MDCG 2021-3

Questions and Answers on Custom-Made Devices

& considerations on Adaptable medical devices and Patient-matched medical devices

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Introduction

This Q&A is a high-level document aimed at addressing the most pertinent questions relating to custom-made devices falling under Regulation (EU) 2017/745 on medical devices (MDR). Further guidance on this subject may be elaborated by the MDCG, as appropriate.

In accordance with Recital 5 of the MDR, certain references to International Medical Device Regulatory Forum (IMDRF) guidance documents and terminology included therein have been taken into account under this Q&A. Specifically, the MDR regulatory status of adaptable medical devices and patient-matched medical devices (introduced by IMDRF PMD WG/N49 FINAL: 2018) is clarified in this Q&A.

1. What is a custom-made device (CMD)?

MDR Article 2(3) defines a 'custom-made device' as any device that:

- is specifically made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications; which gives
- specific design characteristics provided under that person's responsibility; and
- is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.

Examples of CMDs include:

- A dental crown manufactured according to a written prescription provided by a dentist containing specific design characteristics for a particular patient's individual condition.
- An orthosis made in accordance with a written prescription containing specific design characteristic to aid a person with neuromuscular or musculoskeletal impairment of the lower extremity, such as a Knee Ankle Foot Orthosis (KAFO).
- Hand prosthesis intended to replace a lost body part and/or function made in accordance with a written prescription, where the practionner provides patient specific design characteristics necessary for the manufacturing of the device.

Devices which are not considered CMDs may include:

(a) Devices that are mass-produced which need to be adapted to meet the specific requirements of any professional user, hereafter referred to as adaptable medical devices.[1]

(b) Devices that are mass-produced by means of industrial manufacturing processes, potentially made in accordance with the written prescriptions of an authorised person.

[1] An Adaptable medical device is defined in in *IMDRF PMD WG/N49 FINAL: 2018* as a mass-produced medical device that must be adapted or assembled at the point of care, in accordance with the manufacturer's validated instructions, to suit an individual patient's specific anatomo-physio logic features prior to use.

Note 1: Adaptable medical devices (products which fall under (a) above) are mass-produced[2] medical devices which must be adapted, adjusted, assembled or shaped at the point of care, traditionally by a healthcare professional, in accordance with the manufacturer's validated instructions[3] to suit an individual patient's specific anatomo-physiologic features prior to use.

Examples of mass produced adaptable medical devices may include:

- certain spectacle frames and optical glasses (assembled together to form spectacles).
- patient fitted wheelchairs.
- hearing aids (otoplastic and amplifier).
- orthotic braces.
- exo-prosthetics.

According to MDR art. 16(1), a person (e.g. healthcare professional) who adapts, adjusts, assembles or shapes an adaptable medical device for a particular patient is not regarded as a manufacturer, as long as the adaptation, adjustment, assembly and shaping does not modify the device in such a way that compliance with the applicable requirements may be affected or changes the intended purpose.[4]

Note 2: Patient-matched medical devices, as defined by IMDRF,[5] are devices which may fall under point (b) above. A patient-matched device is defined as a medical device that meets the following requirements:

- it is matched to a patient's anatomy within a specified design envelope using techniques such as scaling of the device based on anatomic references, or by using the full anatomic features from patient imaging; and
- it is typically produced in a batch through a process that is capable of being validated and reproduced; and
- it is designed and produced under the responsibility of a manufacturer even though the design may be developed in consultation with an authorized healthcare professional.

Different from a custom-made device, these devices are typically produced in batches or through mass production and do not require a written prescription by an authorised person (see Q6 for more information on written prescriptions).

In particular, a patient-matched medical device is held under the sole accountability of the manufacturer who is entirely responsible for the design, safety, performance and overall compliance of the device.

[2] A mass-produced medical device is defined in *IMDRF PMD WG/N49 FINAL: 2018* as a medical device that is based on standardised dimensions/designs; that is not designed for a particular individual; and that is typically produced in a continuous production run or homogenous batch.

[3] These instructions are those deemed necessary for the adaptation of the device and should not be confused with instructions for use referred to in Annex I Chapter III 23.1d of Regulation (EU) 2017/745 on medical devices.

[4] Please note that components of a system or procedure pack, which can be assembled at the point of care are not subject of this Q&A.

[5] IMDRF PMD WG/N49 FINAL: 2018

It must be underlined that products which are adaptable medical devices or patient-matched medical devices (as defined by IMDRF) are not qualified as CMDs and must follow the 'standard' MDR regulatory pathway for placing on the market.

Examples of patient-matched devices:

- Plates used to fix a broken bone, which are made by 3D printing, based on a template model and DICOM files/ images of the patient. The plates are printed within the validated dimensional ranges allowed by the specified design envelope under the sole responsibility of the manufacturer.
- Cutting guides used in procedures such as knee arthroplasties, or guides used for pedicle screw placement, that are made by 3D printing based on MR or CT data to match a specific patient.
- Mandibular implants produced by a 3D printing manufacturer, from a template model and DICOM files.
- Made to order contact lenses which are produced on request typically in batches with validated or verified production processes using standardised tools and materials and within clearly specified dimensions. No specific or individual design process necessary.
- An externally worn orthosis to support, prevent or assist body functions, based on external 3D scan images and or measures, by a manufacturer who produces this under his sole responsibility, within validated parameters.

