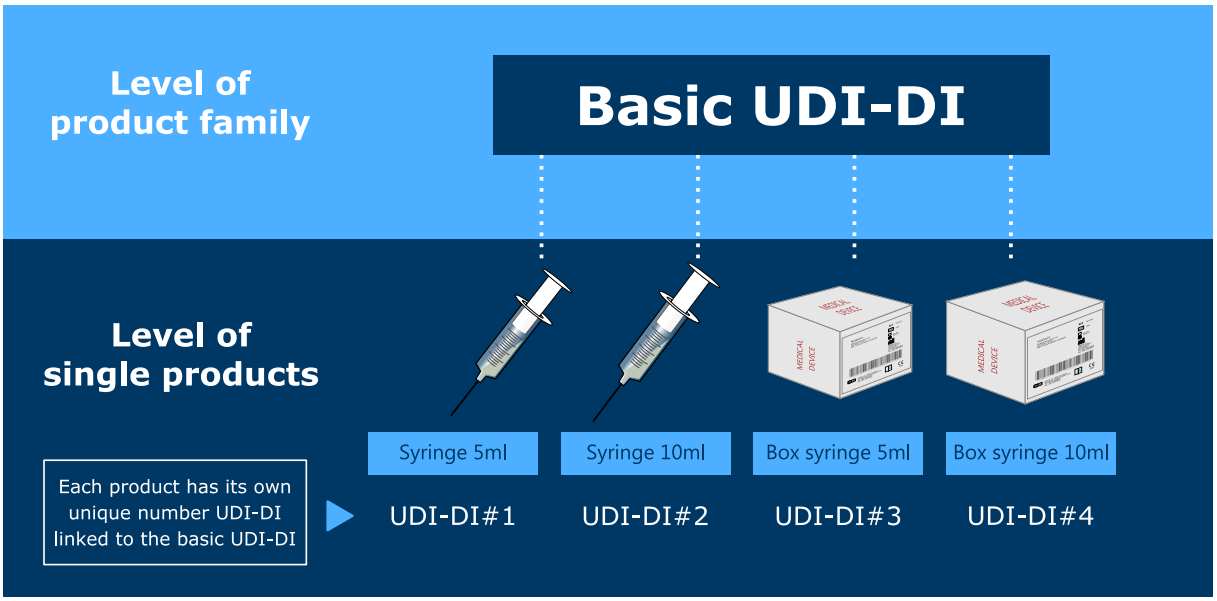
UNIQUE DEVICE IDENTIFICATION (UDI)

Unique Device Identifier (UDI) is a requirement of the EU MDR 2017/745 and IVDR 2017/746 to provide the traceability of medical devices in Europe.

Basic UDI-DI

The European UDI regulations require basic UDI-DI. The basic UDI-DI is the highest level of identification of the product hierarchy within the EUDAMED database. It is a static code that identifies a product family or a product model. It does not appear in text form or in a barcode on the products or product packaging.



UDI-DI & UDI-PI

- UDI-DI is a device identifier specific to a device, providing access to the information laid down in Part B of Annex VI of both MDR and IVDR.
- UDI-PI is a production identifier that identifies the unit of device production and if applicable the packaged devices, as specified in Part C of Annex VI.