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EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

D5.1 Submission Dossier Template – Supplement for Medical Devices

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Document history and contributors

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0.1	17-05-2023	First draft
0.2	23-06-2023	Second draft
0.3	11-07-2023	Draft for CSCQ validation
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Participants

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CEB	

The work in EUnetHTA 21 was a collaborative effort. While the agencies in the Hands-on Group actively wrote the deliverable, the entire EUnetHTA 21 consortium was involved in its production throughout various stages. This means that the Committee for Scientific Consistency and Quality (CSCQ) reviewed and discussed several drafts of the deliverable prior to validation. Afterwards the Consortium Executive Board (CEB) endorsed the final deliverable prior to publication.

Associated HTAb

The draft deliverable was reviewed by associated HTAb. The draft template was note open for public consultation, as the draft guidance on the submission dossier template underwent public consultation between 04.07.2022 and 02.08.2022. Furthermore, a dedicated meeting was held with Health Technology Developers on July 13, 2023 to discuss the template.

Associated HTA bodies who reviewed	Dachverband der Österreichischen Sozialversicherung, [DVSV], Austria Norwegian Institute of Public Health, [NIPH], Norway Evaluation and Planning Unit – Directorate of the Canary Islands Health Service, [SESCS], Spain Regione Emilia-Romagna, [RER], Italy Health Information and Quality Authority [HIQA], Ireland DPA, Malta

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General remark

While many parts of the submission dossier template for medicinal products also apply to medical devices (MDs), including in-vitro diagnostics (IVDs), the specificities of MDs require some adjustments to be made to the template. Thus, a separate submission dossier template for MDs will be developed at a later stage outside of EUnetHTA21 (i.e. by the relevant subgroup(s) of the HTA Coordination Group) once the template for medicinal products has been finalised. The current supplement for MDs mainly provides MD-specific tables to be completed by the health technology developer (HTD) in Part 2 (Background) of the submission dossier template. The supplement is based on the submission dossier guidance.

List of abbreviations

Abbreviation	Meaning
CEB	Consortium Executive Board
CSCQ	Committee for Scientific Consistency and Quality
EMDN	European Medical Device Nomenclature
EU	European Union
FSCA	Field safety corrective action
HaDEA	European Health and Digital Executive Agency
HTA	Health Technology Assessment
HTAR	Regulation (EU) 2021/2282 of the European Parliament and of the Council on HTA assessment
HTD	Health Technology Developer
IVD	In vitro Diagnostic Medical Device
IVDR	In vitro Diagnostic Medical Device regulation (Regulation (EU) 2017/746)
MD	Medical Device
MDR	Medical device regulation (Regulation (EU) 2017/745)
MRI	Magnetic resonance imaging
PACA	Preventive action or corrective action
UDI-DI	Unique device identification-device identifier (according to Regulation (EU) 2017/745)

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1 MD-specific tables for Part 2 (Background) of the submission dossier template

The following table replaces Table 5 in Section 2.2.1 (Characteristics of the health technology) of the submission dossier template for medicinal products. The sources of information must be provided for each item of the table.

A detailed description of the medical device and its constituents must be provided in a separate section outside the table. It shall include the composition, the technologies involved and the technical characteristics of the medical device under assessment.

Additionnally, any section from the table needing detailed explanations should be developed outside the table following the same listing order as per the table.

Table 1: Characteristics of the health technology (medical devices (including IVDs))

Device trade name(s)	
HTD submitting the dossier	[also specify whether it is the MD manufacturer or an authorised representative]
Name of manufacturer if different from HTD submitting the dossier	
Device description according to the EMDN	
Risk class of the device	[according to the MDR or IVDR]
Specific medical purpose of the device	[according to Article 2(1) MDR]
Description of the main stages of the development of the technology	[e.g. when previous versions of the technology are available, the main changes made to these different versions shall be described]
Model(s) of the device/ reference number(s)/ Software version	
Intended purpose of the device	
Indication(s) and target population(s)	
Contraindications and/or restrictions for use and/or limitations of the device	
Brief description of the device including its constituents	
Mode(s) of action (MDs) or test principle (IVDs)	
If applicable, specific description for the connected technology	
For medical devices with an embedded decision-making system based on machine learning processes (technologies falling within the scope of artificial intelligence): description of the functions built or evolving using these technologies	
footnotes (please delete this line if it is not needed)	
EMDN: European Medical Device Nomenclature; HTD: health technology developer; IVD: in vitro diagnostic; IVDR: in vitro diagnostic medical device regulation; MD: medical device; MDR: Medical device regulation	

The following table replaces Table 6 in Section 2.2.1 (Characteristics of the health technology) of the submission dossier template for medicinal products. The sources of information must be provided for each item of the table.

Any section from the table needing detailed explanations should be developed outside the table following the same listing order as per the table.

Table 2: Characteristics of use (by (sub)population or patient group if appropriate) (medical devices (including IVDs))

Specific feature of the device, if relevant	[Examples (can be deleted as appropriate): to administer and/or remove a medicinal product to act as a companion diagnostic to emit hazardous, or potentially hazardous, levels of ionising and/or nonionising radiation to be operated together with other devices or products]
Description of (surgical) procedures, services and organisational aspects associated with the use of the device	
Suggested profile and training for users	
If applicable, MRI compatibility	[For implantable MDs liable to give rise to artefacts, the potential impact of these artefacts on MRI interpretation and the associated recommendations for use shall be documented. For AIMDs, specify the limits of compatibility with MRI procedures and the main precautions to be taken. Where applicable, the AIMD deactivation measures required to conduct the test shall be specified.]
footnotes (please delete this line if it is not needed)	
AIMD: active implantable medical devices; MD: medical device; MRI: magnetic resonance imaging	

The following table replaces Table 8 in section 2.2.3 (Regulatory status of the technology) of the submission dossier template for medicinal products. The sources of information must be provided for each item of the table.

Table 11 of the submission dossier template for medicinal products named “Regulatory status in Australia, Canada, China, Japan, the United Kingdom and the United States of America” should be filled in for MDs as well.

Note that tables 7, 9 and 10 of the submission dossier template for medicinal products should not be filled in for MDs.

Table 3: Regulatory information on the health technology (medical devices (including IVDs))

Basic UDI-DI	
Risk class of the device	
Name, identification number and country of Notified Body that issued the CE marking	
Date of initial CE marking	
Expiry date of current certificate	
Date on which the MD was first placed on the EU market in the course of commercial activity	
Date and reference of the expert panel opinion (MD) or expert panel view (IVD)	
In the course of the post-market surveillance (when relevant, e.g. MD already marketed outside the EU): - Have PACAs been conducted? - Have serious incidents been reported or FSCAs been issued?	 □ Yes* □ No □ Yes* □ No * The corresponding details shall be provided in Appendix
footnotes (please delete this line if it is not needed)	
CE: conformité européenne; FSCA: field safety corrective action; IVD: in vitro diagnostic medical device; MD: medical device; PACA: preventive action or corrective action; UDI-DI: Unique Device Identification-Device Identifier	