioning.

Personal data under the GDPR are “*any information relating to an identified or identifiable natural person ('data subject')*” (Art. 4(1)). An identifiable natural person is a person “*who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person*” (Art. 4(1)). Different pieces of information, which collected together can lead to the identification of a particular person, also constitute personal data.

Data concerning health are “*personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status*” (Art. 4(15)).

Personal data concerning health should include all data pertaining to the health status of a data subject which reveal information relating to the past, current or future physical or mental health status of the data subject. This includes information about the natural person collected in the course of the registration for, or the provision of, health care services to that natural person; a number, symbol or particular assigned to a natural person to

uniquely identify the natural person for health purposes; information derived from the testing or examination of a body part or bodily substance, including from genetic data and biological samples; and any information on, for example, a disease, disability, disease risk, medical history, clinical treatment or the physiological or biomedical state of the data

Personal data that have been de-identified, encrypted or pseudonymised but can be used to re-identify a person remain personal data and fall within the scope of the GDPR.

Personal data that have been irrevocably rendered anonymous in such a way that the individual is not or no longer identifiable are no longer considered personal data. **For data to be truly anonymised, the anonymisation must be irreversible.**⁹⁹⁹

⁹⁹⁹ Article 29 Working Party Opinion 05/2014 on Anonymisation Techniques https://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/files/2014/wp216_en.pdf



6.3.1.3. Who is responsible ?

Box 4 – GDPR actors

- **Controller** is “the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data”^{hhh} (Art. 4(7)).

Joint controllers: Where two or more controllers jointly determine the purposes and means of processing, they shall be joint controllers. In this case, they have to sign an arrangement defining their respective responsibilities and the essence of this arrangement shall be made available to the data subject. The data subject may exercise his or her rights under this Regulation in respect of and against each of the controllers.

- **A processor** is “a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller” (Art. 4(8)).
- **Data subject** : Depending on whom the data can be linked to, the patient, the treating physician or other persons involved in the data processing can be considered as the data subject and thus benefits from the rights included in the GDPR.
- **Third party** means a natural or legal person, public authority, agency or body other than the data subject, controller, processor and persons who, under the direct authority of the controller or processor, are authorised to process personal data.

In order to identify who has to comply with the obligations and who benefits the rights stipulated in the GDPR, the concepts of data subject, processor and data controller have to be interpreted. For DMTs, different actors are eligible for one or more roles depending on the concrete actions on data.

The GDPR acknowledges that there may be more than one controller, and it reconfirms the concept of joint controllers where two or more controllers together determine the purposes and means of processing data. In case of joint controllers (Article 26) or in case of a controller and a processor (Article 28) contracts must formally determine their respective responsibilities with regard to compliance with the GDPR, as in case of any breach both parties will need to justify their accountability. The GDPR does not address data sharing between independent controllers, and in most cases, such relationships are also set out in a contract⁷⁷.

For DMTs, several data processing could occur. The question of who determines the purpose and methods of the personal data processing (and therefore who is responsible as data controller) might therefore be complex.

Given the diversity of DMTs, it is difficult to define who would be the data controller. However, one should not automatically think that the physician or hospital using an app or prescribing it is the controller of the data. Indeed apps are mostly commercial products offering a service and meant to be connected to devices of the same provider. It is possible that in some cases, the DMT is only a “transmission” platform allowing the communication between patients and their HCP but it is also possible that a DMT is connected to sensors, treat the information coming from the sensors and generates the output requested by the manufacturer for its own purposes (maintenance, marketing etc.) . The HCPs use the tool to monitor their patients but they are not always defining the purposes and methods of the data processing.

According to the Article 29 Working Party, apart from the app provider, operating system and device manufacturers could also be controllers when

^{hhh} Processing under the GDPR is “any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means,” including collection, use, disclosure by transmission, storage, structuring, and erasure (Art. 4(2)).



they access and process an individual's personal data for **their own purposes**, “such as the smooth running of the device, security, etc.

This would include user generated data (e.g. user details at registration), data automatically generated by the device (e.g. if the device has a ‘phone home’ functionality for its whereabouts) or personal data processed by the OS or device manufacturer resulting from the installation or use of apps.”

