

New GS1 Standard enables surgical instrument traceability systems, improving patient safety and optimising asset management

Brussels, Belgium, 18 December 2009 – Leading healthcare providers are implementing, or have implemented, Automatic Identification and Data Capture (AIDC) systems to ensure traceability of surgical instruments throughout the instrument reprocessing cycle, in particular to and from the sterilisation department. “An instrument traceability system allows us to improve patient safety by reducing errors and ensuring instrument availability for surgery,” said Frédérique Frémont, CHI Robert Ballanger Hospital, France and member of the Global Leadership Team of GS1 Healthcare. “It also allows us to save costs through a more efficient logistics process and improved asset management.”

Two-dimensional bar codes directly marked on the instrument (Direct Part Marking) significantly simplify data collection on specific instruments and enable healthcare providers to effectively leverage IT systems for instrument traceability.

GS1 Healthcare, a global, voluntary user group, recognised the need for global standards for direct part marking of small surgical instruments and established a work group in March 2009 to develop the appropriate industry standards. That work group has now concluded its work through the GS1 Global Standards Management Process (GSMP) and is pleased to announce the immediate availability of the Application Standard for Small Medical / Surgical Instrument Marking.

“Global standards are key success factors for process improvements for suppliers. Healthcare is a global business where supply chain partners exchange goods and information. Country-specific non-standard requirements have a major impact on product assortment and on supply chain management,” said Volker Zeinar, Global Coordination Auto-ID Affairs, B Braun and member of the Global Leadership Team of GS1 Healthcare.

“Hospitals should adopt global healthcare industry standards; some hospitals are implementing instrument traceability systems based on proprietary bar codes, but those will not be compatible with instruments marked by various suppliers,” said Frédérique Frémont.

“GS1 Healthcare assembled a strong work group, representing a balance between local and global requirements, including manufacturers, distributors, hospitals, industry trade groups, and regulatory agencies. This standard is a significant step forward in our goal of improving patient safety”, said Grant Hodgkins, co-chair of the work group and member of the GS1 Healthcare Global Leadership Team.

The ratified standard takes into account the very specific requirements of marking surgical instruments, including their small size, the need to remain readable throughout the intended life

span of the item, and the need to be biocompatible. This standard provides the possibility of industry-wide adoption by manufacturers and healthcare providers of:

- GS1 DataMatrix – a two-dimensional bar code that enables Direct Part Marking of a large amount of data on a small space
- GTIN (Global Trade Item Number) – a GS1 Identification Key assigned to an item to retrieve pre-defined information about that item
- Serial number in an Application Identifier (AI(21))

Camera-based (image) scanners automatically capturing this data in the sterilisation department will enable surgical instrument traceability and improve patient safety and efficiency.

NOTES FOR EDITORS:

About GS1 and GS1 Healthcare

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, with the Global Office in Brussels, Belgium.

GS1 Healthcare is a global, voluntary healthcare user group developing global standards for the healthcare supply chain and advancing global harmonisation. GS1 Healthcare consists of participants from all stakeholders of the Healthcare supply chain: manufacturers, wholesalers & distributors, as well as hospitals and pharmacy retailers. GS1 Healthcare also maintains close contacts with regulatory agencies and trade organizations worldwide. For more information, visit www.gs1.org/healthcare.

Contact: Jan Denecker, GS1 Global Office, jan.denecker@gs1.org, +32 2 788 78 36 (office)

###