الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

Ref. 2023-MDGUD-Q2-004

Custom-Made Medical Devices Guideline

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

June 2023

Version 1.0

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1. Introduction

Custom-made device means any device specifically made in accordance with a written prescription of any person authorized by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.

In this guideline, the additional requirements will be explained in detail. The requirements below will replace the CE certificate, and its verification. The rest of the requirements per the guideline of importation will still be required to be provided in the application.

2. Requirements

For custom-made devices, the legal manufacturer or its EU authorized representative shall provide the following:

1. **statement** containing all the following information:

— The name and address of the manufacturer, and of all manufacturing sites.
— If applicable, the name and address of the authorised representative.
— Data allowing identification of the device in question.
— A statement that the device is intended for exclusive use by a particular patient or user, identified by name, an acronym, or a numerical code.
— The name of the person who made out the prescription and who is authorised by national law by virtue of their professional qualifications to do so, and, where applicable, the name of the health institution concerned.
— The specific characteristics of the product as indicated by the prescription.
— A statement that the device in question conforms to the general safety and performance requirements set out in Annex I and, where applicable, indicating which general safety and performance requirements have not been fully met, together with the grounds.
— Where applicable, an indication that the device contains or incorporates a medicinal substance, including a human blood or plasma derivative, or tissues or cells of human origin, or of animal origin as referred to in Regulation (EU) No 722/2012.

- A Declaration from the manufacturer for the following:

    - The manufacturer shall take all the measures necessary to ensure that the manufacturing process produces devices which are manufactured in accordance with the documentation referred to in Section 2(MDR).
    - The statement referred to in the introductory part of Section 1(MDR) shall be kept for a period of at least 10 years after the device has been placed on the market. In the case of implantable devices, the period shall be at least 15 years. Section 8 of Annex IX(MDR) shall apply.
    - The manufacturer shall review, and document experience gained in the post-production phase, including from PMCF as referred to in Part B of Annex XIV(MDR), and implement appropriate means to apply any necessary corrective action, in that context, it shall report in accordance with Article 87(1) to the competent authorities any serious incidents or field safety corrective actions or both as soon as it learns of them.

2. Local Clinic prescription.