The Global Language of Business

June 2019

# Be ready for UDI in the EU!

## Unique Device Identification for Medical Devices in Europe

GS1, since 2013, is an accredited issuing agency for the US FDA for the UDI (Unique Device Identification) Rule in the US. Currently most of the medical devices are identified with a GS1 identifier and GS1 MO's across the world are supporting their users in the implementation. UDI enables the globally unique identification of medical devices, and with that, improves patient safety and Healthcare business processes. A single, global system of standards is fundamental to enable an efficient and effective implementation of UDI by all Healthcare stakeholders worldwide.

The EU Regulation on medical devices ("EU MDR", 2017/745) and the EU Regulation on in-vitro diagnostic devices ("EU IVDR", 2017/746) provide the legal requirements for the European Unique Device Identification (UDI) system within Europe. GS1 is also designated as an issuing entity for the UDI in the EU.

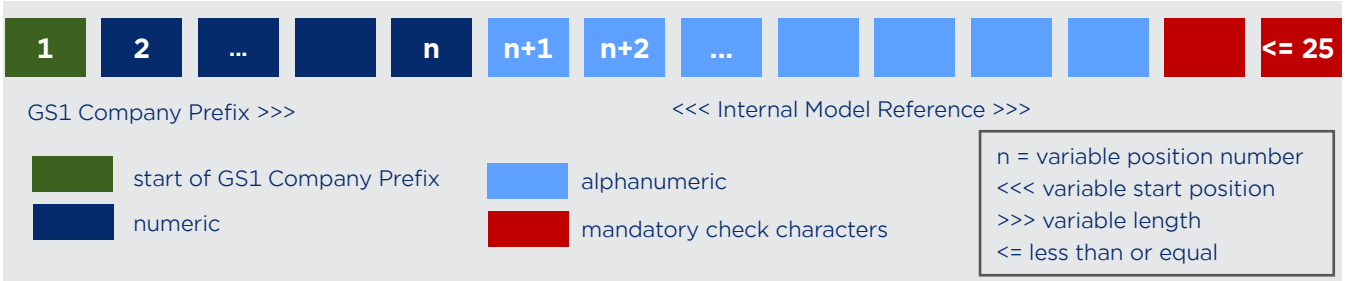
### GS1 Standards for UDI in the EU

In difference to the US FDA regulation, the EU regulations introduce a new identifier – the "Basic UDI-DI". It allows to group medical devices with similar features within the EU regulatory database EUDAMED. It is assigned outside of the normal trade item supply chain. The assignment must be done by the medical devices manufacturer or authorised representative, before the product can be submitted for market registration/approval to the competent authorities.

## Unique Device Identification in GS1 terms

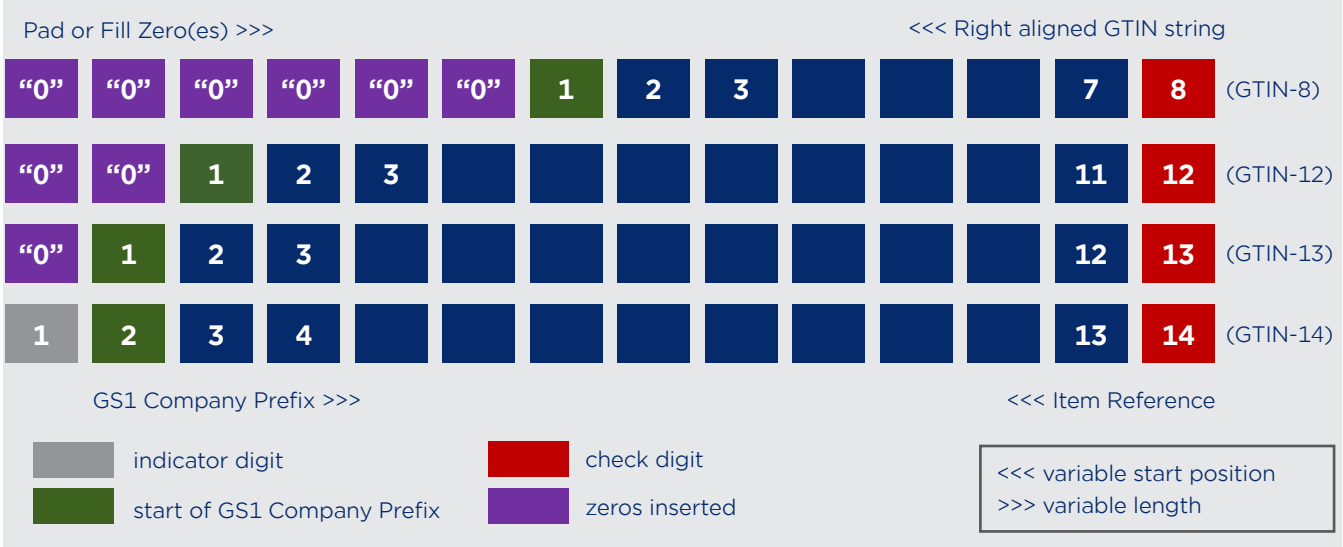
| **UDI regulatory requirements**<br>EU MDR and EU IVDR | **GS1 standards**<br>Product Identification |
|---|---|
| **Basic UDI-DI**<br>« New » level of identification in the EU | **GMN** (Global Model Number)<br>No Application Identifier (AI) for regulated medical devices |
| **UDI-DI**<br>Device Identifier (DI) | **GTIN**<br>Global Trade Item Number |
| **UDI-PI**<br>Production Identifier (PI)<br>*(if applicable)* | **AI**<br>Application Identifier (AI)<br>• Expiration date AI(17) - e.g. 141120<br>• Batch – lot AI(10) - e.g. 1234AB<br>• Serial number AI(21) - e.g. 12345XYZ |
| *Production Identifier data will vary by medical device type and manufacturer current practice.* | |
| **UDI-DI + UDI-PI = UDI** | **GTIN or GTIN + AI(s) = UDI** |

## Composition of the GMN (Basic UDI-DI)




To calculate the GMN check characters:
www.gs1.org/services/check-character-calculator

## Composition of the GTIN (UDI-DI)




To calculate the GTIN check digit:
www.gs1.org/services/check-digit-calculator

## Benefits

The implementation of UDI can enhance patient safety and improve efficiency in the healthcare supply chain. The system is expected to unambiguously identify medical devices throughout the global supply chain by providing precise information for healthcare professionals, thereby providing a secure global supply chain allowing for more accurate reports of adverse events, more effective management of medical device recalls and reduction of medical errors.

Interested in learning more about UDI?
www.gs1.org/healthcare/udi

Contact your local GS1 Member Organisation:
www.gs1.org/contact

## About GS1 Healthcare

GS1 Healthcare is a neutral and open community bringing together all healthcare stakeholders to lead the successful development and implementation of global GS1 standards, enhancing patient safety, and operational and supply chain efficiencies.

The development and implementation of GS1 standards is led by the experts who use them: pharmaceutical and medical device manufacturers, wholesalers, distributors, group purchasing organisations, hospitals, pharmacies, logistics providers, solution providers, governmental and regulatory bodies, and trade associations. Evidence available from industry implementations shows that GS1 identification, data capture and data sharing standards in healthcare deliver tangible benefit to all stakeholders. GS1 Healthcare members include more than 100 leading healthcare organisations worldwide.

For more information about GS1 standards in healthcare, go to www.gs1.org/healthcare

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