

MDCG 2019-5

Registration of legacy devices in EUDAMED

April 2019

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

This document deals with registration of devices, which can continue to be placed on the market under Directive certificates by virtue of Article 120(3) of Regulation 745/2017 (MDR), and Article 110(3) of Regulation 746/2017 (IVDR) after the relevant MDRs application dates. Those products are, for the purpose of this document, referred to as “legacy devices”¹. All following considerations, which are made in relation to the MDR shall apply to the IVDR, mutatis mutandis.

Art 120(3) of the MDR lays down that the requirements of the MDR relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply to legacy devices placed on the market after the application date of the MDR in place of the corresponding requirements of the Directives.

The MDR is not explicit in requiring that these “legacy devices” are subject to relevant UDI obligations. The MDR device registration requirements (Annex VI Part A Section 2 and Part B that are complementary) make the Basic UDI-DI and UDI-DI the access keys for device-related information in the future Eudamed, which is reflected in the database design. Therefore, any registration of a device is normally possible in Eudamed only if a proper Basic UDI-DI and UDI-DI are assigned to the device and registered in the database together with the other device-related data.

In light of this, taking all views heard into account, and considering that Article 120(3):

- Refers to legacy devices to be registered in line with MDR provisions,
- Lacks any explicit reference to UDI obligations for legacy devices

the MDCG considers it appropriate to adapt the Eudamed design to allow the registration of legacy devices in Eudamed in the absence of a (Basic) UDI-DI.

This is intended to prevent any technical constraint to the applicability of Art 120(3) for legacy device registration in Eudamed.

A comprehensive description of the technical implications is provided in the Annex.

¹ It shall be noted that, in other contexts, the term “legacy devices” might be used with a different meaning.

Annex

Basic considerations related to functioning of future registration of legacy devices in Eudamed

1. Legacy devices – covered by a valid Directive certificate - that will continue to be placed on the market after the MDR date of application should be registered in Eudamed without a Basic UDI-DI and UDI-DI. The registration deadlines for those devices is clearly the one referred to in Article 123(3)(e): 18 months after the date of application (provided that Eudamed is fully functional on time)².
2. However, in case of serious incident or field safety corrective action to be reported during the 18 months referred to in point 1, where the legacy devices have not been registered in Eudamed yet, they must be registered at the moment of the serious incident/field safety corrective action reporting.
3. Point 1 will be applicable only to the devices that are not already registered as MDR devices.

NOTE: All the Directive-compliant devices which have been placed on the market ahead of the general application dates and will not continue to be placed on the market afterwards, should be registered in Eudamed (without a Basic UDI-DI and UDI-DI) only if a serious incident report and/or a field safety corrective action report (with the field safety notice) occurs after the application date.

Technical implementation in Eudamed

4. **Legacy devices that will be registered in Eudamed will need two other unique access keys (IDs) to replace the Basic UDI-DI and UDI-DI for the sake of the workability of Eudamed.**
5. For this purpose, a Eudamed DI will be assigned to the device instead of the Basic UDI-DI and a Eudamed ID will be assigned by Eudamed instead of the UDI-DI allowing the system to work and to keep the design of Eudamed as close as possible to the MDR design. These Eudamed DI and Eudamed ID will be unique for a given legacy device.
6. The Eudamed DI could be either entirely generated by Eudamed or the manufacturer could partly assign the DI code. On the other hand, the Eudamed ID will be always automatically and fully generated by Eudamed

² It should be noted that all class I devices that are not sterile and/or with a measuring function under the Directives, are not eligible for any grace period. When placed on the market after the MDR date of application, they will have to be MDR compliant and be registered in EUDAMED as MDR devices.

from the Eudamed DI. The proposed rules for the assignment (still under discussion) are that Eudamed DI start with character "B", where Eudamed ID will start with character "D" (only difference between Eudamed DI and Eudamed ID). Beside this first character, the Eudamed DI/ID will include the SRN of the manufacturer, a number (assigned by the manufacturer or Eudamed) and a check digit.

7. The relationship between the Eudamed DI and a Eudamed ID will be one to one.
8. Furthermore, the registration of the legacy devices will require the manufacturer to enter the directive certificate identification (NB number, certificate number, revision number and expiry date) since they will not be registered in Eudamed by the NBs.

In case a legacy device has been already registered in Eudamed and that same device becomes at any point in time an MDR compliant device, that MDR device should be considered as a new device requiring a new registration (due to the change in the applicable legislation) with a Basic UDI-DI and UDI-DI in Eudamed. However, only a UDI-DI should be entered, if another device with the same Basic UDI-DI has already been registered. Eudamed should facilitate this (copy) process and allow the linking between the MDR device and the corresponding legacy device.