Manufacturers of apps are indeed not necessarily only processors on behalf of the hospitals / physicians **because they establish, at least partly, the objectives (‘purposes’) of the data processing, determine which data should be collected, and determine the methods (‘means’) for obtaining those data.**

In some situations, certain manufacturers are even explicitly required to equip their CE marked medical devices with systems allowing certain functionalities such as to determine the capacity of the power supply and alert the user in case this power supply becomes criticalⁱⁱⁱ. Certain monitoring apps must also be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of healthⁱⁱⁱ. These two objectives are defined by the legislation but the concrete data to be collected and means to do so are defined by the manufacturer. In addition, in the context of their post-marketing surveillance obligations, manufacturers must implement a specific plan prior to the placing on the market to monitor their device. The specific content of this plan is defined by the manufacturer who must define which measures (including, for instance which data) need to be collected to monitor the safety, performance and benefit risk balance of their device or remote monitoring device. However, legal guidance from the European Commission and European Data Protection Board is needed clarify this issue.

Indeed, manufacturers may also act as data processors when analysing and storing the data collected.

Hospitals as well as self-employed physicians working in private practice or as private/independent practitioners in a hospital are indeed also data controllers when they determine the clinical indications for collecting data

remotely using apps services, the details of the procedure, and which data are collected and analysed from individual patients.

Finally, third-party service providers are data processors if they function under delegated authority from a data controller to collect, analyse, and transmit data acquired from the app. An agreement between the controller and the processor must also be drafted ⁷⁷

6.3.1.4. Duties of the data controller and of the data processor

According to the Regulation, the **data controller** (or joint controllers) is (are) responsible for being able to demonstrate GDPR compliance with the following principles:

- Data must be collected for **the legitimate purposes specified explicitly** to the data subject when the data are collected and not further processed in a way incompatible with the initial purposes;
- Personal health data used in remote monitoring applications must be **processed fairly and lawfully**;
- The collection must be **transparent to the data subject**;
- The data collected must be **adequate, relevant and limited to what is necessary in relation to the purposes** for which they are processed (‘data minimisation’); The controller should therefore balance the necessity of the personal data against the purpose;
- Personal data must be accurate and, where necessary, kept up to date;
- Moreover, data must be kept in a form that permits identification of data subjects for **no longer than is necessary for the specified purpose**;
- Processing must be done in such a way as to ensure appropriate **security, integrity, and confidentiality** (e.g. by using encryption).

By default, DMTs manufacturer should ensure that personal data is processed with the highest privacy protection (for example only the data necessary should be processed, short storage period, limited accessibility)

ⁱⁱⁱ Paragraph 18.2 of Annex I, Chapter II MDR.18.2

ⁱⁱⁱ Paragraph 18.4 of Annex I, Chapter II MDR.



so that by default personal data isn't made accessible to an indefinite number of persons ('data protection by default'). Privacy by default (art. 25 GDPR) means that, wherever the user has a choice with respect to the processing of his or her data but does not take any action to express a preference, by default the service provider (for instance an app) has pre-selected the least privacy invasive and compliant choice. This must ensure that only personal data which are necessary for each specific purpose of the processing are processed.

Privacy by design (art. 25 GDPR) shall also be implemented. It means that the privacy implications of a service (for instance an app) and its use have been considered at each step of its development, and that the organisation offering this service made design and implemented choices that will support the privacy of its users wherever possible.

The **data processor** processes personal data only on behalf of the controller. The duties of the processor towards the controller must be specified in a contract or another legal act. For example, the contract must indicate what happens to the personal data once the contract is terminated. A typical activity of processors is offering IT solutions, including cloud storage. The data processor may only sub-contract a part of its task to another processor or appoint a joint processor when it has received prior written authorisation from the data controller.

An entity can be a data controller, or a data processor, or both.

6.3.2. Legal ground for data processing

In some countries, the legal ground for certain data processing by reimbursed apps can only be the consent and certain uses are prohibited (marketing). These requirements are however part of the reimbursement conditions and are not included in the GDPR.

The **controller or the joint controllers** determine the primary purpose of the data collection. A specific and legitimate reason is needed for any personal data that are collected. Personal data can only be used for the specified reasons.

According to article 6(1)(a)-(f), processing of personal data (not health data) shall be lawful only if and to the extent that at least one of the following applies:

- The data subject has given **consent** to the processing of his or her personal data for one or more specific purposes;
- Processing is necessary for the performance of **a contract** to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract;
- Processing is necessary for compliance with a **legal obligation** to which the controller is subject;
- Processing is necessary in order to protect the **vital interests of the data** subject or of another natural person;
- Processing is necessary for the performance of a task carried out in the **public interest** or in the exercise of official authority vested in the controller;
- Processing is necessary for the purposes of **the legitimate interests pursued by the controller** or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child.

