MDCG 2022-4 Rev 2

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

Revision 2 - May 2024

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Revision table

MDCG 2022-4 revision 1 changes
Adjustments all over the document to align it to MDCG 2022-15 and to reflect the views of MDCG as expressed in action n.3 of MDCG 2022-14
MDCG 2022-4 revision 2 changes
Adjustments all over the document to align it to Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

1 Introduction

Article 120 of the Medical Device Regulation (EU) 2017/745 (MDR), as amended by Regulation (EU) 2023/607[1], states that devices which are covered by valid[2] 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 market[3] or put into service[4] after the date of application of the MDR under certain conditions until[5]:

(a) 31 December 2027, for all class III devices, and for class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors;

(b) 31 December 2028, for class IIb devices other than those covered by point (a) of this paragraph, for class IIa devices, and for class I devices placed on the market in sterile condition or having a measuring function[6].

The abovementioned conditions require, among others, that a notified body, either the one that issued the certificate under the MDD or the AIMDD or the one with which the manufacturer has signed the written agreement for MDR certification (see section 4.1), continues carrying out appropriate surveillance in respect of all of the applicable requirements relating to the

[1] Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices. To facilitate application of Regulation (EU) 2023/607 the European Commission published a *Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices*. Part D of this document addresses in particular "Appropriate surveillance to be performed by notified bodies"; https://health.ec.europa.eu/document/download/592008f6-3456-4afb-a13a-733a87da1b00_en?filename=mdr_proposal_extension-q-n-a.pdf.
[2] For the term "valid certificate" please see details in Article 120 (2) and (3a) MDR.
[3] See MDR Article 2(28).
[4] See MDR Article 2(29).
[5] For determining the respective dates, the classification according to the MDR applies.
[6] See MDR Article 120(3a)

legacy devices[7] which are subject to the surveillance requirements according to Article 120(3e). 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(3e) of the MDR.

To appropriately address application of transitional provisions to devices covered by certificates according to the MDD or the AIMDD, this guidance[8] should be read in conjunction with guidance MDCG 2020-3 Rev. 1 on significant changes[9].

This revision of the document is in line with the MDCG position reported in MDCG 2022-14[10], action n.3.

For the purpose of this document, 'legacy devices' should be understood as devices, which, in accordance with the transitional provisions established in Article 120 of the MDR, are placed on the market after the MDR date of application (26 May 2021) and no longer than the dates reported in the first paragraph above if certain conditions are fulfilled.

2 Scope

Appropriate surveillance only applies to legacy devices that are covered by a certificate issued in accordance with the MDD or AIMDD. Legacy devices for which the conformity assessment procedure pursuant to the MDD did not require the involvement of a notified body, but that require the involvement of a notified body under the MDR are not subject to appropriate surveillance under Article 120 MDR.[11]

This guidance document outlines the activities to be performed by notified bodies[12] as part of the appropriate surveillance defined in Article 120(3e) 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.

[7] 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; MDCG 2021-25 is in the process of being revised to align it with the MDR as amended by Regulation 2023/607.

[8] This guidance was drafted initially in line with MDCG 2021-25 on application of MDR requirements to 'legacy devices' and 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 https://health.ec.europa.eu/system/files/2022-09/mdcg_2022-15_en.pdf

[9] MDCG 2020-3 Rev. 1 "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://health.ec.europa.eu/document/download/800e8e87-d4eb-4cc5-b5ad-07a9146d7c90_en?filename=mdcg_2020-3_en.pdf.

[10] MDCG 2022-14 MDCG Position Paper – Transition to the MDR and IVDR – Notified body capacity and availability of medical devices and IVDs https://health.ec.europa.eu/system/files/2022-08/mdcg_2022-14_en.pdf.

[11] See also *Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices* https://health.ec.europa.eu/document/download/592008f6-3456-4afb-a13a-733a87da1b00_en?filename=mdr_proposal_extension-q-n-a.pdf.

[12] 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 "previously notified" bodies.

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.1[13]) as long as the respective authority responsible for notified bodies has the right to and does monitor notified body's activities under Article 120(3e) MDR; and
- notified bodies designated in accordance with Article 42 of the MDR which have signed a written agreement in accordance with MDR Annex VII Section 4.3, second subparagraph, with a manufacturer of a legacy device or of a device intended to substitute this device.

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

Article 120(3c) MDR lays down conditions to be met by legacy devices to continue being placed on the market or put into service until the relevant date established in Article 120(3a). These conditions include, among others, that legacy devices continue to comply with the applicable Directive and that the manufacturer no later than 26 May 2024 has put in place a quality management system in accordance with the MDR. In addition, since the MDR's date of application (26 May 2021), 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 respective Directive[14]. Those MDR requirements are subject to the notified body's surveillance activities as described in section 4.

