CAMD Transition Sub Group

FAQ – MDR Transitional provisions

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Glossary:

- AIMDD/MDD compliant device = device that is compliant with Directive 90/385/EEC/ Directive 93/42/EEC
- AIMDD/MDD certificates = certificates in accordance with Directive 90/385/EEC/ Directive 93/42/EEC
- DoA = date of application of the MDR
- MDR = Medical Device Regulation (EU) 2017/745
- MDR compliant device = device that is compliant with the MDR
- MDCG = Medical Device Coordination Group
- MFR = manufacturer
- PRRC = person responsible for regulatory compliance
- NB = notified body
- "old" NB = NB that has issued an AIMDD/MDD certificate
- The Directives = Directives 90/385/EEC, 93/42/EEC

Document History

Version	**Publication**	**Note**
V1.0	17/01/18	Original publication

Contents:

I - Issue: Transition in general		
1	Question:	When does the Medical Devices Regulation (EU) 2017/745 (= MDR) apply?
	Answer:	The MDR shall apply from 26 May 2020 (= date of application (DOA)), see Art. 123 para 2 MDR. There are however exceptions to that general rule. Some provisions apply earlier (e.g. regarding notified bodies or the Medical Device Coordination Group), some later (e.g. regarding UDI labelling). For the exceptions, see Art. 123 para 3 MDR (earlier application: a-c, i; postponed application: d –h).
2	Question:	When do the Directives 90/385/EEC, and 93/42/EEC [= the Directives] cease to apply?
	Answer:	In general the Directives 90/385/EEC and 93/42/EEC are repealed with effect from 26 May 2020 (= DoA), see Art. 122 MDR. However there are some exceptions, e.g. • in order to deal with devices that are compliant with the Directives or • to serve as a “back up” in case EUDAMED is not fully functional at DoA (see Art. 122 MDR).
3	Question:	What is the applicable legislation **until** 26 May 2020 (= DoA)?
	Answer:	Laws and regulations adopted by Member States in accordance with the Directives (= Directives regime). There are however exceptions (see for example Art. 123 para 3 a – c, i MDR and Art. 120 para 5 and 6 MDR).

II - Issue: Placing on the market of **MDR compliant** devices until 26 May 2020 (Art. 120 para 5-7 MDR)		
4	Question:	Is it possible to place a device, which is compliant with the MDR (= **MDR compliant device**), on the market prior to 26 May 2020 (= DoA)?
	Answer:	**Yes**, see Art. 120 para 5 MDR. Manufacturers (= MFR) are – until 26 May 2020 (= DoA) normally required to place devices on the market that comply with the Directives (= AIMDD/MDD compliant devices), however Art. 120 para 5 MDR offers the **option** to place MDR compliant devices on the market before DoA.
5	Question:	Is it possible for **all types of devices** (for all different risk classes I – III) compliant with the MDR (= MDR compliant device) to be placed on the market prior to 26 May 2020 (according to Art. 120 para 5 MDR)?
	Answer:	**Yes**, all types of **devices** - regardless of their risk class – may be placed on the market according to Art. 120 para 5 MDR. This includes for example custom made devices (Art. 2 para 3 MDR) and systems and procedure packs (Art. 2 para 10 and para 11 MDR). **However**, devices being subject to the "clinical evaluation consultation procedure" according to Art. 54 MDR (= certain class III and class IIb devices) may not be placed on the market in accordance with Article 120 para 5 MDR before the Medical Device Coordination Group (MDCG) and the expert panels have been established (see Art. 120 para 7 MDR). Depending on the risk class of the device, conformity assessment may require the involvement of a **NB designated and notified in accordance with the MDR** (see Art. 120 para 6 MDR). In this case, such devices cannot complete a conformity assessment, and therefore may not be placed on the market, before NBs have been designated and notified under the MDR.

