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Unique Device Identifier

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The National Organization for Medicines ("EOF" as per its Greek initials) published on Thursday November 13th, 2025, an announcement on the unique device identifier ("UDI") system provided for in the Regulation (EU) 2017/745 on medical devices and of the Regulation (EU) 2017/746 on in vitro diagnostic medical devices.

UDI is a series of numeric or alphanumeric characters created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market. On such basis, EOF reiterates the specifications of the applicable legislation. Highlighting the fact that the UDI system consists of:

(a) the creation of a UDI, which includes:

- a UDI device identifier ("UDI-DI"), which refers to a specific manufacturer and product;
- a UDI production identifier ("UDI-PI"), which identifies the production unit of the device and, where applicable, the packaged devices;

(b) placing of the UDI on the labelling or packaging of the device;

(c) storage of the UDI by economic operators, healthcare institutions and healthcare professionals, under the applicable framework,

(d) the establishment of an electronic system for the unique identification of a device ("UDI database").

The UDI carriers should be placed on the labelling of the device and on all higher levels of packaging. Higher levels of packaging do not include shipping containers.

EOD also reminds with its announcements to stakeholders the timeline for implementing the mandatory placement of the UDI on all categories of devices.

Finally, it is noted that a new UDI-DI is required whenever there is a change that could lead to incorrect identification of the device and/or uncertainty in its traceability. Any change to one of the following data elements in the UDI database requires a new UDI-DI:

- device name or trade name;
- device version or model;
- single-use device;
- sterile packaging;
- requirement for sterilization before use;
- quantity of devices per package;
- critical warnings or contra-indications (indicatively containing latex or DEHP).

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