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## Discussion paper on the barcoding of medical devices using GS1 standards

### Purpose

This paper aims at providing recommendations on the barcoding of medical devices using GS1 standards to ensure the type of barcode used can be selected based on the symbology suitable for each packaging level and the anticipated scanning environments. The goal is to support global harmonisation of Unique Device Identification (UDI) regulatory requirements for the type of barcode used, which should be based on the application of use. This document also aims to stimulate the discussion on the acceptance and readability of DataMatrix along the healthcare supply chain, in particular by solution providers and healthcare providers.

It is important to clarify that that document does not refer to the possible application of more than one barcode to each product. That document refers to the possible choice of one suitable type of barcode to be applied to each product according the scanning environment, packaging specifications, etc. The recommendations in this paper take into account the current effort on the desire to apply only one barcode to each product.

As articulated in the GS1 General Specifications, regulatory requirements will always supersede GS1 standards when applied to healthcare products.

### Audience

The main target audience for this paper is regulators developing UDI requirements and supply chain actors applying and scanning barcodes on medical devices.

### Scope

This paper focuses on regulated medical devices in the context of the UDI requirements developed and implemented worldwide.

### Issue statement

According to the IMDRF global framework and all UDI legislations around the globe, no specific type of barcode is required to implement UDI requirements as long as they are compliant with the relevant ISO/IEC Standards. All GS1 barcodes are compliant with the ISO/IEC standards listed in the IMDRF Guidance<sup>1</sup>.

Given the variety of products considered as medical devices, it is key to enable manufacturers to apply the most relevant barcode depending on the packaging line capabilities and space constraints of the device packaging, the volume of data to be encoded in the barcode as well as on the scanning environment. The avoidance of requiring a specific barcode type for a specific country, also ensures there are no limitations to market access and product availability that specific country labelling and global inconsistencies can inadvertently create.

As regulators may mandate the use of a specific type of barcode for a particular use case, GS1 users wanted to align and develop this recommendation on what types of barcode would be the preferred option depending on the packaging specifications and scanning environment.

### Discussions

Mainly because of regulatory requirements, wholesalers and distributors must be able to manage and verify identification and traceability related data encoded in the barcode applied to medical products. They must be able to scan various type of barcodes, 2D in parallel to linear barcodes, and most importantly, be able to easily

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<sup>1</sup> <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-190321-udi-sag.pdf> The IMDRF Unique Device Identification system (UDI system) Application Guide contains an extensive listing of ISO/IEC standards including those related to linear and 2D barcodes.

identify the bar code to be scanned on the product and ensure it is readable. This can be assured by allowing the manufacturers to choose the most suitable type of barcode depending on the application use.

End-users and in particular healthcare providers, need to be able to scan all types of barcodes. Some healthcare providers are currently scanning DataMatrix on secondary packaging of pharmaceutical products and can access the relevant data with a single scan. In practice, the most important need of healthcare providers is to ensure that products can be scanned easily for inventory management and at point of care without confusion and capturing accurate information, irrespective of barcode type. Here again, this can be assured by allowing the manufacturers to choose the most suitable type of barcode depending on the application for use.

## Recommendations

To ensure the harmonised implementation of the UDI requirements while aligning with industry practices/plans and the need for the highest level of patient safety, the recommendation is to assure the type of barcode used can be selected based on the application of use, as specified in the IMDRF UDI Application Guide.

Another recommendation is to apply one single barcode to each packaging/label/device, when possible or utilise the ISO UDI symbol. While additional data elements may be useful for supply chain management, the UDI-regulated data encoded in the barcode should be aligned with only those required by UDI regulations and listed by the IMDRF UDI Application Guide.

Lastly, and potentially, a discussion could be launched on how to support an increased use of DataMatrix on the relevant packaging levels and to enhance the readability of DataMatrix by solution providers and hospitals. This should focus on allowing sufficient time for future migration (e.g. new devices, new lines first, type of devices, specific markets, readiness for third party logistic partners to handle DataMatrix), implementations and education, as well as supporting enhanced capability within solutions utilised within clinical settings.