Until the European database on medical devices (EUDAMED), or its relevant modules, are mandatory to be used, manufacturers or their authorised representatives are expected to apply the respective national provisions and to take into account MDCG 2021-1 Rev. 1[15].

'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[16]. 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.

[13] 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.
[14] In accordance with Article 120(3), 2nd subparagraph, which has been replaced by Article 120(3d) MDR.
[15] 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.
[16] To determine the applicability of requirements which are dependent upon the risk class of a device (e.g., Article 85 or Article 86 MDR) the legacy device's risk classification in accordance with the MDD should be taken into account. A possible change of their risk class under the MDR is relevant only for determining the end of the transitional period.

Periodic safety update reports (PSURs) need to be drawn up by manufacturers in accordance with Article 86 MDR. 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 are not subject to surveillance according to Article 120(3e) MDR[17]. Examples are Article 15[18], Article 16(3) and (4), Article 18, Article 25, Article 27, and Article 32[19]. 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 (for result and consequences of such a comparison see section 5).

4 Surveillance according to Article 120(3e) MDR

4.1 General

According to Article 120(3e) MDR, the notified body that issued the MDD or AIMDD certificate shall continue to be responsible for the appropriate surveillance in respect of the applicable requirements relating to the devices it has certified. 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 assessment activities according to Article 52 of MDR.

If the notified body that issued the MDD or AIMDD certificate is not designated under the MDR, its responsibility for the appropriate surveillance will end on 25 September 2024, at the latest. No later than 26 September 2024, the notified body with which the manufacturer has signed the written agreement for MDR certification will be responsible to carry out this appropriate surveillance in respect to legacy devices being covered by the application according to Article 120(3c), point (e), MDR. The responsibility for appropriate surveillance can be transferred to the MDR notified body earlier than 26 September 2024 through an agreement with the manufacturer.[20] In any case, the MDR notified body is not responsible for conformity

[17] See also question n. 11 of *Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices* https://health.ec.europa.eu/document/download/592008f6-3456-4afb-a13a-733a87da1b00_en?filename=mdr_proposal_extension-q-n-a.pdf.

[18] 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.

[19] See MDCG 2021-25 "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. MDCG 2021-25 is in the process of being revised to align it with the MDR as amended by Regulation 2023/607.

[20] See also part D, and especially question n. 15, of *Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices* https://health.ec.europa.eu/document/download/592008f6-3456-4afb-a13a-733a87da1b00_en?filename=mdr_proposal_extension-q-n-a.pdf.

assessment activities carried out by the notified body that issued the MDD or AIMDD certificate; its responsibility is limited to the activities carried out under the appropriate surveillance under Article 120(3e). Likewise, and even though devices are placed on the market or put into service with its identification number, the notified body that issued the MDD or the AIMDD certificate will not be responsible for the surveillance activities performed by the MDR notified body.

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-group[21] and relevant MDCG guidance[22].

Following the information by the manufacturer, the notified body needs to identify:

- which of the existing MDD or AIMDD certificates are used to place devices on the market or put them into service,
- if their scopes remain unchanged,
- which devices are covered by the certificates, and
- which devices are covered by the formal application(s) according to Article 120(3c), point (e) MDR.

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 (old) notified body and the manufacturer should cover the "appropriate surveillance" activities concerning 'legacy devices' to be performed by the notified body during the transition period, as well as the right to suspend, restrict or withdraw concerned certificates.

According to Article 120(3c), point (e) MDR, and following a formal application, lodged no later than 26 May 2024, a written agreement[23] in accordance with section 4.3, second subparagraph, of Annex VII MDR needs to be signed between the manufacturer and a notified body designated under the MDR not later than 26 September 2024.

When the manufacturer has signed a written agreement with a notified body that is different from the one that issued the relevant certificate under the MDD or the AIMDD, arrangements

[21] See https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_camd_mdr_en.pdf. Please, note that this document is not aligned with provisions introduced by Regulation (EU) 2023/607.
[22] 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.
[23] See also question n. 9 of *Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices* https://health.ec.europa.eu/document/download/592008f6-3456-4afb-a13a-733a87da1b00_en?filename=mdr_proposal_extension-q-n-a.pdf.

for the transfer of the appropriate surveillance need to be defined in an agreement between the manufacturer, the MDR notified body and, where practicable, the notified body that issued the MDD or AIMDD certificate.[24] Those arrangements will replace the contract described in the first paragraph above with reference to the relevant rights and obligations for the appropriate surveillance in respect to devices covered by the written agreement referred to in Article 120(3c), point (e) MDR.

Whether the MDR notified body is the one which issued the MDD or the AIMDD certificates or not, it needs to ensure that a contract / written agreement covering all necessary rights and obligations for the "appropriate surveillance" in respect to the legacy devices as well as for all devices, including substitute devices, covered by formal applications according to Article 52 and/or Article 120(3c), point (e) MDR, is in place.

