



Press Release

FOR IMMEDIATE RELEASE

GS1 Accredited as Issuing Agency for Unique Device Identification by the U.S. Food and Drug Administration

BRUSSELS, Belgium (17th December 2013) – **GS1, a leading global standards organisation, today received accreditation by the U.S. Food and Drug Administration (FDA) as issuing agency for unique device identifiers (UDIs).** Global GS1 Standards meet the government's criteria for UDIs and will help manufacturers to address requirements of the new FDA UDI regulation, which was published in September 2013 to support patient safety and supply chain security.

The Unique Device Identification system aims at creating a common worldwide system for product identification that will improve healthcare business processes and patient safety. The U.S. FDA UDI rule is the first to be released but is expected to be followed by other similar regulations worldwide.

“GS1’s single, global system of standards across the entire healthcare supply chain is fundamental to enable an efficient and effective implementation of UDI by all healthcare stakeholders worldwide and to assist them in complying with the new regulation.” said Miguel Lopera, President and CEO of GS1, which has headquarters in Brussels, Belgium.

The GS1 System is an integrated suite of global standards that provides for accurate identification and communication of information regarding products, assets, services and locations. GS1 Standards, including the Global Trade Item Number[®] (GTIN[®]), are already in use by leading healthcare manufacturers, and are recognised across the healthcare industry as a unique identifier of medical/surgical products for every level of packaging. Healthcare manufacturers in the U.S and around the world can create and maintain a compliant UDI number (i.e. GTIN) by following the requirements of the U.S. FDA UDI Rule and the GS1 General Specifications.

“Global GS1 Standards support the FDA’s vision for a harmonised global supply chain, which is increasingly important as healthcare products are manufactured, shipped and sold across borders,” says Siobhan O’Bara, senior vice president, industry engagement, GS1 US. *“Using GS1 Standards, healthcare organisations around the world are able to uniquely identify and locate medical devices from product conception through every step of the supply chain lifecycle, improving product movement visibility and patient safety.”*

According to the FDA rule, a UDI number generally must be applied to the medical device label, its packaging, and in some cases the device itself. By unambiguously identifying medical devices, GS1 Standards benefit patients, the healthcare system and the medical device industry. GS1 standards assist healthcare organisation around the world to quickly and efficiently identify devices when recalled, improve the accuracy and specificity of adverse event reports and provide a foundation for a global, secure distribution chain. They also offer a clear way of documenting device use in electronic health records and clinical information systems. GS1’s global coding systems are compliant with relevant international ISO standards.

The GS1 System is the most widely used set of supply chain standards in the world and is used by most stakeholders in Healthcare supply chains.

For more information, visit the new 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 dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility in supply chains. GS1 is driven by more than a million companies, who execute more than six billion transactions a day with the GS1 System of Standards. GS1 is truly global, with local Member Organisations in 108 countries, and with Global Office in Brussels, Belgium. For more information, visit <http://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 60 leading Healthcare organisations worldwide. For more information about GS1 Healthcare, please visit www.gs1.org/healthcare