الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

Ref. 2022-MDGUD-Q1-002

Medical Devices Labeling Guideline

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

Feb 2022

Version 1.1

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

Contents

1. Introduction

This guideline is intended to guide all importers, healthcare facilities and users to the importance of **medical devices labeling.** The main aim of correct labeling is to ensure that the medical devices are used according to the manufacturer's instructions and not in a way other than that for which it was intended.

Medical device labeling is intended to assist end-users in understanding the medical device and assure safe and effective use of it, it gives information about:

- Proper use and adequate directions for operating the medical devices
- Risks, and benefits of the device in language the user can understand
- Recognition, storage, assembly, and troubleshooting.

Labeling is not useful, of course, if it cannot be understood or if it does not communicate critical information about the medical device to the person trying to use it.

2. Definitions

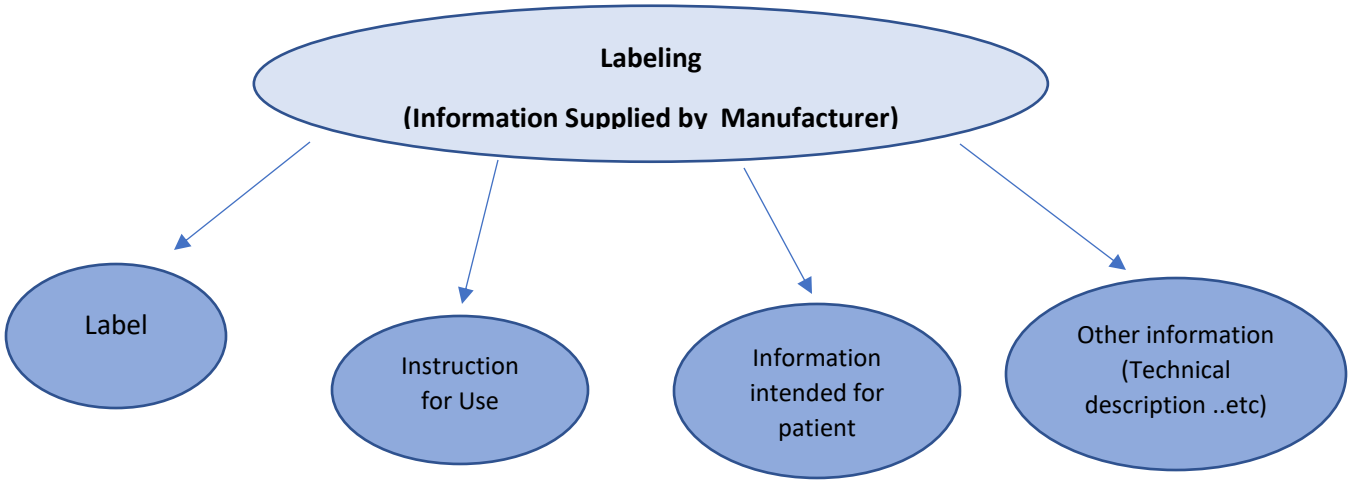
Label:

Written, printed, or graphic information either appearing on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices.

Symbol on medical device label:

graphical representation appearing on the label and/or associated documentation of a medical device that communicates characteristic information without the need for the supplier or receiver of the information to have knowledge of the language of a particular nation or people**.**

Labelling:
Includes the label, instructions for use, and any other information supplied by the manufacturer that is related to identification, technical description, intended purpose and proper use of the medical device.