In addition, in principle, the processing of **sensitive data, such as health data, is prohibited** (Article 9.1). However, article 9.2.a allows the processing of health data on the basis of **explicit consent of the person concerned**. Processing of sensitive data is also allowed if it is necessary for the provision of health care or treatment, or for management of health or social care systems and services, on the basis of Union or Member State law or pursuant to contract with a health professional. Finally, health data can also be processed for reasons of public health such as ensuring 'high standards of quality and safety of medical devices, on the basis of EU or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy' (Article 9.2.i).⁷⁷



When data are processed to treat the patient, the processing must happen under the responsibility of a professional or another person subject to the obligation of professional secrecy. Manufacturers of certain apps qualifying as medical device could claim that their obligations under the medical device regulation, and in particular, the requirement to conduct post-market surveillance, could constitute an acceptable legal ground to collect a whole range of health personal data. In a recent report ordered by the European Commission, it is concluded that the European legislation does not allow medical devices companies or even authorities to process personal data for post market surveillance. Therefore, unless the national rules allow that, these data need to be either fully anonymised or their processing must be based on consent^{kkk}.

Given the above-mentioned uncertainties, consent of the patient is usually always asked by the manufacturers for processing health data of patients using DMTs.

Under the GDPR, consent must be freely given, specific, informed, unambiguous, and where consent is used as a justification for processing special categories of data, such as health data, such consent must be explicit (Article 9(2) (a) GDPR). Data controllers should pay particular attention to the condition of a “freely given” consent. As stated in the Working Party 29 Guidelines on consent, this element implies real choice and control for data subjects (see more details in Box 5 – Consent).

When data are collected for scientific purposes (which could be the case even in the context of post market vigilance), it is not always possible to identify all the purposes for which the collected data will be processed for scientific research at the time of data collection. Therefore, data subjects should be able to give their consent with regard to certain areas of scientific research, in accordance with recognised ethical standards for scientific research.

Box 5 – Consent^{III}

- The basic requirements for the effectiveness of a valid legal consent are defined in Article 7 and specified further in recital 32 of the GDPR. Consent must be freely given, specific, informed and unambiguous. In order to obtain freely given consent, it must be given on a voluntary basis. The element “free” implies a real choice by the data subject. Any element of inappropriate pressure or influence which could affect the outcome of that choice renders the consent invalid. In doing so, the legal text takes a certain imbalance between the controller and the data subject into consideration.
- For consent to be informed and specific, the data subject must at least be notified about the controller’s identity, what kind of data will be processed, how it will be used and the purpose of the processing operations as a safeguard against ‘function creep’. The data subject must also be informed about his or her right to withdraw consent anytime. The withdrawal must be as easy as giving consent. Where relevant, the controller also has to inform about the use of the data for automated decision-making, the possible risks of data transfers due to absence of an adequacy decision or other appropriate safeguards.
- The consent must be bound to one or several specified purposes which must then be sufficiently explained. If the consent should legitimise the processing of special categories of personal data, the information for the data subject must expressly refer to this.

There must always be a clear distinction between the information needed for the informed consent and information about other contractual matters.

^{kkk} https://ec.europa.eu/health/sites/default/files/ehealth/docs/ms_rules_health-data_en.pdf.

^{III} https://ec.europa.eu/health/sites/default/files/ehealth/docs/ms_rules_health-data_en.pdf.



Last but not least, consent must be unambiguous, which means it requires either a statement or a clear affirmative act. Consent cannot be implied and must always be given through an opt-in, a declaration or an active motion, so that there is no misunderstanding that the data subject has consented to the particular processing. That being said, there is no form requirement for consent, even if written consent is recommended due to the accountability of the controller. It can therefore also be given in electronic form.

- While consent is being relatively frequently used in the context of DMTs, this choice has important consequences. Indeed, if a controller chooses to rely on consent for any part of the processing, he must be prepared to respect that choice and stop that part of the processing if an individual withdraws consent. Strictly interpreted, this means the controller is not allowed to switch from the legal basis consent to legitimate interest once the data subject withdraws his consent. This applies even if a valid legitimate interest existed initially.