4.3 Review of Quality Management System documentation

For manufacturers making use of the transitional provisions established in Article 120 MDR the notified body needs to verify the following:

- If the scope of devices covered by the MDD or the AIMDD certificate(s) remains or is changed.
- Which devices are discontinued or are not covered by the application according to Article 120(3c), point (e). This includes also the need to consider devices intended to substitute legacy devices.
- The manufacturer's transition plan for MDR compliance.
- If the manufacturer has adjusted its quality management system according to the requirements of Article 120(3c), point (b) MDR concerning significant changes, taking into account the content of MDCG 2020-3 Rev. 1 ("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 MDR or has changed its quality management system completely to adapt to MDR requirements[25].
- In respect to the new post-market surveillance (PMS) requirements:
  - If all appropriate processes relating to post-market surveillance including risk management and clinical data feed into the post-market surveillance plan.
  - If the outputs of all post-market surveillance activities are included and reflected in a PSUR, when applicable, and that the PSUR update cycle is appropriate and according to its current risk class as defined in Article 86 MDR (see section 3).

[24] See also questions n. 13 and n. 14 of *Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices* https://health.ec.europa.eu/document/download/592008f6-3456-4afb-a13a-733a87da1b00_en?filename=mdr_proposal_extension-q-n-a.pdf.

[25] Please note that according to Article 120(3e) MDR it is not the task of the notified body to verify compliance of the manufacturer's QMS with Article 10(9) MDR as part of the appropriate surveillance.

4.4 Audit activities and outcome

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. As part of the surveillance, notified bodies will review evidence in the technical documentation.

Considering the overall intention of Article 120(3d) MDR that certain MDR 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 MDD/AIMDD and the MDR in a meaningful way (see section 5).

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

Based on the audit programme, individual audit plans should be drafted (for the different scenarios, see section 5) and the audits performed accordingly. In respect to the new PMS requirements, notified bodies should verify and document PMS processes and availability and updates of individual PMS plans, PMS reports and/or PSURs in the context of its auditing activities.

In accordance with MDCG position paper 2022-14 (action n.3) in case of MDD devices falling under classes IIa and IIb, notified bodies should discontinue the technical documentation assessments on a sampling basis according to existing sampling plans under the MDD in line with NBOG BPG 2009-4[26] and focus on technical documentation assessments according to the MDR instead. However, deficiencies identified in previous audits need to be followed up.

The outcome of the surveillance activities carried out by the notified body in accordance with the transitional provisions established in the MDR and further clarified in this guidance, should be clearly documented and provided to the manufacturer. Although assessment of the compliance with the MDR of the entire QMS will be performed as part of MDR conformity assessment activities, notified bodies should pay attention if one or more conditions defined in Article 120(3c) may be no longer met and report such situations clearly to the manufacturer. In cases where the transitional period ceases to apply, the notified body should consider any impact on the MDD or AIMDD certificates.

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 take action, i.e. suspend, restrict or withdraw the certificate, and inform the relevant competent authority.

[26] 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.

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 MDR[27].

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

The comparison table in the Annex shows that AIMDD/MDD requirements for 'legacy devices' are covered by MDR requirements. This is why, depending on the specific situation of a manufacturer, audits to be performed under Article 120(3e) MDR and audits according to Article 52 MDR and the respective procedures set out in Annexes IX or XI should be combined focussing on assessment of compliance with MDR requirements[28]. When establishing procedures for activities to be performed in the context of the appropriate surveillance in respect of applicable requirements relating to the MDD or the AIMDD certified devices, the notified body could distinguish between various scenarios, e.g.:

a) Manufacturers of 'legacy devices' that are not going to make use of the revised transitional provisions established in Article 120 of the MDR introduced by Regulation (EU) 2023/607, applicable to them until 25 May 2024,

b) Manufacturers of 'legacy devices' and MDR devices that have already implemented the MDR requirements in their systems and whose application for MDR certification – either for a part or the full scope of the Directive certificates – is already 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 partially different types of devices, i.e. overlapping scopes certificates,

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

For scenario (a), notified bodies should perform surveillance assessments under the Directives and verify implementation of MDR 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 2020-3 Rev. 1.

For scenarios (b) to (d), surveillance activities can be performed only according to MDR (i.e., no need for additional AIMDD or MDD activities), taking into account the Annex to this document.

Depending on the individual scenario, notified bodies should couple MDR audits and surveillance audits according to Article 120(3e) MDR based on an assessment of the individual circumstances. The assessment and the decision should be justified and documented in case

[27] In line with the principles outlined in MDCG 2020-3 Rev. 1notified bodies are not allowed to issue any new MDD or AIMDD certificates. Changes of certificates as listed should be communicated as written decisions / statements.
[28] See MDCG 2022-14, action n. 3.

the notified body deems not appropriate to couple MDR audits and surveillance audits according to Article 120(3e) MDR, e.g., different scope, different manufacturing sites.

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



Annex_to_Guidance_
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