



Call to Action

New EU Unique Device Identification system requires new identifier: Basic UDI-DI



With recent approval by the European Parliament on 5 April 2017, new medical device regulations for both general and in-vitro diagnostic devices are helping to advance the unique device identification (UDI) system in Europe. GS1 has been provisionally designated by the European Commission (EC) as one of the UDI-issuing entities for the EU. Yet, to be considered for final designation as an UDI-issuing entity, GS1 must meet specific selection criteria—one being the provision of a solution that implements the “Basic UDI-DI”.

Background

Since 2013, GS1 has been an accredited issuing agency for the U.S. Food and Drug Administration (FDA) UDI

regulation. Today, more than 85 percent of all medical devices in the FDA’s Global UDI Database (GUDID) use the GS1 Global Trade Item Number® (GTIN®) as the primary device identifier. Furthermore, GS1 Member Organisations across the world are supporting their users in the implementation of GTINs and other GS1 standards.

Implementing UDI enables the identification of *all* medical devices, resulting in improved patient safety by:

- Allowing more accurate reporting, reviewing and analysing of adverse event reports so that problem devices can be identified and corrected more quickly.
- Reducing medical errors by enabling healthcare professionals and others to more rapidly and precisely identify a device and obtain important information concerning the characteristics of the device.
- Enhancing analysis of devices on the market by providing a standard and clear way to document device use in electronic health records, clinical information systems, claim data sources and registries. A more robust post market surveillance system can also be leveraged to support premarket approval or clearance of new devices and new uses of currently marketed devices.

- Providing a standardised identifier that will allow manufacturers, distributors and healthcare facilities to more effectively manage medical device recalls.
- Providing a foundation for a global, secure distribution chain, helping to address counterfeiting and diversion and prepare for medical emergencies.
- Leading to the development of a medical device identification system that is recognised around the world.

Source: US FDA

The approved EU regulations provide the legal requirements for the UDI system used throughout Europe. However, a major difference when compared to the FDA’s regulation is that these regulations introduce a new identifier called the Basic UDI-DI.

Defined in the regulations: “The Basic UDI-DI is the primary identifier of a device model. It is the DI assigned at the level of the device unit of use. It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity.” It is not applied physically on packaging or the devices.

The Basic UDI-DI assignment must be done before the product can be submitted for market registration and approval by authorities—a step that is typically not part of the trade item supply chain. The Basic UDI-DI also aims to support market surveillance activities and clinical investigations.

The new identifier may be applied in broader use cases than the immediate requirement of Healthcare. However, no sector beyond GS1 Healthcare has an expressed and immediate commitment to urgently develop and deploy this identifier. This identifier will fill a critical gap to ensure GS1 standards meet the need of medical device manufacturers to comply with the EU regulatory requirements. The timing for GS1 to develop and deploy this new identifier presents a challenge, but also a unique opportunity for GS1 as it will allow GS1 to qualify as a UDI issuing entity in the EU.

Even so, one needs to be sensitive to all who want to determine the broader applicability of the solution to this required Basic-UDI identification. To that end, we will abide by these two developmental principles.

1. By end of July 2017, GS1 will approve a standard that allows room for future use cases, if required, while clearly documenting as a priority its applicability to the healthcare use case.

2. Leaders in other sectors will be asked if there are requirements for additional use case examples.

What is the urgent need?

A new standard must be developed to enable the implementation of the Basic UDI-DI for medical device companies

worldwide and, as a result, allow them to use GS1 standards for UDI in Europe.

The development timeline is a challenging one given the following considerations:

- The new EU regulations are scheduled to be published in the Official Journal by early May.
- The deadline for the initial implementation step is three years for medical devices and five years for in-vitro diagnostic devices.
- Medical device companies will need to adapt their systems based on the new requirements and resulting standards.
- GS1 will need to be finalised as a designated UDI issuing entity.

The GS1 staff is committed to facilitating the GS1 Global Standards Management Process (GSMP) as efficiently as possible. Yet, input and commitment from the healthcare community is critical for a relevant standard that meets an accelerated timeline.

Who should work on the standard?

GS1 is looking for broad participation since all players involved in the supply chain for medical devices will be affected by the new regulations.

We need experts in the working group based on the following:

- Solid understanding of the GS1 system of standards
- Knowledge of regulatory affairs, particularly EU related, and public policy
- Familiarity with medical device design, registration and manufacturing practices
- Involvement in the distribution and administration of medical devices
- Engagement with the medical device industry regarding its IT systems or consultation on UDI

We also ask that all working group members keep in mind the urgency of this work, which will require some prioritisation.

Join our working group today!

If you are interested in being part of this exciting work effort, join our working group at <http://www.gs1.org/standards-development-work-groups#BasicUDI-DI>

Act now since the kick-off call is planned for 27 April at 7:30am to 9:00am EDT / 13:30 to 15:00 CET.

Also, ensure that you and your organisation have signed the required GS1 Intellectual Policy documents for participation. The GS1 Intellectual Property Policy can be eSigned [here](#) and Work Group Opt-In Agreement can be eSigned [here](#).

Need to know more?

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