6.3.3. Primary vs. secondary purpose

Primary purpose is not defined by the GDPR. However, secondary use is defined as processing of personal data for purposes “*other than those for which the personal data were initially collected*” (original, primary purposes) (recital 50 of the GDPR).

In the context of DMTs, the initial vs. secondary purpose of the processing depend on how you interpret the situation. It could be argued that the whole data processing happens for the purposes of provision of health care by healthcare providers to the patient concerned and that the data processing by the manufacturer for the purpose of control of its devices or system for the purpose of ensuring high standards of quality and safety of healthcare and of medical products and medical devices is a secondary purpose ^{mmm}.

^{mmm} https://ec.europa.eu/health/sites/default/files/ehealth/docs/ms_rules_health-data_en.pdf

Secondary use allowed only where the processing is compatible with the original purposes. In this case, no separate legal basis (other than that which originally allowed the collection of the personal data) is required.

The following should be taken into account, inter aliaⁿⁿⁿ:

- Any link between the original, primary purposes (for which the personal data have been collected) and the secondary purposes of the intended further processing;
- The context in which the personal data have been collected: relationship between data subjects and the controller, the reasonable expectations of data subjects;
- The nature of the personal data: data concerning health is a special category;
- The possible consequences of the intended further processing for data subjects;
- The existence of appropriate safeguards, e.g. encryption or pseudonymisation of data further processed.

Secondary use is lawful when:

- Processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller Union or Member State law may determine and specify the tasks and purposes for which the further processing should be regarded as compatible and lawful.
- Further processing for scientific research purposes are considered to be compatible lawful processing operations.
- The legal basis provided by Union or Member State law for the processing of personal data may also provide a legal basis for further processing.

ⁿⁿⁿ https://www.ema.europa.eu/en/documents/presentation/presentation-32-electronic-health-record-access-share-expand-project-secondary-use-healthcare-data_en.pdf



However, if the manufacturer has collected the data on the basis of consent or following a legal requirement, no further processing beyond what is covered by the original consent or the provision of the law is possible. Further processing would require obtaining new consent or a new legal basis.

The data protection regulations provide for a number of relaxations for the benefit of scientific research activities (possibility of re-using data initially collected for other purposes, possibility of processing sensitive data, possibility of derogating from the rights of the data subjects, possibility of keeping data for a longer period of time, exception to the duty to inform and the right to erasure, etc.).

6.3.4. Information and rights of the data subject

Individuals are granted the right to obtain information from the data controller about the nature and use of the data stored, and they have the right of access to their own data. With certain exemptions (such as when the security of the state must be protected) they have the right to be forgotten and to have their data erased from a particular database (Article 17). Data subjects also in general have the right to 'data portability' which means that they can receive their personal data in a 'structured, commonly used and machine-readable format', thereby allowing them to transmit those data to another controller without hindrance from the controller to which personal data have been provided (Article 20).

6.3.4.1. The right to data portability

The question of which rights patients have to the data collected remotely by digital medical technologies beyond what is summarised in their medical records and the question of what format they can claim for this data (raw or

granular format) are not defined in the legislation and are not widely explored in the literature.

The Data Protection Working Party explicitly mentions in its guideline that the right to data portability "may also include other raw data such as the heartbeat tracked by a wearable device". The right of data portability complements the right of access under Art. 15 of the GDPR. 31 Art. 20(1) of the GDPR states that the personal data concerning the data subject should be received "*in a structured, commonly used and machine-readable format.*" The Data Protection Working Party's guidelines also clarify that "where the personal data requested are processed by a data processor, the contract concluded in accordance with Article 28 of the GDPR must include the obligation to assist *'the controller by appropriate technical and organizational measures, ... to respond to requests for exercising the data subject's rights.'*"

6.3.4.2. Privacy notices

Part of the reluctance of HCPs and user to use DMTs is related to the fear that data would be used in a way that is contrary to their wishes. In the past, the Belgian consumer protection association had revealed that a significant proportion of health applications did not comply with the GDPR, including due to insufficient user information⁰⁰⁰.

Article 13 of the GDPR defines which information should be provided to the data subject where personal data are collected.

This includes;

- the identity and the contact details of the controller and, where applicable, of the controller's representative;
- the contact details of the data protection officer, where applicable;

⁰⁰⁰ <https://www.test-aankoop.be/gezond/dagelijkse-verzorging/e-health/dossier/applicaties-food-health>; <https://www.test-aankoop.be/gezond/dagelijkse-verzorging/e-health/nieuws/voedings--en-gezondheidsapps-respecteren-de-privacy-niet>.