2. Can parts, components or materials specifically intended to be used in a custom-made device, adaptable medical device or patient-matched medical device be placed on the market as medical devices according to the MDR?

In accordance with Article 2(1) MDR, the intended purpose of a medical device can be achieved either alone or in combination with other devices or products. Certain parts, components or materials may carry a medical intended purpose and can thus fulfil the definition of a medical device. By analogy, parts, components or materials of custom-made devices, adaptable medical devices or patient-matched medical devices may be CE-marked medical devices.

Accordingly, it is possible for "intermediate products" which are specifically intended for the manufacture of CMDs, adaptable medical devices or patient-matched medical devices to be also placed on the market as medical devices, as these products are specifically intended to become a part or component of a final CMD, adaptable medical device (finally adapted) or patient-matched medical device.[6] Instructions for use provided by the manufacturer of these CE marked devices should be followed when performing further preparatory processing, preparation, configuration, installation, assembly, adaptation or fitting in order to meet the needs of the user or patient prior to their use.

[6] This essentially applies to dental ceramics and modular components for prosthesis, if these intermediate products are specifically intended to be used for the manufacture of CMDs, adaptable medical devices or patient-matched medical devices.

3. Are there specific considerations/requirements which must be taken into account by manufacturers of devices referred to in Question 2?

Manufacturers of devices referenced in question 2 shall fulfil all relevant and applicable requirements of the MDR. To determine the risk classes of those products, it is necessary to consider:

- the intended medical purpose of the final CMD, adaptable medical device or patient-matched medical device;
- whether it is an implantable medical device (i.e. whether the part, component or material is intended to be used in the manufacturing of an implantable CMD, adaptable medical device or patient-matched medical device)[7];
- the risks related to the intended contact or interaction of the product as a part, component or material in the final CMD, adaptable medical device or patient-matched medical device with the patient's body.[8]

If any of the physical, chemical or biological properties of those products referred to in question 2 change during the manufacturing of the CMD, patient-matched medical device or the adaptation process of the adaptable medical device (e.g. plastics, metallic compounds, ceramic fluids for crowns), compliance of the finished product with the general safety and performance requirements of MDR Annex I has to be demonstrated.

It is important to note that the manufacturer must also demonstrate that these products do not create unacceptable risks to the persons performing the relevant preparatory processing (such as preparation, configuration, installation, assembly, adaptation or fitting) to the needs of the patient prior to their use.

The clinical evaluation conducted by the manufacturer should focus on demonstrating the clinical benefit related to the intended medical purpose of the products when used as parts, components or materials of a custom-made devices, adaptable medical devices or patient-matched medical devices.[9]

To perform a post-market clinical follow-up (PMCF), liaison with the authorised person responsible for the issuing of the relevant written prescription, CMD manufacturers who have utilised the part, component or material and persons adapting the final device is necessary.

Furthermore, the manufacturer of devices referred to in question 2 bears the responsibility over these CE marked medical devices and is responsible for all incumbent MDR obligations such as post-market surveillance activities and vigilance reporting for the parts, components or materials.

[7] Implantable devices encompass those devices which are partially or wholly implanted. Please refer to Article 2(5) of the MDR for the definition of an 'implantable device'.

[8] In general, the risk class of the product is expected to be the same as the risk class of the final CMD, adaptable medical device or patient-matched medical device. For example, if a part, component or material is specifically intended to be used for the manufacture of a Class III implantable custom-made device, then that part, component or material would be classified as a Class III implantable.

[9] For further clarifications on clinical evaluation for custom-made devices, please refer to question 8.

4. Can manufacturers use state of the art industrial manufacturing processes to manufacture CMDs?

As long as the definition of a CMD is fulfilled (refer to question 1) and the device is not mass-produced, manufacturers may use modern state of the art technologies (such as CAD CAM, 3D-Printing etc.) to manufacture CMDs.

5. Does a 3D printed device (additive manufacturing) qualify as a CMD?

A 3D printed device does not qualify as a CMD by default. An assessment should be performed on a case-by-case basis. In order for a 3D printed device to qualify as a CMD, the following requirements must be met:

- a written prescription, containing patient specific design characteristics, of an authorised person is in compliance with the requirements expressed below (see question 6),
- the manufactured device is intended for the sole use of a particular patient, exclusively to meet their individual conditions and needs,
- the device is not mass-produced.

6. What defines a written prescription containing patient specific design characteristics?

A written prescription must be issued by a qualified person authorised by national law. At minimum, it should contain:

- the name of the patient (or pseudonym if relevant),
- specific design characteristics made by the authorised person which are unique to the patient's anatomic-physiological features and/or pathological condition.

