

Use of GS1 2D / Matrix Data Carriers in Healthcare

Purpose

The purpose of this paper is to promote the GS1 Global Healthcare position and guidance on the use of GS1 2D / Matrix Data Carriers (i.e. GS1 DataMatrix, GS1 QR Code) in the healthcare sector. This is done through discussion of the similarities and differences between GS1 DataMatrix and GS1 QR Code data carriers, their use in the healthcare supply chain, and the **Global GS1 Healthcare preference for the use of GS1 DataMatrix** for GS1 Keys typically found on trade items (i.e. GTIN, GRAI, GIAI and SSCC when applicable¹). The GS1 QR Code is an equal choice to be considered by users when encoding information in regards to locations, documents and service relationships (i.e. GLN, GDTI and GSRN).

Executive Summary

The global members of GS1 Healthcare continue to support the use of GS1 DataMatrix as the only endorsed 2D / Matrix data carrier for encoding those GS1 Keys typically found on healthcare trade items. Additionally when considering 2D / Matrix data carriers for the encodation of other GS1 Keys typically used in the healthcare sector, GS1 DataMatrix and GS1 QR Code are considered equal choices for users. For those whose use-cases or processes require a single data carrier selection for all keys, to maintain consistency and to minimize training and additional expenditure, the recommendation is the use of GS1 DataMatrix for all GS1 Keys within those implementations.

GS1 Healthcare 2D Data Carrier* Recommendation Summary		
GS1 Keys for:	GS1 DataMatrix	GS1 QR Code
a) Trade Item Identification <ul style="list-style-type: none"> • GTIN • GRAI • GIAI • SSCC** 	✓	✗
b) Other Identification use cases <ul style="list-style-type: none"> • GLN • GDTI • GSRN • ...etc. 	✓	✓

*NOTE 1: This paper discusses use of GS1 2D/Matrix Data Carriers and does not alter present policy on use of 1D/Linear Data Carriers with GS1 Keys.
 **NOTE 2: At present SSCC is only used with the GS1-128 1D/Linear Data Carrier. SSCC is included above for future use when applicable.

¹ Though seen at this time as a future trend, at present, use of GS1 2D/Matrix data carriers with the GS1 Key SSCC has not been endorsed within the GS1 General Specifications.

Regulatory requirements – GS1 DataMatrix as a preferred option

The unique identification of healthcare products for track and trace purposes from the point of manufacture to the point of administration is a key objective of regulations around the world. More and more regulators are requiring the use of unique identifiers to be encoded into machine-readable forms (also called data carriers). Increasingly, regulators are recommending or requiring GS1 DataMatrix as that data carrier.

For example, GS1 DataMatrix was widely used on secondary packaging in successful drug traceability pilots in Austria, Brazil, Colombia, Serbia, Switzerland and the United States (U.S.), and on primary packaging in Belgium. Its use on pharmaceutical products is already specified by regulators in Argentina, Egypt, France, India, Jordan, Korea, Saudi Arabia, Turkey and the U.S. as well as being required as part of the European Commission's regulation on medicines verification in Europe. It is also recommended for use on vaccines in Canada and is increasingly the primary recommendation on vaccines and human reproduction products in the area of Humanitarian Logistics.

Healthcare industry practices – a drive for one barcode symbol on trade items

While regulatory bodies drive the implementation of GS1 DataMatrix for the fight against counterfeit healthcare products and for better control of the supply chain from the point of manufacture to the point of administration, GS1 QR Code is at this time primarily found on packages as a link to marketing information about a product. However, the inclusion of more than one barcode symbol on the same package or label is not recommended by GS1 Healthcare and its global community. Both goals can be accomplished with a single data carrier.

Multiple barcode symbols on a single item can lead to potentially dangerous confusion for the user. Likewise, it can lead to scanning and reading performance issues as the wholesaler/distributor/caregiver/pharmacist might find it difficult to identify which barcode should be or has been scanned / read. The GS1 Healthcare Provider Advisory Council (HPAC) developed a position paper highlighting issues with barcode symbols, which are hindering the implementation process in hospitals.²

In addition, using multiple symbols takes up valuable package and label space, which could lead to quality issues or other practical manufacturing inefficiencies. When a packaging line must print the barcode and variable information dynamically as well as in multiple places on an item, two or more printing and verification systems may need to be installed and maintained. This leads to more training & processes, more equipment, and more risk of errors that could be avoided.

Although the application of dynamic information in barcode symbols is relatively new to healthcare applications, ISO/IEC Data Matrix was developed and in use in global industrial applications before ISO/IEC QR Code. GS1 DataMatrix, which is derived from ISO/IEC Data Matrix, already has an installed base with background knowledge for application and use in these types of product and packaging applications. GS1 DataMatrix is widely used in the healthcare sector, based upon the "industrial" practices in other sectors.

