MDCG 2022-15

Guidance on appropriate surveillance regarding the transitional provisions under Article 110 of the IVDR with regard to devices covered by certificates according to the IVDD

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1 Introduction

Article 110(2) and 110(3) of Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR) state that devices which are covered by valid certificates issued by a notified body under the Directive 98/79/EC on *in vitro* diagnostic medical devices (IVDD) may be placed on the market[1] or put into service[2] after the date of application of the IVDR and no later than 26 May 2025 under certain conditions.

The abovementioned conditions require that the notified body that issued the certificate under the IVDD continues carrying out appropriate surveillance in respect of the applicable requirements relating to the devices it has certified. Therefore, it is important for manufacturers, notified bodies and national authorities to get clarity on activities to be part of the appropriate surveillance referred to in Article 110(3) of the IVDR.

To appropriately address application of transitional provisions to devices covered by certificates according to IVDD, this guidance, drafted in line with MDCG 2022-4 on appropriate surveillance under the MDR[3] and MDCG 2022-8 on application of IVDR requirements to 'legacy devices'[4], should be read in conjunction with guidance MDCG 2022-6 on significant changes[5].

For the purpose of this document, 'legacy devices' should be understood as devices which, in accordance with Article 110(3) of the IVDR, are placed on the market after the IVDR date of application (26 May 2022) and until the end of the respective transition period set out in the 2nd or 3rd subparagraph of Article 110(3) if certain conditions are fulfilled[6]. In this guidance only devices covered by a valid EC certificate issued in accordance with the IVDD prior to 26 May 2022 are addressed.

2 Scope

This guidance document outlines the activities to be performed by notified bodies[7] as part of the appropriate surveillance defined in Article 110(3) last subparagraph IVDR. To clarify elements to be verified by notified bodies, this guidance document also covers requirements concerning certain manufacturers' obligations, especially in respect of their quality management system.

The document applies to notified bodies that have lawfully issued certificates under the IVDD, regardless of whether or not those notified bodies have applied for designation or are

[1] See IVDR Article 2(21).
[2] See IVDR Article 2(22).
[3] MDCG 2022-4 "Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD"
[4] MDCG 2022-8 "application of IVDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2022 in accordance with Directive 98/79/EC"
[5] MDCG 2022-6 "Guidance on significant changes regarding the transitional provision under Article 110 of the IVDR with regard to devices covered by certificates according to IVDD"
[6] See concepts and terminology defined in MDCG 2022-6 and MDCG 2022-8.
[7] According to Article 110(1) IVDR, from 26 May 2022 any publication of a notification in respect of a notified body in accordance with Directive 98/79/EC becomes void. Irrespective of this, the term "notified body" will be used throughout this document for those "previously notified" bodies.

designated under the IVDR (see MDCG 2019-10 rev.1[8]) as long as the respective authority responsible for notified bodies has the right to and does monitor the notified body's activities under Article 110(3) IVDR.

3 Requirements in respect to the manufacturer's quality management system and related obligations

Article 110(3) IVDR lays down that devices may be placed on the market or put into service until 26 May 2025 when they are covered by valid certificates under the IVDD, provided that they continue to comply with the IVDD and that there are no significant changes in the design and intended purpose. Therefore, in principle, the quality management system approved under the Directive needs to be maintained. In addition, in accordance with the fourth subparagraph of Article 110(3) IVDR, all relevant requirements set out in Chapter VII IVDR on post-market surveillance, market surveillance, vigilance and registration of economic operators and of devices apply to 'legacy devices' in place of the corresponding requirements in the Directive. IVDR requirements will be subject to the notified body's surveillance activities as described in section 4.

Until the European database on medical devices (EUDAMED) is fully functional, manufacturers or their authorised representatives are expected to apply the respective national provisions and to take into account MDCG 2022-12[9].

IVDR requirements that are not related to post-market surveillance, market surveillance, vigilance, registration of economic operators and devices should in principle not apply to economic operators in respect to 'legacy devices'. Examples for provisions not applicable in respect to 'legacy devices' are Article 15[10], Article 16(3) and (4), Article 22, Article 24, Article 29[11]. This is without prejudice to the possibility for economic operators to follow any other IVDR requirements also for 'legacy devices', especially if they deal with both 'legacy devices' and IVDR devices and want to apply the same procedures for all devices.

4 Surveillance according to Article 110(3) IVDR

4.1 General

According to Article 110(3) IVDR, the notified body's activities in principle should be a continuation of the previous surveillance activities under the Directive, as notified bodies designated under the IVDD are not designated to conduct assessments under the Article 48 of IVDR. In the framework of their surveillance activities, notified bodies need to take into account the new requirements resulting from the transitional provisions (see section 3). In

[8] MDCG 2019-10 rev.1 "Application of transitional provisions concerning validity of certificates issued in accordance to the directives". Please, note that MDCG 2019-10 specifically refers to transitional provisions laid down in Regulation (EU) 2017/745 but can be applied by analogy to Regulation (EU) 2017/746
[9] MDCG 2022-12 "Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional (for Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices)".
[10] In case of Member States having introduced the EUDAMED Actor module as compulsory for actor registration, manufacturers as well as authorised representatives can indicate that information related to the person responsible for regulatory compliance is not applicable (e.g. "N.A.") providing a justification in the registration request for the relevant Competent Authority.
[11] See MDCG 2022-8.

doing that, notified bodies should consider clarification provided by e.g. the CAMD transition sub-group[12] and relevant MDCG guidance[13].

