



The Global Language of Business



MEDIA RELEASE

GS1 welcomes the adoption of the EU UDI system and the recognition of GS1's role and experience in the new Regulations

Brussels, Belgium, 5 April 2017 – GS1, the international standards Organisation, welcomes the adoption today of the final EU Regulations on medical devices and on in-vitro diagnostics. GS1 global standards will be used by manufacturers to implement the new EU system of Unique Device Identification (UDI), patient safety and supply chain security.

The UDI system intends to provide a globally harmonised framework for identification of medical devices to enhance quality of care, patient safety and business processes.

The EU Medical Device Regulation (MDR) and In-vitro Diagnostic Regulation (IVDR), adopted today, define the requirements for the EU UDI system.

GS1 applauds and welcomes the final adoption of the new EU rules on medical devices by the European Parliament, following the adoption by the Council last month.

This vote marks a significant achievement, and is the culmination of over four years of intensive work by the Council, the European Parliament and the European Commission with the active support of the business community, civil society and other stakeholders.

The GS1 system is an integrated suite of global standards that provides accurate identification and communication of information regarding products, patients, assets, services and locations. GS1 standards, including the Global Trade Item Number® (GTIN®), are already widely used by leading healthcare manufacturers.

The GTIN is accepted across the global healthcare industry as a unique identifier for medical and surgical products at every level of packaging. Since 2013, GS1 has been accredited as an issuing agency for UDI by the U.S. Food and Drug Administration (FDA).

"UDI systems based on GS1 standards will benefit patients, the healthcare system, and the medical device industry. GS1 standards assist healthcare organisations around the world to quickly and efficiently identify medical devices in the case of recall. They improve the accuracy and specificity of adverse event reporting and provide a foundation for a global, secure distribution chain. They also offer a clear way of documenting use of medical devices in electronic health records and clinical information systems", stated Miguel Lopera, GS1's CEO.

Bruno Aceto, GS1 in Europe's Chairman, said *"The EU has made safety and integrity of the global healthcare supply chain a strategic priority by adopting legislation for UDI for medical devices. The successful implementation of UDI by all healthcare stakeholders, from manufacturers to healthcare providers, will depend on several factors, including a globally standardised and harmonised system. The 47 national organisations composing GS1 in Europe, the European platform of GS1, are available to help companies implement the GS1 standards to answer regulatory requirements."*

GS1 has already started work to ensure that healthcare manufacturers from around the world, can create and maintain UDI numbers by following the EU Regulations and the GS1 General Specifications. According to the Regulations, a UDI number must be applied to the medical device label, its packaging and, in some cases, the device itself. Required product data must be submitted to Eudamed, the central European database. GS1's global identification and coding systems are compliant with relevant international ISO standards.

For more information, please visit the GS1 UDI resource web page:
<http://www.gs1.org/healthcare/udi>

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About GS1

GS1 is a neutral, not-for-profit Organisation that develops and maintains the most widely used global standards for efficient business communication. We are best known for the barcode, named by the BBC as one of “the 50 things that made the world economy”. GS1 standards improve the efficiency, safety and visibility of supply chains across physical and digital channels in 25 sectors. Our scale and reach – local Member Organisations in 112 countries, 1.5 million user companies and 6 billion transactions every day – help ensure that GS1 standards create a common language that supports systems and processes across the globe. Find out more at www.gs1.org.

About GS1 Healthcare

GS1 Healthcare is a global, voluntary user community bringing together all Healthcare supply chain stakeholders, including manufacturers, distributors, Healthcare providers, solution providers, regulatory bodies and industry associations. The mission of GS1 Healthcare is to lead the Healthcare sector to the successful development and implementation of global standards by bringing together experts in Healthcare to enhance patient safety and supply chain efficiencies. GS1 Healthcare members include over 70 leading Healthcare organisations worldwide. For more information about GS1 Healthcare, please visit www.gs1.org/healthcare.

About GS1 in Europe

GS1 in Europe is the European platform of GS1 gathering 47 GS1 in Europe Member Organisations. GS1 in Europe’s role is to encourage and facilitate the collaboration of GS1 Member Organisations (MOs) in Europe in order to lead the development and implementation of harmonised, user-driven solutions for improving the Supply & Demand Chain of European companies. GS1 in Europe also builds relationships with the European Commission and other relevant European institutions, in close collaboration with European industry associations to deliver first-hand and up-to-date information relevant to European businesses. More information at www.gs1.eu.