6	Question:	As a MFR, which obligations **of the MDR** do I need to fulfil in order **to place** a **MDR compliant** device **on the market <u>before</u>** the DoA according to Art. 120 para 5 MDR?
	Answer:	As many obligations as are possible, while taking into account that • EUDAMED is not fully functional and • the MDR is not fully applicable at that point in time. Generally speaking, that is to say that: • first, **the device** as such needs to be MDR compliant (see Annex I) and • second, the **MFR** has to comply with the MDR. In particular, the MFR shall undertake an **assessment of the conformity of that device in accordance with the applicable conformity assessment procedures set out in Art. 52 MDR**. This may, depending on the risk class of the device, necessitate the involvement of a notified body designated and notified **in accordance with the MDR** (see Art. 120 para 6 MDR). The following requirements of the **MDR** need to be fulfilled by the MFR (non-exhaustive list): • clinical evaluation • risk management • QMS • Post-market surveillance • Technical documentation and other reports • Liability for defective devices

		However, exceptions/adaptations are possible/necessary, particularly due to the fact that EUDAMED may not be fully functional before the DoA. For example: • in the absence of a fully functional EUDAMED some **requirements of the Directives** shall – where necessary - apply in place of the relevant provisions of the Regulation (e.g. registration of devices and economic operators). • **A person responsible for regulatory compliance** (PRRC, Art. 15 MDR) needs to be available but not necessarily registered until EUDAMED is available. . • The **assignment of an UDI** (Art. 27 para 3 MDR) is not possible as long as there are - no issuing entities designated by the Commission according to Art. 27 para 2 MDR or - as long as the legal fiction according to Art. 120 para 12 does not apply (it shall apply from 26 May 2019, see Art. 123 para 3 i MDR). It is of no significant use as long as there is no UDI database. • An **implant card and the information according to Art. 18 MDR** need to be provided, however without the UDI related content (as the requirement to place the UDI carrier on the devices will be stepwise introduced after the DoA).
7	Question:	Are **MDR compliant devices** placed on the market according to Art. 120 para 5 MDR subject to the so called **"sell off" provision** in Art. 120 para 4 MDR (see below)?
	Answer	**No**, the possibility of their being made available/put into service is not time-limited.

III - Issue: Placing on the market of **devices in conformity with the Directives** after 26 May 2020 (Art. 120 para 2 -3 MDR)		
8	Question:	Do **certificates** issued by notified bodies **in accordance with the Directives** (= **AIMDD/MDD certificates**) prior to 25 May 2020 remain valid after the DoA?
	Answer:	**Yes**, as specified in Art. 120 para 2 MDR. In general, they remain valid until the end of the period indicated on the certificate. Certain AIMDD/MDD certificates (Annex 4/IV, refer to Art. 120 para 2 first sentence MDR) become void at the latest on 27 May 2022, others (refer to Art. 120 para 2 second sentence MDR) on 27 May 2024 at the latest. In other words, after 27 May 2024 there will be no more valid AIMDD/MDD certificates.
9	Question:	**What kind** of certificates **remain valid** according to Art. 120 para 2 MDR?
	Answer:	**All** certificates which are commonly issued **by Notified Bodies** with reference to the Council Directives MDD and AIMDD. That is [see for example NBOG BPG 2010-3, similar NB-MED/2.5.1Rec 4]: – **EC Design-Examination Certificate** (Annex II section 4 MDD, Annex 2, section 4 AIMD) – **Certificate of Conformity** (Annex IV MDD, Annex 4 AIMD) – **EC Type Examination Certificate** (Annex III MDD; Annex 3 AIMD) – **EC Certificate Full Quality Assurance System** (Annex II excluding section 4 MDD; Annex 2 section 2 AIMD) – **EC Certificate Production Quality Assurance** (Annex V MDD, Annex 5 AIMD)

		– **EC Certificate Product Quality Assurance System** (Annex VI MDD)
10	Question:	May a "**declaration of conformity**" be considered as a "certificate" according Art.120 para 2 MDR?
	Answer:	No, since it is not a certificate issued by a NB.
11	Question:	Is it possible for a MFR to have **valid MDR and valid AIMDD/MDD certificates in parallel** until the 27 May 2024 expiry date?
	Answer:	Yes.
12	Question:	May devices, that are compliant with the Directives (= **MDD/AIMDD compliant devices**), be placed on the market/put into service after 26 May 2020 (= DoA)?
	Answer:	**Yes**, under **certain conditions** (see answer on question 17) as specified in Art. 120 para 3 MDR. In general, after 26 May 2020, devices need to comply with the **MDR** in order to be placed on the market/put into service (see Art. 5 MDR). However, for a limited time (depending on the validity of the MDD/AIMDD certificates) there is the **option** to continue to place devices on the market that are compliant with the Directives. Making use of this option may postpone the immediate need for a new certificate under the MDR.
13	Question:	May MFRs of **class I devices**, **that are compliant with the Directives**, make use of the derogation in Art. 120 para 3 MDR (= be placed on the market after the DoA)?
	Answer:	**No**, they **must comply with the MDR**, unless the device concerned is a class I device with **measurement function or in sterile condition** covered by a **valid MDD certificate**.