Following the information by the manufacturer, the notified body needs to identify which of the existing IVDD certificate(s) will continue to be used and if their scopes remain unchanged.

In addition, the notified body needs to ensure that their rights and duties as notified body will continue to apply under their new status (see section 4.2).

4.2 Contractual relation

As mentioned in the "CAMD MDR/IVDR Transition Subgroup: FAQ – IVDR Transitional provisions Q. 15" notified bodies need to ensure that the previous rights and duties under the Directives remain applicable also after the IVDR date of application. This needs to be done on a contractual basis. In particular, existing contracts between the notified body and the manufacturer should cover surveillance activities concerning 'legacy devices' to be performed by the notified body during the transition period (i.e. until 26 May 2025), as well as the right to suspend, restrict or withdraw concerned certificates.

4.3 Review of Quality Management System documentation

For manufacturers making use of Article 110(3) IVDR the notified body needs to verify the following:

- If the scope of devices covered by the IVDD certificate(s) remains or if and which devices are discontinued. To that end, it is important for the notified body to consider the manufacturer's transition plan for IVDR compliance.
- If the manufacturer has adjusted its quality management system according to the requirements of Article 110(3) IVDR concerning significant changes, taking into account the content of MDCG 2022-6 ("change regime").
- If the manufacturer has made the necessary adjustments to the quality management system on post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices. This can be done by verifying that the manufacturer has changed the procedures for post-market surveillance etc. (see section 3) in line with the IVDR or has changed its quality management system completely to adapt to IVDR requirements, which cover also those in the Directive.
- If all appropriate processes relating to post-market surveillance, including risk management and performance data, feed into the post-market surveillance plan.

4.4 Audit activities

Based on the outcome of the documentation review (section 4.3) the notified body needs to adjust the audit programme by identifying the individual audits (scope(s), objectives, sequence) and the respective audit activities, including, if appropriate, unannounced audits.

[12] See FAQ_IVDR_180117_V1.0-1.pdf (camd-europe.eu)
[13] See https://ec.europa.eu/health/md_sector/new_regulations/guidance_en, especially https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_guidance_significant_changes_annexes_en.pdf.

Considering the overall intention of Article 110(3) IVDR that certain IVDR provisions already apply to 'legacy devices', the audit activities to be performed by notified bodies should focus on those new provisions. In that context notified bodies should combine surveillance activities under the IVDD and the IVDR in a meaningful way (see 5.1).

Concerning the new elements required, manufacturers should make available PMS plans and any PMS reports to their notified bodies in the framework of surveillance audits in order to allow the notified body to verify that the quality management system has been appropriately adapted and remains compliant for the certificate(s) issued under the IVDD.

Based on the audit programme, individual audit plans should be drafted (for the different scenarios see section 5.1) and the audits performed accordingly.

4.5 Information to Competent Authorities

In cases where the audit activities reveal a major non-conformity, which may present an unacceptable risk to the health or safety of patients, users or other persons, the notified body needs to inform the relevant competent authority.

In case certificates issued under the IVDD are suspended, re-instated, restricted, cancelled by the manufacturer or withdrawn, the notified body needs to comply with its notification obligations according to Article 112 IVDR[14].

5 Possible scenarios for the surveillance according to Article 110(3) IVDR

Depending on the specific situation of a manufacturer, the individual audits to be performed under Article 110(3) IVDR may be combined with audits according to Article 48 IVDR and the respective procedures set out in Annexes IX or XI.

5.1 On-site audits

When establishing procedures for activities to be performed in the context of the appropriate surveillance in respect of applicable requirements relating to the IVDD certified devices, the notified body could distinguish between four possible scenarios presented below:

a) Manufacturers of 'legacy devices' that have not applied for certification under the IVDR (and are not going to adapt or have not adapted their systems to IVDR with the exception to those requirements specified under Article 110(3) IVDR),

b) Manufacturers of 'legacy devices' and IVDR devices that have already implemented the IVDR requirements in their systems and whose application for IVDR certification is being reviewed by the notified body that issued the IVDD certificate(s),

c) Manufacturers of 'legacy devices' and IVDR devices already certified by the same notified body under the IVDR for the same and / or partially different types of devices, i.e. overlapping scopes of certificates,

d) Manufacturers of 'legacy devices' and IVDR devices already certified by another notified body under the IVDR.

[14] In line with the principles outlined in the MDCG 2022-6: notified bodies are not allowed to issue any new IVDD certificates. Changes of certificates as listed should be communicated as written decisions / statements.

For scenario (a), notified bodies should perform surveillance assessment under the Directive and verify the application of IVDR requirements “relating to post-market surveillance, market surveillance, vigilance, registration of economic operators”. Under that scenario, they should also verify if the manufacturer has taken care of the principles outlined in MDCG 2022-6.

For scenarios (b) to (d), in case the notified body that issued the certificate(s) under the IVDD is already designated under the IVDR, surveillance activities may be performed according to IVDR.

In case the notified body that issued the certificate(s) under the IVDD is not designated under the IVDR, scenario (d) is to be treated like scenario (a).

In addition, for scenario (c), notified bodies may decide to couple IVDR audits and surveillance audits according to Article 110(3) IVDR provided that they perform an assessment of the individual circumstances. The assessment and the decision should be justified and documented considering elements such as similarities in the scope covered by the IVDD and IVDR certificates, same manufacturing sites and other relevant aspects.

The notified body’s procedures should appropriately describe the different scenarios applied.