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MDCG Position Paper:

UDI assignment between manufacturers and distributors

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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.

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Background

It was noted a common practice among distributors to assign their own UDI-DIs under their own brand name and obtaining UDI-DI codes from issuing entities. While it is correct to have two different UDI-DIs under two brand names, they should be linked only to the manufacturer both in the UDI/Device registration module[1] of the European Database on Medical Devices (Eudamed)[2] and in the databases or internal documents of the EU UDI issuing entities[3].

This **MDCG Position Paper** aims at explaining the point to clarify the situation and avoid confusion, misunderstandings or potential misuse arising from differing interpretations between manufacturers and distributors, as well as the EU UDI issuing entities. This should ensure clarity, transparency and consistency across EU Member States in their enforcement of the provisions of the EU Medical Device Regulations on UDI and the operation of Eudamed.

Regulatory framework: relevant provisions

- Regulation (EU) 2017/745 on medical devices[4] ('the MDR'):

Article 10(7): **Manufacturers shall comply with the obligations relating to the UDI system referred to in Article 27** and with the registration obligations referred to in Articles 29 and 31.

Article 27(1)(a)(i): The Unique Device Identification system ('UDI system') described in Part C of Annex VI shall allow the identification and facilitate the traceability of devices, other than custom-made and investigational devices, and shall consist of the following:
… production of a UDI that comprises the following:
… **a UDI device identifier ('UDI-DI') specific to a manufacturer and a device**, providing access to the information laid down in Part B of Annex VI.

Annex VI, Part C, 2.2: The manufacturer shall assign and maintain unique UDIs for its devices; 2.3: Only the manufacturer may place the UDI on the device or its packaging.

- Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices[5] ('the IVDR'):

Articles 10(6): **Manufacturers shall comply with the obligations relating to the UDI system referred to in Article 24** and with the registration obligations referred to in Article 26 and 28.

Article 24(1)(a)(i): The Unique Device Identification system ('UDI system') described in Part C of Annex VI shall allow the identification and facilitate the traceability of devices, other than devices for performance studies, and shall consist of the following:
… production of a UDI that comprises the following:
… **a UDI device identifier ('UDI-DI') specific to a manufacturer and a device**, providing access to the information laid down in Part B of Annex VI.

[1] https://health.ec.europa.eu/medical-devices-eudamed/udidevice-registration_en.

[2] https://health.ec.europa.eu/medical-devices-eudamed_en.

[3] https://health.ec.europa.eu/medical-devices-topics-interest/unique-device-identifier-udi_en#udi-issuing-entities.

[4] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/745/oj).

[5] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176, ELI: http://data.europa.eu/eli/reg/2017/746/oj).

Annex VI, Part C, 2.2: The manufacturer shall assign and maintain unique UDIs for its devices; 2.3: Only the manufacturer may place the UDI on the device or its packaging.

Description of the issue

It has been reported that some companies consider it compliant with the MDR/IVDR that **the assignment of the UDI is performed by a distributor** who, on the basis of an agreement signed with the manufacturer (possible under Article 16(1)(a) MDR/IVDR), makes available on the EU market a device under its own name, while maintaining the manufacturer's indication on the label.

It means that the distributor receives an alphanumeric code from an EU UDI issuing entity, so that the UDI-DI code is linked to the distributor and to the device manufactured by the manufacturer.

It also means that within the Basic UDI-DI, the manufacturer lists two groups of UDI-DIs and register all of them in Eudamed: (1) the UDI-DIs that the manufacturer itself has assigned to the device marketed under its own brand; and (2) the UDI-DIs assigned by the distributor who markets the same device but under its own brand, while keeping the manufacturer data on the label. Therefore, in Eudamed, the same device would have different UDI-DIs (some that the EU UDI issuing entity has given to the manufacturer and some to the distributor).

Discussion and conclusions

The issue described in the previous paragraph highlights the problem that distributors obtain UDI-DI codes in their own name from EU UDI issuing entities. In the case described, although it would be appropriate to assign two different UDI-DI codes to the same device that is made available on the EU market under two different trade names, **such assignment must be made solely by the manufacturer**. This means that EU UDI issuing entities should ensure that the entity to which they provide and link the UDI-DI codes is the company acting as the manufacturer. This situation should not preclude the possibility of a third party, other than the manufacturer, interacting with the EU UDI issuing entities on behalf of the manufacturer.

In this context, the EU UDI Helpdesk[6] indicates that "The MDR/IVDR only set out the actor legally responsible for UDI obligations but does not provide instruction regarding any arrangement whereby additional actors execute activities such as UDI application and assignment to medical devices on behalf of the actor who holds the legal responsibility. As such, the manufacturer may in principle delegate the practical operation of UDI assignment and application to a third party (e.g. under a contractual agreement), however the ultimate legal liability for complying with UDI obligations remains with the manufacturer".

The provisions of the MDR and IVDR, and the indications provided by the EU UDI Helpdesk, should not be interpreted that any other economic actors (authorised representatives, distributors, importers) than the manufacturer may assign UDIs to devices. **The manufacturer, as indicated on the label of the device and the device documentation, is the only entity which can assign UDIs to the device intended to be placed on the EU market (and receive codes from the EU UDI issuing entities, being the codes linked to the manufacturer) and the only entity which can register the device in Eudamed**.

[6] EU UDI Helpdesk - UDI assignment - Obligations https://webgate.ec.europa.eu/udi-helpdesk/en/udi-assignment/obligations.html.