



UNIQUE DEVICE IDENTIFIER (UDI) FOR MEDICAL DEVICES USED IN THE GAS INDUSTRY

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Amendments to Doc 227/20

Section	Change
1	Updated legislative references
5.5	Updated how Eudamed-DI is assigned to legacy devices
8	Clarified implementation criteria for legacy devices
9.1.1	Unit of use UDI-DI declared not applicable; UDI-PI included more details for application flexibility
9.1.2	Unit of use UDI-DI declared not applicable; UDI-PI included more details for application flexibility
9.2	Clarified that bulk deliveries may occur with different types of shipping containers
9.1.2	Unit of use UDI-DI declared not applicable; UDI-PI included more details for application flexibility
9.4	Removed the concept of configurable device; Included possible different interpretation of UDI-DI and UDI-PI; removed not suitable examples, according with the new UDI-DI and UDI-PI interpretations.
11	Updated references

NOTE Technical changes from the previous edition are underlined

1 Introduction

On the 25th May 2017, the new European Regulation EU 2017/745 on Medical Devices, (MDR) came into force and replaced the Directive 93/42/EEC and its national transpositions ¹[1]. It has come into full application on the 26th May 2021, but for certain legacy devices the transition period has been extended up to 2028 [2].

It introduces, among others, totally new requirements concerning the registration and traceability of medical devices put on the market via an identification system based on a Unique Device Identifier (UDI).

This UDI system is expected by the European Commission to facilitate easier traceability of medical devices, significantly enhance the effectiveness of the post-market safety-related activities for devices, allow for better monitoring by competent authorities, help to reduce medical errors, fight against falsified devices, improve purchasing and waste disposal policies and stock-management by health institutions and other economic operators.

Article 27 of the MDR lays down that the UDI system shall consist of:

- production of a UDI by the manufacturer of the device;
- placing of the UDI carrier on the label of the device or on its packaging;
- storage of the UDI by economic operators; and
- establishment of an electronic database for UDIs part of the EUDAMED database.

2 Scope and purpose

2.1 Scope

This publication applies to the medical devices put on the market by the gas manufacturers according to the new medical device regulation EU 2017/745 [1] and concerns the implementation of the requirements related to the UDI system.

2.2 Purpose

This publication has been prepared to enable EIGA members to understand the overall UDI system and to efficiently implement these new requirements for the medical devices they are putting on the market as the legal manufacturer in compliance with the regulatory timeframe.

It addresses the production of the UDI, the associated labelling and the registration of the medical devices in the UDI - EUDAMED database with a focus on the specificities of medical device gases and medical pipeline systems.

This publication has been updated in February 2024 with the new information available at that time [3,5, 7, 9, 10] It will be updated if significant changes to European guidelines are published.

¹ References are shown by bracketed numbers and are listed in order of appearance in the reference section.

3 Definitions

For the purposes of this publication, the following definitions apply.

3.1 Publication terminology

3.1.1 Shall

Indicates that the procedure is mandatory. It is used wherever the criterion for conformance to specific recommendations allows no deviation.

3.1.2 Should

Indicates that the procedure is recommended.

3.1.3 May

Indicates that the procedure is optional.

3.1.4 Will

Is used only to indicate the future, not a degree of requirement.

3.1.5 Can

Indicates a possibility or ability.

3.2 Technical definitions

3.2.1 Automatic identification and data capture (AIDC)

AIDC is a technology used to automatically capture data. AIDC technologies include bar codes, smart cards, biometrics and RFID.

3.2.2 Human Readable Interpretation ('HRI')

HRI is a legible interpretation of the data characters encoded in the UDI carrier.

3.2.3 Issuing entity

Legal entity enabled by means of implementing acts of The European Commission to operate a system for assignment of UDIs.

3.2.4 Legacy device

Devices, which can continue to be placed on the market under Directive certificates by virtue of Article 120(3) of MDR after the MDR application dates.

3.2.5 Model

One medical device or a family of medical devices with variations that have shared characteristics (variants) and have a common CE technical documentation.

3.2.6 Unit of use (UoU)

The UoU refers to an individual medical device in instances when a UDI is not labelled at the level of the device, for example in the event of several units of the same device being packaged together (e.g. several units contained in a plastic bag) or when the device dimension, shape or material make it impossible to be labelled. Its purpose is to associate the use of a device to/on a patient.