14	Question:	May devices that are excluded from the scope of the MDR (e.g. via Art. 1 para 6 lit h) nonetheless benefit from Art. 120 para 3 MDR?
	Answer:	**No**, these devices do not fall under the MDR, thus Art. 120 para 3 MDR is not applicable.
15	Question:	May **MDD/AIMDD compliant devices**, which under the MDR will be **subject to an "upgrade" in risk class** ("up-classification")**,** e.g. formerly class IIa -> then class III, benefit from Art. 120 para 3 MDR?
	Answer:	**Yes**, under the conditions specified in Art. 120 para 3 MDR (e.g. **valid AIMDD/MDD certificate**). Devices which are in a different respectively higher risk class in MDR than under the Directives are not as such excluded from the scope of Art. 120 para 3 MDR.
16	Question:	If, according to Art. 120 para 3 MDR, a MFR intends to place a **MDD/AIMDD compliant device** on the market after the DoA, that, under the MDR, will be **subject to an "upgrade" in risk class** ("up-classification")**,** what is the **relevant risk class** with regard to the applicable MDR requirements listed in Article 120 para 3 MDR (e.g. PSUR)?
	Answer:	The risk class under **MDD/AIMDD**.
17	Question:	What are the **requirements** for the placing on the market/putting into service of **MDD/AIMDD compliant devices** according to Art. 120 para 3 MDR after DoA?
	Answer:	See Art. 120 para 3 MDR. In short: 1. **A valid** AIMDD/MDD certificate according to Art. 120 para 2 MDR [**All** certificates necessary for the placing on the market of the device in question need to be valid, e.g. a class III device needs to have a valid QMS as well as product specific certificate.] 2. Continuous **compliance of the device** with the **Directives**

		3. **No significant changes** in the design and intended purpose [If there is a significant change in either the design **or** the intended purpose, Art. 120 para 3 MDR cannot be claimed. Qualification of a change as "**significant**" according to Art. 120 para 3 MDR shall be determined on a case by case basis. However, - **limitations of the intended purpose** - **design changes related to corrective actions** assessed and accepted by the Competent Authority are <u>not</u> considered "**significant**" in the sense of Art. 120 para 3 MDR.. 4. **Application of MDR requirements** in place of the corresponding requirements of the Directives with regard to: a. **Registration of economic operators and of devices** (see Art. 31 MDR and Art. 29 MDR) b. **Post market surveillance** (PMS) (see Art. 83-86, 92 MDR including Annex III but without the PMS having to be an integral part of the QMS) c. **Market surveillance** (see Art. 93 – 100 MDR, but device standards to be met = Directives) d. **Vigilance** (see Art- 87-92 MDR) However exceptions are possible in the case that EUDAMED is not fully functional in time (then see Art. 123 para 3 d and e MDR). Moreover, the "old" NB which issued the AIMDD/MDD certificate shall continue to be responsible for the appropriate surveillance of all the applicable requirements relating to the devices it has certified. This should be agreed on between the "old" NB and the MFR on a **contractual basis**.

IV - Issue: The **so called "sell off" provision** of Art. 120 para 4 MDR		
18	Question:	What is the so called "sell off" provision (Art. 120 para 4 MDR) about?
	Answer:	It is intended to **limit the time** during which **AIMDD/MDD compliant devices,** that have already been placed on the market (either before the DoA or by virtue of Art. 120 para 3 after the DoA), **may be made available** e.g. by a **distributor**. After May 27, 2025 these devices may not be made available/put into service (= deadline). If such devices are still within the supply chain by this date - i.e. have not reached the final user as being ready for use (e.g. the hospital) - they are not "marketable" any more. This provision is thus primarily dealing with the **"making available"** of AIMD/MDD compliant devices once they have been placed on the market, e.g. within the supply chain. It does not apply to the **"placing on the market"** of these devices by the **MFR**. Please also note, that this provision is not intended to apply to **second hand sales** (see recital 3). This means, once a device has been made available to the final user (e.g. the hospital) as being ready for use, the **further making available** of this device is not subject to/covered by the MDR.
19	Question:	Does Art. 120 para 4 MDR enable MFRs to place **MDD/AIMDD compliant devices** on the market until May 27, **2025**?
	Answer:	**No.** Art. 120 para 4 MDR is **not** applicable to the "placing on the market" of MDD/AIMDD compliant devices (see question 18). The only way to place MDD/AIMDD compliant devices on the market after DoA is Art. 120 para 3 MDR (see questions 12-17). Given that MDD/AIMDD certificates will no longer be valid after May 27 2024, this option ceases to exist from that date onwards.