The following (non-exhaustive) additions can accompany a written prescription and if so, also constitute specific design characteristics:

- models (physical or 3D model data).
- moulds (e.g. for dental or orthotic purposes).
- dental impressions.

Note: Dimensions and/or geometric parameters (such as DICOM files from CT scans) are not considered specific design characteristics on their own. Additional measured data or information[10] by the prescribing person is necessary as part of a written prescription in order for the definition of a CMD to be met.

[10] Such as the thickness and trajectory of a plate, the number, type and positions of fixation screws, choice of material, shall also be provided for in the prescription to be considered as containing specific design characteristics.

7. Shall the authorised person referred to in the definition of a CMD be a healthcare professional?

No. The Regulation explicitly states that it should be any person authorised by national law. Therefore, it is up to Member States to establish who qualifies as an authorised person.

8. What are the obligations of CMD manufacturers according to the MDR?

With the absence of stated exceptions, CMD manufacturers must meet nearly all of the MDR requirements. Although the authorised person issuing the written prescription primarily determines the design and intended purpose of the CMD, it is the responsibility of the CMD manufacturer to consider which MDR Annex I requirements are applicable to the device at hand.

Additionally, and as any other medical device manufacturer, CMD manufacturers shall establish, document, implement, maintain, keep up to date and continually improve a quality management system (QMS) that shall ensure compliance with the MDR in the most effective manner and in a manner that is proportionate to the risk class and the type of device. The QMS must address all elements described in Article 10(9) of the MDR.

To implement an MDR compliant post-market surveillance system, the CMD manufacturer should establish appropriate communication channels with relevant healthcare providers/professionals or patients to receive feedback on the quality, performance and in particular the clinical performance and safety of the devices in the field.

For risk management, post-market surveillance and clinical evaluation life cycle processes as defined by the MDR, CMD manufacturers should apply these obligations to groups of devices with the same intended purpose, materials used, process utilised, same principal design etc. and not to each individual CMD.

In accordance with Article 87(1) of the MDR, CMD manufacturers shall report to the competent authorities any serious incidents and/or field safety corrective actions as soon as they learn of them.

9. Which obligations of CMD manufacturers differ from those of other medical device manufacturers?

The conformity assessment procedure for all types of CMDs is described in MDR Annex XIII. In accordance with section 1 of Annex XIII, and in place of a declaration of conformity, CMDs shall be accompanied by an Annex XIII statement. This statement shall be made available to the particular patient or user identified by a name, an acronym or a numerical code.

A conformity assessment procedure covering QMS certification by a notified body (in accordance with Chapter I of Annex IX or Part A of Annex XI of the MDR) is applicable to Class III implantable CMDs.[11] According to Article 56 (5), the registration of QMS-certificates issued for Class III implantable CMD shall be entered into EUDAMED. In addition, manufacturers may

[11] Article 52(8) MDR.

have to comply with national requirements on the registration of economic operators and devices.

CMD manufacturers are exempt from device UDI registration, assignment and labelling requirements. As such, and although they must appoint a person responsible for regulatory compliance (PRRC) in accordance with Article 15 of the MDR, they are not required to register these persons in EUDAMED.

In addition, Article 32(1) prescribes that a Summary of Safety and Clinical Performance (SSCP) is not required for a custom-made device.

As for post-market surveillance, a report for Class I devices according to Article 85 MDR and a Periodic Safety Update Report (PSUR) for class IIa, IIb and III according to Article 86 MDR, must be established by the CMD manufacturer. Both the post-market surveillance report and the PSUR must be part of the CMD documentation according to Section 2 of Annex XIII of the MDR.

In case of Class III implantable CMDs, PSURs are not required to be sent to notified bodies but must be part of the CMD documentation according to Section 2 of Annex XIII of the MDR.

10. What are the implications for a CMD manufacturer using CE-marked devices referred to in question 2 instead of non-CE marked devices?

In both cases, it is the responsibility of the CMD manufacturer to establish full compliance of the CMD with the MDR.

Where a CMD manufacturer uses a CE marked device, part, component or material (as described in Q2) for the purpose of manufacturing a CMD, then the CMD manufacturer may take into consideration the compliance of these aforementioned CE-marked products with the general safety and performance requirements of the MDR. When performing a clinical evaluation for the CMD, the CMD manufacturer can make use of the clinical evaluation performed for the aforementioned CE marked products, as this clinical evaluation (see also answer to Q3) can support the fulfilment of the general safety a performance requirements and demonstrating clinical evidence necessary for the final CMD.

When the CMD manufacturer has to perform further preparatory processing, preparation, configuration, installation, assembly, adaptation or fitting to the needs of the patient prior to the device's use, this must be done in accordance with the instructions provided by the manufacturer of the CE-marked device.

It must be noted that it is not possible to presume conformity or to rely on clinical evaluations of non-CE marked devices. It is also not possible to presume conformity or to rely on clinical evaluations of CE

marked devices when they are being used outside of their intended purpose or outside the instructions provided by the manufacturer.