CAMD Transition Sub Group

FAQ – IVDR Transitional provisions

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Glossary:

- IVDD compliant device = device that is compliant with Directive 98/79/EEC
- IVDD certificates = certificates in accordance with Directive 98/79/EEC
- DoA = date of application of the IVDR
- IVDR = In-Vitro Diagnostics Medical Device Regulation (EU) 2017/746
- IVDR compliant device = device that is compliant with the IVDR
- MDCG = Medical Device Coordination Group
- MFR = manufacturer
- PRRC = person responsible for regulatory compliance
- NB = notified body
- “old” NB = NB that has issued an IVDD certificate
- The Directive = Directive 98/79/EEC

Document History

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

Contents:

I - Issue: Transition in general		
1	Question:	When does the In-Vitro Medical Device Regulation (EU) 2017/746 (= IVDR) apply?
	Answer:	The IVDR shall apply from 26 May 2022 (=date of application (DOA)), see Art. 113 para 2 IVDR. There are however exceptions to this provision. Some provisions apply earlier (e.g. regarding notified bodies or the European Union reference laboratories), some later (e.g. regarding UDI labelling). For the exceptions see Art. 113 para 3 IVDR (earlier application: b-d & h, postponed application: a & e – g).
2	Question:	When does Directive 98/79/EEC [= the Directive] cease to apply?
	Answer:	Directive 98/79/EEC will be repealed with effect from 26 May 2022 (=DOA) see Art 112 IVDR. However, there are some exceptions, e.g. in order to deal with devices that are compliant with the Directive or to serve as a "back up" in case EUDAMED is not fully functional at DoA (see Art. 112 IVDR).
3	Question:	What is the applicable legislation until 26 May 2022 (=DOA)?
	Answer:	Laws and regulations adopted by Member States in accordance with the Directive (= Directive regime). There are however exceptions (see for example Art. 113 para 3 b-d, h and Art 110 para 5 and 6 IVDR).

II - Issue: Placing on the market of **IVDR compliant devices** until 26 May 2022 (Art. 110 para 5-7 IVDR)		
4	Question:	Is it possible to place a device, which is compliant with the IVDR (= **IVDR compliant device**), on the market prior to 26 May 2022 (= DoA)?
	Answer:	**Yes**, see Art. 110 para 5 IVDR. Manufacturers (= MFR) are – until 26 May 2022 (= DoA) normally required to place IVDs on the market that comply with the Directive (= IVDD compliant devices), however Art. 110 para 5 IVDR offers the **option** to place IVDR compliant devices on the market before DoA.
5	Question:	Is it possible for **all types of IVDs** (for all different risk classes A-D) compliant with the IVDR (= IVDR compliant device) to be placed on the market prior to 26 May 2022 (according to Art. 110 para 5 IVDR)?
	Answer:	**Yes**, all types of **IVDs** - regardless of their risk class – may be placed on the market according to Art. 110 para 5 IVDR. **However**, IVDs being subject to the procedures laid down in Article 48 (3) and (4) IVDR (= class D devices) may **not** be placed on the market in accordance with Article 110 para 5 IVDR before the necessary appointments to the Medical Device Coordination Group (MDCG) and the expert panels and of EU reference laboratories have been made (see Art. 110 para 7 IVDR). Depending on the risk class of the device, conformity assessment may require the involvement of a NB designated and notified in accordance with the IVDR (see Art. 110 para 6 IVDR). 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 IVDR.
6	Question:	As a MFR, which obligations of the IVDR do I need to fulfil in order to place an IVDR compliant device on the market before the DoA according to Art. 110 para 5 IVDR?
	Answer:	As many obligations as are possible, while taking into account that

		• EUDAMED may not be fully functional and • the IVDR is not fully applicable at that point in time. Generally speaking, that is to say that: • first, the **device** as such needs to be IVDR compliant (see Annex I) and • second, the **MFR** has to comply with the IVDR. 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. 48 IVDR. This may, depending on the risk class of the device, necessitate the involvement of a notified body designated and notified in accordance with the IVDR (see Art. 110 para 6 IVDR). The following requirements of the MDR need to be fulfilled by the MFR (non-exhaustive list): • performance 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 Directive** 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 IVDR) needs to be available but not necessarily registered until EUDAMED is available. The **assignment of an UDI** (Art. 24 para 3 IVDR) is not possible as long as there are - no issuing entities designated by the Commission according to Art. 24 para 2 IVDR and - as long as the legal fiction according to Art. 110 para 10 does not apply (it shall apply from 26 May 2019, see Art. 113 para 3 h IVDR). It is of no significant use as long as there is no UDI database.
7	Question	Are **IVDR compliant devices** placed on the market according to Art 110 para 5 IVDR subject to the so called “sell off” provision in Art. 110 para 4 IVDR (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 **IVD devices in conformity with the Directive** after 26 May 2022 (Art. 110 para 2 -3 IVDR)		
8	Question:	Do **certificates** issued by notified bodies **in accordance with the Directive** (= **IVDD certificates**) prior to 25 May 2022 remain valid after the DoA?
	Answer:	Yes, as specified in Art. 110 para 2 IVDR. In general, they remain valid until the end of the period indicated on the certificate. The exception to this are IVDD certificates (Annex VI, refer to Art. 110 para 2 first sentence IVDR) become void at the latest on 27 May 2024. All IVDD certificates issued from 25 May 2017 shall become void by 27 May 2024. In other words, after 27 May 2024 there will be no more valid IVDD certificates.
9	Question:	What **kind** of certificates **remain valid** according to Art. 110 para 2 IVDR?
	Answer:	All certificates which are commonly issued **by Notified Bodies** with reference to the Council Directive IVDD. That is [see for example NBOG BPG 2010-3]: – **EC Design-Examination Certificate** (Annex III section 6, Annex IV, section 4 and section 6 IVDD) – **Certificate of Conformity** (Annex VI IVDD) – **EC Type Examination Certificate** (Annex V IVDD) – **EC Certificate Full Quality Assurance System** (Annex IV excluding sections 4 and 6 IVDD) – **EC Certificate Production Quality Assurance** (Annex VII IVDD)

