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Bar Coding for Medical Devices Is Becoming a Regulatory Requirement

For many years, medical device manufacturers primarily used bar codes internally to track products as they moved from manufacturing facilities to labeling sites to distribution centers. Then, regulatory bodies began requesting bar codes to be placed on devices for reimbursement purposes. More recently, some of Europe's national competent authorities (CAs) have lobbied for the implementation of bar coding in their country for traceability and patient safety reasons. Clearly, a pattern is emerging, and medical device manufacturers placing products in the European marketplace would be well-advised to consider their bar code strategy going into 2009.

In Turkey (which is not yet a member of the European Union), manufacturers were able to apply temporary bar codes to products with a CE mark that had been registered by a Turkish distributor contained in the national data bank ((UlusalBilgiBankası UBB). As of January 1, 2009, EAN-13 (or HIBC) barcodes are mandatory for medical devices and IVD products sold in Turkey. The law that made bar codes mandatory initially applied only to pharmaceutical products; in the spring of 2008, Turkish authorities decided to apply it to medical devices, as well.

Within the European Union, the most recent developments involving the bar coding of medical products come from the French CA, which goes by the acronym AFSSAPS. In September 2008, the agency published a set of recommendations regarding traceability for medical device manufacturers. Here is a summary of the document.

Manufacturers and distributors of medical devices should identify to users those medical devices that fall under the scope of special traceability rules. This applies to devices containing blood derivatives, cardiac valves, and all implantable devices including teeth.

Manufacturers should establish a codification system accessible to users that uniquely identifies devices and that takes into account the ongoing harmonization efforts of such a system. It should include at a minimum the designation or reference of the device; the name or reference of the manufacturer or its European authorized representative; and the lot or serial number of the device.

The packaging should include detachable stickers with the aforementioned information in order to allow the information to be processed at the pharmacy, user, and patient levels and within the parameters of the patient file.

A 1- or 2-D bar code system should be used, and this bar code should appear on the packaging. To prevent bar code-related errors, all necessary information should appear in a single, easy-to-identify bar code.

EUCOMED, the pan-European medical device industry association supports the goals of GS1 Healthcare (formerly GS1 HUG, or global Healthcare User Group). GS1 Healthcare offers a forum where authorities, healthcare professionals, health insurance companies, pharmacies, manufacturers, and distributors can discuss these issues and their requirements

In conclusion, the time is ripe to develop a bar code strategy that takes into account current and emerging EU requirements. Elements to consider include the choice of linear and/or 2-D

data matrix bar code types. The latter are advantageous when small packs and labels are involved, but currently they are not widely required for medical devices. Below are some examples of the GS1 128 (also called EAN 128), 2D Matrix, and 2D Linear bar codes.

GS1-128 (previously referred to as UCC/EAN-128 or EAN-128)
GS1-128 (UCC/EAN-128) bar codes can carry all GS1 keys and attributes but cannot be used to identify items crossing POS (retail point of sale)

GS1-128	
	• GS1-128 • 48 Alphanumeric capacity • Carries Application Identifiers • Unique GS1 Identifier • Not Omnidirectional

GS1 DataMatrix
GS1 DataMatrix is the only 2-D Matrix symbol specified for use by GS1. It is increasingly becoming the symbol of choice for healthcare applications. Because it requires camera-based scanners, it is currently specified for healthcare products that do not cross POS and direct part marking

GS1 DataMatrix	
 (01)07612345678900(17)100503 (10)AC3453G3	• GS1 DataMatrix (version ECC 200) • 3116 Numeric capacity • 2335 Alphanumerics capacity • Carries Application Identifiers • Unique GS1 Identifier • Camer-based (imaging) scanners only

Composite Component
Composite Component is the only 2-D linear symbol specified by GS1. It is called a component because it is only used with a linear bar code like GS1-128 or RSS.

Composite Component	
	

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