²http://www.gs1.org/docs/healthcare/20121017_FINAL_HPAC_Position_Paper_Bar_Code_Issues.pdf

However, consumers are not informed on the benefits of this two-dimensional (2D) barcode data carrier and often may not be able to distinguish it from QR Code. The creation and scanning of GS1 DataMatrix have been improved and optimised to better meet the needs of the supply chain, and to enable consumers to easily scan it with a smart phone.

In light of this, it is important to acknowledge all the work accomplished over the past years by the industry to maintain ISO/IEC Data Matrix and improve its printing quality, given that all these efforts can also be applied to the B2C needs.

Data Matrix and QR Code - similar technical capabilities

In comparing the data carriers; ISO/IEC Data Matrix (known in the GS1 System as GS1 DataMatrix) and ISO/IEC QR code (known in the GS1 System as GS1 QR Code) from a technical and practical implementation point of view (e.g., amount of data to be encoded, high-level technical capabilities of 2D / Matrix barcodes, error prevention and detection, etc.), there is no significant practical advantage to use one versus the other. Both data carriers are 2D / Matrix barcode symbologies that can encode large amounts of data in small areas and employ "error detection" and "error correction". Potentially, the only unique benefit in the use of QR code over Data Matrix is a higher efficiency when encoding (Japanese) Kanji characters. However, this does not serve as a particular competitive advantage in the GS1 System, because only digits (numbers), the Roman alphabet and a set of selected characters are allowed to be encoded in GS1 standard symbologies.

Over the last few years, there has been a significant growth of free and downloadable applications (referred to as 'apps') on smart phones and mobile communication devices that allow the consumer to remotely access information about a particular item or product. Both GS1 DataMatrix and GS1 QR Code can facilitate connectivity to product information with these types of apps. Previously, B2C apps were limited to scanning QR Code or other proprietary symbols. Nowadays, new apps have been developed which can scan Data Matrix as well, giving greater user flexibility.

In the future, through GS1's increased efforts, apps will be able to access product information via the GS1 Global Trade Item Number (GTIN), encoded dynamic product data, access to a trusted URL all via the 2D barcode data carriers (i.e., GS1 DataMatrix, GS1 QR Code). This is partially enabled by additional information in the GS1 Application Identifiers (AIs) associated with the GTIN and encoded in the data carrier. For example, when scanning a GS1 DataMatrix on pharmaceutical packaging, the user will be able to identify the GTIN of the trade item and any relevant, encoded AIs; such as expiration date, lot/batch number and/or serial number. It potentially could then provide access to the product's Electronic Information for Use (EIFU), patient leaflet, or maybe even to an instructional online video.

GS1 Healthcare current activities - GS1 DataMatrix and Apps

- GS1 is working to enable the use of smart phones to read both GS1 DataMatrix and GS1 QR Code barcode symbols
- GS1 has developed a healthcare demo and survey app to demonstrate the B2C capabilities of GS1 DataMatrix

2D / Matrix Data Carrier Selection – GS1 Global Healthcare Conclusions

Considering all the aspects of this discussion, GS1 Healthcare and its global members continue to strongly support the implementation and use of GS1 DataMatrix as the only endorsed 2D / Matrix data carrier for encoding those GS1 Keys typically found on trade items (i.e. GTIN, GRAI, GIAI and SSCC when applicable³). In this regard GS1 DataMatrix is the only permitted GS1 2D matrix barcode data carrier for use with those GS1 Keys when associated with healthcare products (i.e. regulated healthcare trade items).

When considering GS1's 2D / Matrix data carriers for the encodation of the other GS1 Keys typically used in the healthcare sector (i.e. GLN, GDTI and GSRN) GS1 Healthcare and its Global Members see no overwhelming reason to mandate only the use of GS1 DataMatrix and consider GS1 QR Code an equal choice to be considered by users.

For those individual healthcare users or groups of healthcare users whose specific applications or processes may require a single data carrier selection for all GS1 Keys within their use-case, the primary recommendation would be the use of GS1 DataMatrix for all keys to maintain consistency with existing healthcare product use and minimize the need for additional or "cross" training, duplication of processes, further expenditures, etc.

To help bring awareness of the positive effects of the use of GS1 DataMatrix as the single 2D / Matrix data carrier for healthcare trade items and the addition of the use of both GS1 DataMatrix or GS1 QR Code for the encodation of the rest of the GS1 Keys used in the healthcare supply chain, GS1 Global Healthcare encourages any new investments and education in the areas of printing and scanning to encompass use of GS1 DataMatrix and/or GS1 QR Code as applicable.

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, and to view this paper please visit www.gs1.org/healthcare.

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