

## Recommendation: Using GS1 barcodes to access digital content about healthcare products

### Purpose

This document is intended to drive discussion, and provide recommendations, about the use of GS1 barcodes to access digital content.

The document is designed to be read in the context of the current discussions within the GS1 Healthcare community (GS1 HC), as well as regulatory developments relating to the Electronic Patient Information Leaflet (ePIL), Electronic Instructions for Use (eIFU), and other forms of eLabelling.

As articulated in the GS1 General Specifications, regulatory requirements will always supersede GS1 standards when applied to healthcare products. Global harmonisation and alignment on the GS1 standards will increase interoperability, safety, and efficiency.

### Audience

The main target audience for this paper is regulators and competent health authorities developing requirements relating to accessing digital content about healthcare products.

### Data carriers allow the identification information on the pack to be captured

The GS1 identifiers can be captured using different type of “data carriers”, as shown in the visual below.



### Issue statement

[The 2021 GS1 HC paper discussing the role of the GS1 DataMatrix in Healthcare](#) “recommends the implementation of GS1 DataMatrix as the ONLY globally endorsed 2D / Matrix data carrier for product

identification for healthcare products, when the scanning environment, data and regulatory requirements make the usage of a 2D instead of a linear barcode necessary.”

Given technical and/or regulatory constraints, the use of an additional barcode, usually a QR Code, is sometimes chosen to provide access to digital content. However, using GS1 standards, such as the GS1 Digital Link standard, can avoid the proliferation of additional barcodes on medicinal products, which presents an additional complexity in packaging management and a risk of confusion at the point of scan.

## **Discussion**

For identification purposes, the GS1 DataMatrix is required by more than 70 regulations across the world for traceability of medicines. The WHO Policy paper on traceability of medical products<sup>1</sup> also refers to the use of the GS1 DataMatrix for traceability purposes.

In countries where a globally harmonised traceability system for medicines is not yet implemented, GS1 linear barcodes are often used for identification of medicines.

For medical devices, the regulations for Unique Device Identification (UDI) do not require the use of a specific type of Automatic Identification and Data Capture (AIDC) technology, and in practice the type of barcode chosen (i.e., GS1 linear barcode or GS1 DataMatrix) depends on the type of medical device and its usage. GS1 is one of the agencies authorised by regulators to provide the AIDC standards for UDI, and GS1 barcodes are the most commonly used for medical device UDI implementation globally.

Beyond regulations about identification and traceability for medical products, more and more regulators are developing requirements for accessing digital content about healthcare products. Mainly because mobile phones can today natively scan QR codes, these requirements often rely on a QR Code to be applied on the packaging to enable access to digital content. Some mobile phone operating system providers are also already enabling native scanning of GS1 Data Matrix; others are expected to follow.

In the meantime, the current ability natively scan only QR code results in a proliferation of barcodes applied to the packaging, and undermines the ability to easily find the right barcode to verify product identification and/or to access digital content.

## **Recommendation**

GS1 HC’s recommendation is for the GS1 barcode to be used both for identification and traceability purposes, and to access digital content. GS1 HC’s aspirational goal is for the GS1 DataMatrix to be used in such cases.

GS1 HC does **NOT recommend the use of QR codes for product identification and traceability.**

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<sup>1</sup> WHO “Policy paper on traceability of medical products”  
<https://www.who.int/publications/i/item/policy-paper-on-traceability-of-medical-products>



If a 2D barcode (i.e., QR Code) is needed, in addition to the GS1 barcode applied for identification and traceability purposes, it should be strictly limited to accessing digital content, should leverage the GS1 Digital Link standard, and should contain the same identifier as the GS1 barcode.

In regulations and in tender requirements about access to digital content, the GS1 recommendation is to leverage the already present GS1 barcode to both identify the product and to access digital content.

In cases where this is not possible, a reference to a 2D barcode should be included in the regulation as an option, instead of a mandate for a specific type of GS1 barcodes. This is critical to allow flexibility and to avoid complex and costly packaging changes.

### **Reference Documents**

- GS1, “GS1 General Specifications, Release 23,” Ratified, Jan 2023  
<https://ref.gs1.org/standards/genspecs/>
- The GS1 Digital Link Standard  
<https://www.gs1.org/standards/gs1-digital-link>
- GS1 Digital Link in Healthcare: A single barcode for identification, authentication and access to information for medical products  
<https://www.gs1.org/docs/Digital-Link/2019.GS1-Digital-Link.pdf>
- The key role of GS1 DataMatrix barcodes for product identification in healthcare (2021)  
<https://www.gs1.org/docs/healthcare/position-papers/GS1-DataMatrix-Position-Paper-FINAL.pdf>
- Accessing online product information with the GS1 Digital Link Standard  
[https://gs1go2.azureedge.net/cdn/ff/VDs3uKZZSd-OB2FbaMaKXWI2wUdXZiR-F18oQEpIpE/1693232781/public/2023-08/accessing-online-product-information-with-the-gs1-digital-link-standard\\_1.pdf](https://gs1go2.azureedge.net/cdn/ff/VDs3uKZZSd-OB2FbaMaKXWI2wUdXZiR-F18oQEpIpE/1693232781/public/2023-08/accessing-online-product-information-with-the-gs1-digital-link-standard_1.pdf)

