الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

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MDR Transition Guideline

National Health Regulatory Authority (NHRA)

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1. Introduction

In light of what is happening in Europe regarding the transition from Medical Directives to Regulations, and despite the steady increase in the number of notified bodies designated in accordance with those Regulations, the overall capacity of notified bodies is still not sufficient to ensure the conformity assessment of the large number of devices covered by certificates issued in accordance with the previous Directives before the scheduled deadline of the transitional period.

This guideline is intended to guide you through the best solutions formulated for different scenarios that you might face in this period.

The requirements below will replace the verification of the CE certificate only. The expired CE certificate, and the rest of requirements per the guidelines will still be required to be attached in the application.

2. Cases

Case 1

In importation, if the production of the device to be imported was before the expiry of the MDD Quality Assurance Certificate.

In this case, the required documents that will replace the CE certificate verification will be:

1. A Letter from the Legal Manufacturer stating that the product was manufactured before the MDD Quality Assurance Certificate expiry.
2. A letter issued by the Notified Body stating that Legal Manufacturer is transitioning to MDR (the letter must be related to the device by a scope, previous certificate, or a specific name mentioned).

~~**Case 2**~~ – **this case is no longer valid.**

In importation, and in case the Legal Manufacturer will not apply under the MDR:

Depending on the medical device risk classification, a letter should be issued by the Legal Manufacturer if it is a self-declared device or issued by the Notified Body if it is class Is or IIa and higher. This letter must confirm the following:

(a) those devices continue to comply with previous medical device directives.

(b) there are no significant changes in the design and intended purpose.

(c) the devices do not present an unacceptable risk to the health or safety of patients, users, or other persons, or to other aspects of the protection of public health.

Case 3

As per the latest amendments in Regulation (EU) 2023/607, Certificates that were still valid on 26 May 2021 and that have expired before 20 March 2023 are eligible for extension in case the manufacturer and a notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex 7 of the MDR OR when a competent authority of a Member State has granted a derogation, if you fall under either cases, kindly provide the following:

- The Agreement OR The Derogation letter and a proof that the letter is genuine.
- The Confirmation letter issued by the Notified Body confirming that the Legal Manufacturer met the applicable conditions, and its verification.

  An alternative to the agreement or derogation letter is to provide the Manufacturer's Declaration. (refer to Annex I)

Case 4 – expires on the 27th of September 2024.

Certificates that were still valid on 26 May 2021, that have not been withdrawn afterwards and that were still valid at the time of publication of Regulation (EU) 2023/607 are eligible for extension if the following additional conditions are met:

If the manufacturers have put in place an MDR compliant QMS and have lodged a formal application with a Notified Body to sign a formal agreement (No later than 26 September 2024) in respect to the device covered by the expired certificate or in respect to a device intended to substitute that device.

In that case, applicant needs to provide:

- The Manufacturer's Declaration. (refer to Annex I).
- The Confirmation letter issued by the Notified Body confirming that the Legal Manufacturer met the applicable conditions, and its verification.

After 26th of September 2024, all certificates under this case will fall under Case 3 assuming that the agreement was signed between the Notified Body and the manufacturer prior to this date.

Case 5

For active and non-active medical devices, applicants can still use Manufacturer's Declaration of Conformity issued before 26 May 2021, as they potentially benefit from the extended transition period if the manufacturers have put in place an MDR compliant QMS and have lodged a formal application with a Notified Body for MDR Conformity Assessment.

In that case, applicant needs to provide:

- The Confirmation letter issued by the Notified Body confirming that the Legal Manufacturer met the applicable conditions, and its verification.

For devices up-classified under the MDR, previous Manufacturer's Declaration of Conformity should follow the following deadlines:

- 31 December 2027 for Class III (excluding custom-made implantable) and IIb implantable legacy devices.
- 31 December 2028 for other Class IIb, Class IIa, Class Is and Class Im legacy devices.

For In-vitro diagnostic devices that did not require the involvement of a notified body under IVDD but do so under the IVDR can potentially benefit from the extended transition periods. (Excluding Class A non-sterile, new devices and devices with significant change) For devices up-classified under the IVDR, previous Manufacturer's Declaration of Conformity has the following deadlines:

- 26 May 2025 for Class D self-declared IVDD device.
- 26 May 2026 for Class C self-declared IVDD device.
- 26 May 2027 for Class B and Class A sterile self-declared IVDD device.

In the below situation, NHRA requires additional documents that are additional to the documents required in the above cases:

- In case the transfer of surveillance activities of 'legacy' medical devices transfers to another Notifying Body to be MDR certified:

The applicant must provide a signed transfer Tripartite Agreement between the manufacturer, the new notifying body, and the old notifying body (refer to Annex I) OR what is equivalent for it as per the EU regulation amendments and recommendations.

3. Annex I

- European Commission's Confirmation letter template.
- MedTech Europe's Manufacturer's Declaration template.
- The European Association of Medical devices Notified Bodies (Team NB)'s Tripartite Agreement template.