10	Question:	May a “declaration of conformity” be considered as a “certificate” according Art.110 para 2 IVDR?
	Answer:	No, since it is not a certificate issued by a NB.
11	Question:	Is it possible for a MFR to have **valid IVDR and valid IVDD certificates in parallel** until the 27 May 2024 expiry date?
	Answer:	Yes.
12	Question:	May devices, that are compliant with the Directive (= **IVDD compliant devices**), be placed on the market/put into service after 26 May 2022 (= DoA)?
	Answer:	Yes, under **certain conditions** (see answer on question 15) as specified in Art. 110 para 3 IVDR. In general, after 26 May 2022, devices need to comply with the IVDR in order to be placed on the market/put into service (see Art. 5 IVDR). However, for a limited time (depending on the validity of the IVDD 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 IVDR.
13	Question:	May MFRs of **IVD devices not listed in Annex II of Directive 98/79/EC**, **that are compliant with the Directive**, make use of the derogation in Art. 120 para 3 IVDR (= be placed on the market after the DoA)?
	Answer:	**No**, they must comply with the IVDR **from** the DoA. However there is an exception with regard to **devices for self-testing** having a valid IVDD certificate. These devices may be placed on the market after DoA under the conditions specified in Art. 110 para 3 IVDR.

14	Question:	May **IVDD compliant devices**, which under the IVDR will be **subject to a "reclassification" in risk class** (now a "rule based classification system")**,** benefit from Art. 110 para 3 IVDR?
	Answer:	**Yes**, under the conditions specified in Art. 110 para 3 IVDR (e.g. **valid IVDD certificate**). Devices which are in a different - respectively higher - risk class in IVDR than under the Directive are not as such excluded from the scope of Art. 110 para 3 IVDR.
15	Question:	What are the **requirements** for the placing on the market/putting into service of **IVDD compliant devices** according to Art. 110 para 3 IVDR after DoA?
	Answer:	See Art. 110 para 3 IVDR. In short: 1. **A valid** IVDD certificate according to Art. 110 para 2 IVDR [**All** certificates necessary for the placing on the market of the device in question need to be valid] 2. Continuous **compliance of the device** with the **Directive** 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. 110 para 3 IVDR cannot be claimed. Qualification of a change as "significant" according to Art. 110 para 3 IVDR 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 **not** considered "**significant**" in the sense of Art. 110 para 3 IVDR.] 4. **Application of IVDR requirements** in place of the corresponding requirements of the Directives with regard to: a. **Registration of economic operators and of devices** (see Art. 28 IVDR and Art. 26 IVDR)

		b. **Post market surveillance** (PMS) (see Art. 78-81, 87 IVDR including Annex III but without the PMS having to be an integral part of the QMS) c. **Market surveillance** (see Art. 88 – 95 IVDR, but device standards to be met = Directives) d. **Vigilance** (see Art- 82-87 IVDR) However exceptions are possible in the case that EUDAMED is not fully functional in time (then see Art. 113 para 3 f IVDR). Moreover, the “old” NB which issued the IVDD 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. 110 para 4 IVDR		
16	Question:	What is the so called "sell off" provision (Art. 110 para 4 IVDR) about?
	Answer:	It is intended to **limit the time** during which **IVDD compliant devices,** that have already been placed on the market (either before the DoA or by virtue of Art. 110 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 IVDD 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 IVDR.
17	Question:	Does Art. 110 para 4 IVDR enable MFRs to place **IVDD compliant devices** on the market until May 27, **2025**?
	Answer:	**No.** Art. 110 para 4 IVDR is **not** applicable to the "placing on the market" of IVDD compliant devices (see question 16). The only way to place IVDD compliant devices on the market after DoA is Art. 110 para 3 IVDR. Given that IVDD 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 IVDR (Art. 113 para 3 a and f, Art. 112 IVDR)		
18	Question:	Do all devices have to be registered according to Art. 26 para 3 IVDR by the DoA?
	Answer:	No, Art. 26 para 3 shall apply from 27 November 2023 as set out in Art. 113 para 3 a IVDR. Please note: currently Art. 27 instead of Art. 26 is cited in Art. 112 para 3a IVDR. This is believed to be an editorial error in need of correction!
19	Question:	Must NBs have entered all the certificate related information of all devices according to Art. 51 para 5 IVDR into EUDAMED by the DoA?
	Answer:	No. Art.51 para 5 IVDR shall apply from 27 November 2023 as set out in Art. 113 para 3a IVDR.
20	Question:	What happens if EUDAMED is **not** fully functional at the DoA? How does this affect the application of obligations and requirements of the IVDR that relate to EUDAMED?
	Answer:	The relevant provisions to refer to are mainly Art. 113 para 3, a and f IVDR. **Art. 113 para 3 a IVDR:** Regardless of when EUDAMED is fully functional Art 26 para 3 IVDR (see remark in question 18) and Art. 51 para 5 IVDR do not apply from 26 May 2022 but from 27 November 2023 (see questions 18 and 19). **Art. 113 para 3 f IVDR:** The different **Articles listed in Art. 113 para 3 f IVDR** (= dealing with e.g. the registration of devices and economic operators, 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 according to Art. 34 para 3 MDR**. Meanwhile (until EUDAMED is fully functional) the **corresponding provisions of the Directive** 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 (Directive regime).Thus, 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 113 para 3 f IVDR needs a closer look and further guidance, which is in progress.