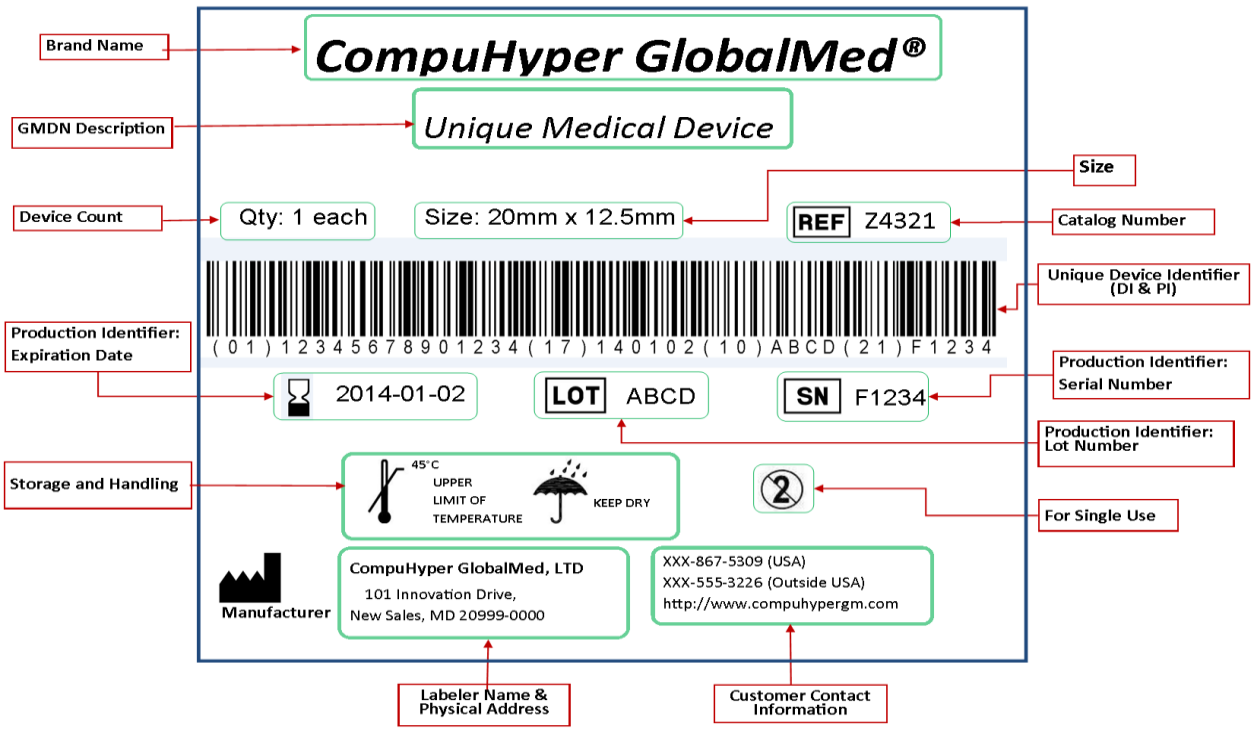
3. Labeling Standard

ISO 15223-1:2016 identifies requirements for symbols used in medical device labelling that convey information on the safe and effective use of medical devices. It also lists symbols that satisfy the requirements of this document.

ISO 15223-1:2016 is applicable to symbols used in a broad spectrum of medical devices, which are marketed globally and therefore need to meet different regulatory requirements.

These symbols may be used on the medical device itself, on its packaging or in the associated documentation. The requirements of this document are not intended to apply to symbols specified in other standards.

The use of symbols on the label as an alternative to written language is permitted in the MDR regulation. Symbols are efficient, cost saving and internationally understood concepts to convey the required information to the user of a medical device.



4. Label Requirements

The information required on the label shall be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit, and/or on the packaging of multiple devices.

This information should be provided in a human-readable format and may be supplemented by with drawings and diagrams to be readily understood by the end-user.

The information on the label should include:

1. Name or trade name of the device.
2. Name and place of the manufacturer.

3. The label shall contain the details needed to identify the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device.

4. Label font should be clear and in Arabic or English.

5. It should indicate the Lot or Serial number (preceded by the words LOT NUMBER or SERIAL NUMBER or equivalent symbol).

6. The label shall indicate the date of manufacture, this may be included as part of the lot number or serial number provided the date is clearly identifiable.

7. The label shall bear an indication of any special storage or handling condition that applies.

8. The label shall indicate (if the device is supplied sterile), its sterile state and sterilization method.

9. The label shall bear warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device, and to any other person. **(e.g. CAUTION RADIATION HAZARD)**

10. The label shall indicate if the device is intended for single use.

11. The label shall indicate if the device contains or incorporates:
    - Medicinal substance
    - Human blood or plasma derivative
    - Tissues or cells (or derivatives of) of human or animal origin.

12. The label shall indicate if the device is custom made, with the words ‘custom made device’.

13. The label shall provide an indication that the device is a medical device. If the device is intended for clinical investigation only, the words ‘exclusively for clinical investigation’

14. The label shall indicate in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body.

5. Fixing CE mark on medical device label

CE mark on medical device label indicates that the device has been manufactured as per the European standards and meets the General Safety and Performance Requirements.

The CE marking shall be affixed visibly, legibly and indelibly to the device or its sterile packaging. Where such affixing is not possible or not warranted on account of the nature of the device, the CE marking shall be affixed to the packaging. The CE marking shall also appear in any instructions for use and on any sales packaging.

The CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out.