PRESS RELEASE

GS1 has been designated as issuing entity for Unique Device Identification (UDI) by the European Commission

FOR IMMEDIATE RELEASE – Brussels, 7 June 2019. GS1, the leading global supply chain standards organization, has been designated by the European Commission as issuing entity for Unique Device Identifiers (UDIs). GS1 global standards meet the EU Commission's criteria for the issuance of UDIs, supporting the EU regulators in ensuring a successful implementation of the UDI system as defined by the EU Medical Device Regulation and In-Vitro Diagnostics Medical Devices Regulation (EU Regulations), and enabling manufacturers to comply with these requirements.

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 GS1 global system of standards is the most widely implemented in the world and is used by all stakeholders in healthcare supply chains. The GS1 identifiers are fundamental to enable an efficient and effective identification of medical devices from product conception through every step of the supply chain lifecycle. Strengthening patient safety is central to GS1's mission in healthcare and GS1 is committed to support the EU Commission, manufacturers and other stakeholders worldwide in implementing the new EU UDI system." said Miguel Lopera, President and CEO of GS1, which has headquarters in Brussels, Belgium.

Since 2013, GS1 is accredited as UDI issuing agency in the U.S.A. and other regulators are also planning to allow the use of GS1 standards as the basis of their national UDI system.

According to EU Regulations, the UDI number is applied to the medical device label, its packaging, and/or the device itself. Required product data must be submitted to EUDAMED (European Database on Medical Devices). In addition, a new identifier was introduced by the EU Regulations: the Basic UDI-DI. GS1 has developed a new key (i.e. Global Model Number-GMN) to support the implementation of this requirement. By using GS1 global standards, Healthcare manufacturers in Europe and around the world are enabled to create and maintain compliant UDIs.

For more information, 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

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About GS1 Healthcare - GS1 Healthcare is a neutral and open community bringing together all related 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. Global members of GS1 Healthcare include more than 100 leading healthcare organisations worldwide.

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