

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

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This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

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1 Introduction

Article 120(2) and 120(3) of the Medical Device Regulation (EU) 2017/745 (MDR) state that devices which are covered by valid certificates issued by a notified body under the Active Implantable Medical Devices Directive 90/385/EEC (AIMDD) or the Medical Devices Directive 93/42/EEC (MDD) may be placed on the market¹ or put into service² after the date of application of the MDR and no later than 26 May 2024 under certain conditions.

The abovementioned conditions require that the notified body that issued the certificate under the MDD or the AIMDD continues carrying out appropriate surveillance in respect of all 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 120(3) of the MDR.

To appropriately address application of transitional provisions to devices covered by certificates according to MDD or the AIMDD, this guidance, drafted in line with MDCG 2021-25 on application of MDR requirements to 'legacy devices'³, should be read in conjunction with guidance MDCG 2020-3 on significant changes⁴.

For the purpose of this document, 'legacy devices' should be understood as devices, which, in accordance with Article 120(3) of the MDR, are placed on the market after the MDR's date of application (26 May 2021) and until 26 May 2024 if certain conditions are fulfilled⁵. In this guidance only devices covered by a valid EC certificate issued in accordance with the MDD or the AIMDD prior to 26 May 2021 are addressed.

2 Scope

This guidance document outlines the activities to be performed by notified bodies⁶ as part of the appropriate surveillance defined in Article 120 (3) second subparagraph MDR. In order to clarify elements to be verified by notified bodies, this guidance document also covers requirements concerning certain manufacturers' obligations, especially in respect to their quality management system.

The document applies to notified bodies that have lawfully issued certificates under the MDD or the AIMDD, regardless of whether or not those notified bodies have applied for designation or are designated under the MDR (see MDCG 2019-10 rev.1⁷) as long as the respective

¹ See MDR Article 2(28).

² See MDR Article 2(29).

³ MDCG 2021-25 "Application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC"

https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2021_25_en.pdf.

⁴ MDCG 2020-3 "Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD"

https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_guidance_significant_changes_annexes_en.pdf.

⁵ See terminology defined in MDCG 2021-25.

⁶ According to Article 120(1) MDR, from 26 May 2021 any publication of a notification in respect of a notified body in accordance with Directives 90/385/EEC and 93/42/EEC becomes void. Irrespective of this, the term "notified body" will be used throughout this document for those "previous" notified bodies.

⁷ MDCG 2019-10 rev.1 "Application of transitional provisions concerning validity of certificates issued in accordance to the directives" https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_application-transitional-provisions-certificates_en.pdf.

authority responsible for notified bodies has the right to and does monitor notified body's activities under Article 120(3) MDR.

Article 110(3) of Regulation (EU) 2017/746 (IVDR) is outside the scope of this guidance document. However, principles outlined in the text and that are common between EU legislations for medical devices and *in-vitro* diagnostic medical devices may be applied also for activities to be performed by notified bodies according to Article 110(3) of the IVDR.

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

Article 120(3) MDR defines that devices may be placed on the market or put into service until 26 May 2024 when they are covered by valid certificates under the MDD/AIMDD, provided that they continue to comply with either of those Directives and that there are no significant changes in the design and intended purpose. Therefore, in principle, the quality management system approved under the Directives needs to be maintained. However, in accordance with the first subparagraph of Article 120(3) MDR, all relevant requirements set out in Chapter VII MDR 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 Directives. MDR requirements will now 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 2021-1 Rev. 1⁸.

'Legacy devices' are also subject to the requirements laid down in Article 85 and Article 86 MDR, based on their classification in accordance with the MDD. During the transition period, a possible change of their risk class under the MDR should not be taken into account. For the purpose of applying the relevant MDR requirements active implantable devices subject to the AIMDD should be considered as class III devices.

Periodic safety update reports (PSURs) need to be drawn up by manufacturers in accordance with Article 86 MDR one year after the date of application of the MDR, i.e. following 26 May 2021. PSURs need to be made available to competent authorities on request (outside EUDAMED).

