nhra BAHRAIN

الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

Ref. 2024-MDGUD-Q1-001

MDR Transition Guideline

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

Jan 2024

Version 1.2

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

Contents

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.

Kindly note that 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 the Legal Manufacturer transition 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~~Case 2~~ – this case is no longer valid.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, if the production of the device is after the expiry of the CE and the certificate is eligible for extension. In this case there are two routes the applicant can take depending on the condition that the legal manufacturer fulfilled:

1. First route, and 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. Provide the following:
   - The agreement.
   - The Confirmation letter issued by the Notified Body confirming that the Legal Manufacturer met all the applicable conditions, and its verification.

     An alternative to the agreement is to provide the Manufacturer's Declaration of Certificate Validity.

2. Second route is when a competent authority of a Member State has granted a derogation, Provide the following:
   - The derogation letter and a proof that the letter is genuine.
   - A valid SFDA MDMA certificate that covers the product.
     An alternative to MDMA certificate will be to provide the confirmation letter from the Notified Body confirming that the Legal Manufacturer met all the applicable conditions, and its verification.

In some situations, mentioned below NHRA might ask for submitting additional documents, this required document will be additional to the documents required in the above cases:

- In case the manufacturer transfers to another Notified Body to be MDR certified:

The applicant must provide a transfer agreement signed by the three entities (the manufacturer, the new notifying body, and the old notifying body) OR what is equivalent for it as per the EU regulation amendments and recommendations.