- the purposes of the processing for which the personal data are intended as well as the legal basis for the processing;
- where the processing is based on point (f) of Article 6(1), the legitimate interests pursued by the controller or by a third party;
- the recipients or categories of recipients of the personal data, if any;
- where applicable, the fact that the controller intends to transfer personal data to a third country or international organisation and the details over the safeguards applicable to this transfer.

In addition to this information, the controller shall, at the time when personal data are obtained, provide the data subject with the following further information necessary to ensure fair and transparent processing:

- the period for which the personal data will be stored, or if that is not possible, the criteria used to determine that period;
- the existence of the right to request from the controller access to and rectification or erasure of personal data or restriction of processing concerning the data subject or to object to processing as well as the right to data portability;
- where the processing is based on point (a) of Article 6(1) or point (a) of Article 9(2), the existence of the right to withdraw consent at any time, without affecting the lawfulness of processing based on consent before its withdrawal;
- the right to lodge a complaint with a supervisory authority;
- whether the provision of personal data is a statutory or contractual requirement, or a requirement necessary to enter into a contract, as well as whether the data subject is obliged to provide the personal data and of the possible consequences of failure to provide such data;

- the existence of automated decision-making, including profiling, referred to in Article 22(1) and (4) and, at least in those cases, meaningful information about the logic involved, as well as the significance and the envisaged consequences of such processing for the data subject.

Where the controller intends to further process the personal data for a purpose other than that for which the personal data were collected, the controller shall provide the data subject prior to that further processing with information on that other purpose and with any relevant further information (period, rectification etc.).

This information should be provided in a privacy notice / privacy policy (art. 12,13, 14 GDPR) which is document where an organisation, public or private, disclose to its users how it applies data protection principles including who is the data controller, what personal information is collected from the user, how the information is collected, how it is used it, whether this information is shared it with any third parties, what are the right of the users regarding their data.

A privacy notice that must be :

- In a concise, transparent, intelligible, and easily accessible form
- Written in clear and plain language, particularly for any information addressed specifically to a child
- Delivered in a timely manner
- Provided free of charge

According to the European Commission's GDPR guideline on Transparency under GDPR^{ppp}, the phrases below are not sufficiently clear as to the purposes of processing. (We took these examples directly from the document.)^{qqq}

^{ppp} Article 29 Working Party Guidelines on transparency under Regulation 2016/679, 29.11.2017 (re.11.04.2018), available at <https://ec.europa.eu/newsroom/article29/items/622227/en>

^{qqq} <https://gdpr.eu/privacy-notice/>



- “We may use your personal data to develop new services” (as it is unclear what the “services” are or how the data will help develop them)
- “We may use your personal data for research purposes” (as it is unclear what kind of “research” this refers to)
- “We may use your personal data to offer personalised services” (as it is unclear what the “personalization” entails)

For apps, the Guideline also recommends that the necessary information should also be made available from an online store prior to download. Once the app is installed, the information still needs to be easily accessible from within the app. One way to meet this requirement is to ensure that the information is never more than “two taps away” (e.g. by including a “Privacy”/ “Data Protection” option in the menu functionality of the app). Additionally, the privacy information in question should be specific to the particular app and should not merely be the generic privacy policy of the company that owns the app or makes it available to the public.

Furthermore, the data subject should be informed of the existence of profiling and the consequences of such profiling. The data subject shall have the right not to be subject to a decision based solely on automated processing, including profiling¹¹¹ which produces legal effects concerning him or her or similarly significantly affects him or her.

6.3.5. GDPR certifications and Guidelines

6.3.5.1. Certification and Codes of conduct

The GDPR explicitly provides the *possibility* of GDPR certification (article 42). Article 43 of the Regulation provides that certification shall be issued and renewed by a certification body with an appropriate level of expertise, after informing the supervisory authority. It is up to each Member State to determine which of the competent national supervisory authority or the national accreditation body will be competent to approve certification bodies. Certification bodies must systematically communicate to the supervisory authority the reasons for issuing or withdrawing the requested certification.

The GDPR also provide for the possibility of approval (EU or national) of Codes of conduct.

¹¹¹ Profiling (art. 4 GDPR): means any form of automated processing of personal data consisting of the use of personal data to evaluate certain personal aspects relating to a natural person, in particular to analyse or predict aspects concerning that natural person’s performance at work, economic situation, health, personal preferences, interests, reliability, behaviour, location or movements.