MDR 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 15⁹, Article 16(3) and (4), Article 18, Article 25, Article

⁸ MDCG 2021-1 Rev. 1 "Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional" https://ec.europa.eu/health/sites/health/files/md_sector/docs/2021-1_guidance-administrative-practices_en.pdf.

⁹ 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.

27, Article 32¹⁰. This is without prejudice to the possibility for economic operators to follow any other MDR requirements also for 'legacy devices', especially if they deal with both 'legacy devices' and MDR devices and want to apply the same procedures for all devices.

A comparison of the quality management system requirements in the MDD and the MDR is provided in the **Annex** of this document. The comparison table could be used to show which MDD or AIMDD requirements are covered by the MDR.

4 Surveillance according to Article 120(3) MDR

4.1 General

According to Article 120(3) MDR, the notified body's activities in principle should be a continuation of the previous surveillance activities under the Directives, as notified bodies designated under the MDD or the AIMDD are not designated to conduct assessments under the Article 52 of MDR. 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 doing that, notified bodies should consider clarification provided by e.g. the CAMD transition sub-group¹¹ and relevant MDCG guidance¹².

Following the information by the manufacturer, the notified body needs to identify which of the existing MDD or AIMDD certificates 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 – MDR Transitional provisions Q. 17" notified bodies need to ensure that the previous rights and duties under the Directives remain applicable also after the MDR 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 2024), as well as the right to suspend, restrict or withdraw concerned certificates.

4.3 Quality Management System documentation review

For manufacturers making use of Article 120(3) MDR the notified body needs to verify the following:

- If the scope of devices covered by the MDD or the AIMDD certificates remains or if and which devices are discontinued. It may be appropriate to consider the manufacturer's transition plan for MDR compliance.

¹⁰ See [MDCG 2021-25](https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2021_25_en.pdf) "Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC" https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2021_25_en.pdf.

¹¹ See https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_camdr_en.pdf

¹² 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.

- If the manufacturer has adjusted its quality management system according to the requirements of Article 120(3) MDR concerning significant changes, taking into account the content of MDCG 2020-3 (“change regime”).
- If the manufacturer has made the necessary adjustments in respect 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 MDR or has changed its quality management system completely to adapt to MDR requirements, including the ones in the Directives.

In respect to the new post-market surveillance (PMS) requirements, this includes that

- all appropriate processes relating to post-market surveillance including risk management and clinical data feed into the post-market surveillance plan,
- if applicable, the output of all post-market surveillance activities are included and reflected in a PSUR, and that the PSUR update cycle is appropriate and according to its current risk class as defined in Article 86 MDR.

4.4 Audit activities

Based on the outcome of the documentation review (section 4.3) the notified body needs to adjust the audit programme identifying the individual audits (scope(s), objectives, sequence) and the respective audit activities, including, if appropriate, unannounced audits. This includes especially the technical documentation assessments on a sampling basis, to be performed until the end of the transition period or, in case the certificate(s) expire before 26 May 2024, until the end of validity of the certificate(s) issued in accordance with the MDD or AIMDD.

Considering the overall intention of Article 120(3) MDR that not all MDR provisions will already apply to ‘legacy devices’, the audit activities to be performed by notified bodies should be a continuation of the previous surveillance activities with a focus on the new provisions.

Concerning PSURs and other new elements required, manufacturers should make available PSURs (outside EUDAMED), PMS plans and 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 MDD or the AIMDD.

Based on the audit programme, individual audit plans have to be drafted (for individual scenarios see section 5.1) and the audits performed accordingly. In respect to PSURs, notified bodies should verify PSUR procedures and availability and updates of individual PSURs in the context of its auditing activities.

In case of MDD devices falling under classes IIa and IIb, notified bodies are requested to continue the technical documentation assessments on a sampling basis according to the existing sampling plan (see NBOG BPG 2009-4¹³). Generally, this activity needs to be continued as planned but the plan may be adjusted depending on the outcome of the documentation review (section 4.3). For details, see section 5.2. As part of technical

¹³ NBOG BPG 2009-4 “Guidance on Notified Body’s Tasks of Technical Documentation Assessment on a Representative Basis” http://www.doks.nbog.eu/Doks/NBOG_BPG_2009_4_EN.pdf.

documentation assessments, the manufacturer should make the PSUR available to the notified body and the notified body will document its evaluation as part of the technical file assessment.

