MDR Transition Guideline

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

April 2025

Version 3

E-Mail: medical_devices@nhra.bh **Website:** www.nhra.bh **Tel.:** 17113299 **/P.O. Box:** 11464

Contents

1. Introduction.....3
2. Requirements 3
3. Annex 1.....5

1. Introduction

In light of what is happening in Europe regarding the transition from MDD to MDR, and despite the steady increase in the number of notified bodies designated in accordance with Regulation (EU) 2017/745 MDR, 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 Directives MDD and AIMDD 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 the requirements per the guidelines will still be required to be provided in the application.

2. Requirements

Expired MDD certificate:

If the MDD certificate has expired but is eligible for extension under Regulation (EU) 2023/607 and its amendments, and the certificate holder has either signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of the MDR, or submitted a formal application to a Notified Body for this purpose, please provide the following:

- The signed agreement between the Notified Body and Manufacturer OR Manufacturer's Declaration (refer to Annex 1 for template).
- The Confirmation letter issued by the Notified Body confirming that the Legal Manufacturer met the applicable conditions, and its verification (refer to Annex 1 for template).

Up-Classified Medical devices:

For devices up-classified under the MDR, applicants can still use the 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.

Previous Manufacturer's Declaration of Conformity has the following dates as a deadline:

- 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.

Additionally, applicants need 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 IVDR only, 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)

Previous Manufacturer's Declaration of Conformity has the following dates as a deadline:

- 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 some situations which are mentioned below, NHRA requires documents in addition to the above-mentioned requirements:

- In case the surveillance activities transfer to another Notified Body to be MDR certified, and the confirmation letter does not clarify it:

  The applicant must provide a signed transfer Tripartite Agreement between the manufacturer, the new notifying body, and the old notifying body (refer to Annex 1 for template).

3. Annex 1

- 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.