Box 6 – Certifications and Codes of conduct

Codes of conduct:

- Associations and representative bodies may prepare Codes for approval, registration and publication by a supervisory authority, or, where processing activities take place across member states, by the European Data Protection Board (“EDPB”). The EU Commission may declare Codes recommended by EDPB to have general validity within the EU.

Codes may be approved in relation to a wide range of topics and adherence to Codes will help controllers and processors demonstrate compliance with GDPR obligations.

- Compliance with Codes will be subject to monitoring, which may be carried out by suitably qualified, accredited bodies. Controllers and processors who are found to have infringed a relevant code may be suspended from participation in the Code and reported to the supervisory authority.

Certifications, seals and marks:

- Certificates can be issued by accredited certifying bodies
- Certification is voluntary but certification will enable controllers and processors to demonstrate compliance with the GDPR.
- Certificates will be valid for three years and subject to renewal.
- EDPB will maintain a publicly available register of all certification mechanisms, seals and marks

6.3.5.2. *Europrivacy certification*

Recently, the European Data Protection Board has approved the first European Data Protection Seal. The certification mechanism encompasses a wide range of data processing operations in many sectors.

This standard is applicable to a wide variety of data processing activities, while taking into account sector-specific obligations and risks and is adapted to emerging technologies, such as AI, IoT, blockchain, automated cars, smart cities, etc

Companies and services can use the certification scheme to:

- assess the compliance of their data processing activities
- select data processors
- assess the adequacy of cross-border data transfers
- assure citizens and clients of the adequate processing of their personal data

6.3.5.3. *Privacy code of conduct on mobile health apps (2015)*

In 2015, the European Commission encouraged industry stakeholders to create a privacy code of conduct on mobile health app. Following various suggestions for improvement from the Working Party (the competent body under the previous EU Directive on data protection), the Code was reworked, and formally submitted for approval under the Data Protection Directive in 2017. In 2018 the Working Party answered that the reworked version of the Code needed to show more added value, particularly through more examples and more indications on what must be done and what is good practice.

This code mainly rephrased the provision of the previous Directive. However, the following principles of this Code should be specifically highlighted:



- The privacy implications of the app have to be considered at each step of the development and wherever the user is given a choice. The app developer has to pre-select the least privacy invasive choice by default.
- There was a distinction made by the industry between advertising based on the processing of personal data (requiring opt-in consent) and advertising not relying on personal data (opt-out consent).
- Any processing for secondary purposes needs to be compatible with the original purpose. Further processing for scientific and historical research or statistical purposes is considered as compatible with the original purpose. Secondary processing for non-compatible purposes requires a new consent.

In the meantime, current General Data Protection Regulation (GDPR) is entered into force and this Code needs to be revised and then approved by the European Data Protection Board to be granted general validity across the EU through an implementing act.^{sss}

6.4. Quality label for mobile health applications

Label2Enable (May 2022 – 2024) aims at supporting the development and implementation of the EU quality label for health apps. The project builds on the work on the ISO 82304–2 label and is compared to the EU Energy Label or the Nutri-Score front-of-pack nutrition label; The aim is to **define requirements for good quality health and wellness apps that can be used by health professionals and patient/citizen.**

The project aims to better inform:

- patients, citizens, and carers who seek to use health apps
- health care professionals who seek to recommend or prescribe apps
- regional and national health care systems who seek to reimburse apps

- regulatory authorities who seek to approve use and reimbursement of apps

The project will foster trust on health apps, helping to identify trustworthy applications that are adequately evaluated against predetermined standards by independent entities. The label should make stand out health apps that are legally compliant, protect doctor-patient confidentiality, and meet data security requirements.

Label2Enable also aims at supporting an **equal use of health apps**. The use of health apps is indeed not yet inclusive. The biggest Users of such apps are found predominantly among younger, more educated and more eHealth literate populations, leaving others underserved and unaware of the benefits they provide. Label2Enable will engage in social policy and stakeholder engagement to enable all patients, citizens, and carers to (consider to) use apps, thanks to the label, supporting communication and trusted recommendations.

The project will also foster **the adoption of the label by health care systems and authorities** as well as app stores, app libraries and other sources who (seek to) store apps, with the goal of having a cross country recognition.

^{sss}

<https://digital-strategy.ec.europa.eu/en/policies/privacy-mobile-health-apps>