AGENCE DU NUMÉRIQUE EN SANTÉ
La transformation commence ici

Is certification to the Interoperability and Security standards for Digital Medical Devices (DMD) required for my Medical Device (MD) ?

Focus on the List of Products and Services (LPP)

Information on the entire system and its components to ensure admissibility :

Useful information to the ANS to assess admissibility :

- architecture diagram of the entire system describing the various functional blocks composing the MD(s) and describing the complete system in which the MD(s) is integrated;
- functional documentation of the entire system, MD's user guide;
- list of MD and non-MD components of the system (sensor, reader, prosthesis, ventilator, software, mobile application, indissociable accessories from the MD, servers, transmitters, communication tools, interfaces…);
- if applicable, the list of essential or compatible collection accessories (necessary for the MD's operation or part of another CE marking);
- name of the MD (complete solution or kit);
- name of the MD operator (see operator definition in the glossary);
- affected pathology(ies) and associated indications;
- information on the desired list of registration for each MD of the system (List of Medical Products and Services (LPPR) (Brand Name (NM) or Generic Line (LG)), List of Remote Medical Monitoring Activities (LATM) (Brand Name or Generic Line), Anticipated Coverage (PECAN) or Transitory Coverage (PECT) (see glossary).

For each MD of the system :

Does the MD include digital functions ?

A MD incorporating digital functions is defined in Article L162-48 II of the CSS, referring to the definition in Article 2 of Regulation (EU) 2017/745 of the European Parliament and of the Council of April 5, 2017, on medical devices.
It can be either a Software as a Medical Device (SaMD) or a Software in a Medical Device (SiMD).

→ No → **Medical Device not admissible for the DMD standards**

Yes ↓

Are these digital functionalities within the scope of CE marking in accordance with regulations 2017/745 or 2017/746, or possibly under European Directives 93/42 or 90/385 or 98/79 ?

→ No → **Medical Device not admissible for the DMD standards**

Yes ↓

Is the MD covered or a candidate for coverage via LPPR ?*

(The digital functionalities of the MD are either explicitly described in an LPPR registration nomenclature or included in a service covered by LPPR.)

*MDs wishing to register on the list of remote medical monitoring activities (LATM) are admissible for certification to the DMD standards.

→ No * → **Medical Device not admissible for the DMD standards**

*The operator is responsible for ensuring that their DMD is not admissible for certification under other standards than these of the LPPR.

Yes ↓

Does the use of the digital MD involve either processing personal data or hosting health data ?

→ No → **Medical Device not admissible for the DMD standards**

Yes ↓

Is the digital MD for individual use (i.e., for the use of a single patient) ?

→ No → **Medical Device not admissible for the DMD standards**

Yes ↓

MD admissible for the compliance certification to the DMD standards

Which mandatory requirement sections apply to each of the MDs included in the scope of the DMD standards ?

For each MD of the system :

For each DMD included in the scope of the DMD standards

In any case → **GDPR**
In any case → **PORT**

Does the DMD involve data hosting (excluding local storage) to perform any of its functionalities (including non-medical functionalities) ?

Yes → **HDS certificate** in accordance with articles R1111-8-8 to R1111-8-11 of the CSP and L1111-8 of the CSP

Does the DMD have patients' access (requiring an identification) ?

Yes → **PGSSIS IEU hors IEU7 et IEU8**

Does the DMD have healthcare professionals' access (requiring an identification) ?

Healthcare professionals are exhaustively listed in the Public Health Code :

- medical professions: doctors, dentists, dental surgeons, and midwives (Art. L4111-1 to L4163-10);
- pharmacy and medical physic professions : community and hospital pharmacists and medical physicists (Art. L4211-1 to L4252-3);
- auxiliary medical professions : nursing aides, childcare assistants, ambulance attendants, dental assistants, nurses, physiotherapists, podiatrists, occupational therapists, psychomotor therapists, speech therapists, optometrists, audioprosthologists, opticians, prosthetists, orthotists, dieticians (Art. L4311-1 to L4394-4).

Yes → **PGSSIS IEPS**
Yes → **PSC**
Yes → **ANN**
Yes → **INS et IEU7 et IEU8**
Yes → **ADM**

Mandatory requirements of the framework :

Requirements applicable based on the digital MD :

Glossary

ADM : Standard's Administration section

ANN : Standard's Health Directory section

CSP : Public Health Code (Code de la Santé Publique)

MD : Medical Device

DMD : Medical Device with digital functions

Operator : In accordance with Article L.165-1-1-1 of the Social Security Code, an operator of a health product other than a drug listed in one of the lists provided for in Articles L. 165-1 or L. 165-11 or covered under Article L. 165-1-1 or L. 165-1-5 is the manufacturer, its agent, or a distributor ensuring the operation of this product. Operation includes marketing or free transfer on the French market of the product. For each product, the operator is :

- The manufacturer or its agent ;
- Failing that, the distributor(s) who directly obtain(s) supplies from the manufacturer or its agent ;
- Failing that, any distributor operating in the French market, if for each marketed product, this distributor does not obtain supplies from an operator of this product, directly or indirectly, nor supply another operator, directly or indirectly.

HDS : Hosting of Health Data (Hébergement des Données de Santé)

IEU : Standard's Electronic User Identification section (for patients)

IEU7 : Standard's Requirement number IEU7 of the PGSSI-S section

IEPS : Standard's Electronic Identification of Healthcare Professionals section

INS : National Health Identity (not to be confused with the national health identifier, which is only a part of it)

LATM : List of Remote Medical Monitoring Activities (Liste des Activités de Télésurveillance Médicale)

LPPR : List of Products and Services (Liste des Produits et Prestations Remboursées)

PECAN : Anticipated Coverage (Prise En Charge Anticipée)

PECT : Transitory Coverage (Prise en Charge Transitoire)

PGSSI-S : General Policy on Health Information Systems' Security

PORT : Standard's Health data portability section

PSC : Pro Santé Connect

GDPR : General Data Protection Regulation