V – Issue: **EUDAMED** and its relevance for the application of certain provisions of the MDR (Art. 123 para 3 d and e, Art. 120 para 8, Art. 122 MDR)		
20	Question:	Do **all devices** have to be **registered according to Art. 29 para 4 MDR** by the DoA?
	Answer:	**No.** Even if EUDAMED is fully functional at the DoA there will be an **18-month "interim phase"** (= EUDAMED fully functional but Art. 29 para 4 MDR not yet applicable) during which the different devices to be placed on the market may be registered **"step by step"** in EUDAMED according to Art. 29 para 4 MDR instead of nationally according to the Directives (see Art. 123 para 3 e and Art. 120 para 8 MDR). However, **at the end** of this "interim phase" it must be ensured that **all** devices of a MFR's portfolio have been registered in EUDAMED. If EUDAMED is not fully functional until a date after the DoA, the 18-month "interim phase" will be postponed accordingly (beginning at the later of the dates referred to in point d) of Art. 123 para 3 MDR).
21	Question:	Must NBs have entered **all the certificate related information of all devices** according to Art. 56 para 5 MDR into EUDAMED by the DoA?
	Answer:	**No.** Even if EUDAMED is fully functional at the DoA there will be an **18-month "interim phase"** (= EUDAMED fully functional but Art. 56 para 5 MDR not yet applicable) during which the relevant information according to Art. 56 para 5 MDR may be registered in EUDAMED **"step by step = certificate by certificate"** instead of nationally according to the Directives (see Art. 123 para 3 e and Art. 120 para 8 MDR). However, at the end of this "interim phase" it must be ensured that all the relevant data regarding all certificates have been registered in EUDAMED. If EUDAMED is not fully functional until a date after the DoA, the 18-month "interim phase" will be postponed accordingly (beginning at the later of the dates referred to in point d) of Art. 123 para 3 MDR).

22	Question:	What happens if **EUDAMED** is **not fully functional** at the DoA? How does this affect the **application of obligations and requirements of the MDR that relate to EUDAMED**?
	Answer:	The relevant provisions to refer to are mainly **Art. 123 para 3 d and e**. **Art. 123 para 3 d MDR:** The different **Articles listed in Art. 123 para 3 d** (= dealing with e.g. the registration of devices and economic operators, clinical investigations, notified bodies, vigilance, post-market surveillance, market surveillance) are **not fully** postponed with regard to their application but generally remain **applicable** from the DoA. **However,** their application is postponed **as far as** the obligations and requirements within these Articles relate to EUDAMED (which is not fully functional yet). **To that extent** they shall **apply** from the date corresponding to **6 months after the date of notice of full functionality**. Meanwhile (until EUDAMED is fully functional) the **corresponding provisions of the Directives** regarding exchange of information **continue to apply**. The principle is that the derogation applies to the electronic exchange of information/upload to EUDAMED. If the derogation is applicable this does not necessarily mean that the information itself does not need to be prepared/exchanged. This exchange of information e.g. reports will have to be done by other means *in lieu* of exchange via EUDAMED (Directives regime). The underlying idea behind this paragraph was to ensure compliance with the new obligations and requirements via the "old" systems as far as possible. The actual practical implication of this concept with regard to the different Articles listed in Art. 123 para 3 d MDR needs a closer look and further guidance, which is in progress. **Art. 123 para 3 e MDR**: For the application of **Art. 29 para 4 MDR and Art. 56 para 5 MDR** in the case that EUDAMED is not fully functional in time, see question 20 and 21.