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 MDD or AIMDD are suspended, re-instated, restricted, cancelled by the manufacturer or withdrawn, the notified body needs to comply with its notification obligations according to Article 122 MDR¹⁴.

5 Possible scenarios for the surveillance according to Article 120(3) MDR

Depending on the specific situation of a manufacturer, the individual audits to be performed under Article 120(3) MDR may be combined with audits according to Article 52 MDR and the respective procedures set out in Annexes IX or XI. In order to do that, the comparison table in the Annex should be used to show that AIMD/MDD requirements are covered by MDR requirements.

5.1 On-site audits

When establishing procedures describing activities to be performed in the context of the appropriate surveillance in respect of all applicable requirements relating to the MDD or the AIMDD 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 MDR (and are not going to adapt their systems to MDR with the exception to those requirements specified under Article 120(3) MDR),
- b) Manufacturers of 'legacy devices' and MDR devices having already implemented the MDR requirements in their systems and whose application for MDR certification is being reviewed by the notified body having issued the MDD or the AIMDD certificate(s),
- c) Manufacturers of 'legacy devices' and MDR devices already certified by the same notified body under MDR for the same and / or different types of devices,
- d) Manufacturers of 'legacy devices' and MDR devices already certified by another notified body under the MDR.

For scenario (a), notified bodies should ensure that criteria already used for surveillance assessment under the Directives should apply in addition to specific verification of MDR requirements "relating to post-market surveillance, market surveillance, vigilance, registration of economic operators".

¹⁴ In line with MDCG 2020-3 notified bodies are not allowed to issue any new MDD or AIMDD certificates. Changes of certificates as listed should be communicated as written decisions / statements.

For scenarios (b) to (d), in case the notified body that issued the certificate(s) under the MDD or the AIMDD is already designated under the MDR, surveillance activities may be performed according to MDR, taking into account the Annex to this document.

In addition, for scenario (c), notified bodies may decide to couple MDR audits and surveillance audits according to Article 120(3) MDR 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 on the scope covered by the MDD and MDR certificates, same manufacturing sites and other relevant aspects.

Notified body's procedures should appropriately describe the different scenarios applied and how

- audit programmes should be established for individual manufacturers,
- audit plans should be drawn up and adapted for individual audits (including reference to scope, objective and duration of the audits),
- the comparison table reported in the Annex to this guidance document has been considered to define notified body's activities relating to appropriate surveillance,
- in case similarities are claimed, these similarities, including scope, manufacturing sites, processes, supplier/subcontractors, etc., have been demonstrated.

5.2 Assessment of technical files on a sampling basis

In case of class IIa and IIb devices, notified bodies are requested to continue applying the sampling plan established under the MDD for the assessment of the technical documentation on a representative basis.

The notified body's procedures can distinguish the different scenarios described in section 5.1.

For scenarios (b) and (c), the notified body may decide to modify the established sampling plans provided that certain conditions are satisfied. In particular, the range of devices covered, including their intended purpose, by the MDR applications or certificates in comparison with the scope of MDD or AIMDD certificates should be taken into account. Devices and their technical documentations in the MDD sampling plan, which are already subject to an application under the MDR, can be omitted. For such devices, the notified body should

- have already finalised the MDR application review or have issued the MDR certificates,
- apply MDCG 2019-13 concerning sampling of devices for the assessment of the technical documentation,
- make appropriate reference to the sampling plan established under the MDR in the MDD sampling plan and,
- if applicable, inform the competent authority according to section 4.5.

Notified bodies procedures should specify in which cases deviations from or adaptations to the sampling plans established under the MDD may be made.

Annex Comparison table – quality management system requirements in the MDD and the MDR



Annex_to_Guidance_
appropriate_surveillance



医课汇
公众号
专业医疗器械资讯平台
WECHAT OF
HLONGMED



hlongmed.com
医疗器械咨询服务
MEDICAL DEVICE
CONSULTING
SERVICES



医课培训平台
医疗器械任职培训
WEB TRAINING
CENTER



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