GS1 DataMatrix

A tool to improve patient safety
through visibility in the supply chain

Visibility enabled by GS1 DataMatrix in Healthcare

Global standards for automatic identification provide an opportunity to make the healthcare supply chain safer as well as more efficient and accurate. Healthcare regulators and trading partners have realised that a global standardised identification system from manufacturer to patient treatment is imperative to comply with the increasing need for product traceability around the world.

The GS1 System, globally endorsed by the healthcare community, is the most widely used identification system worldwide with more than 5 billion transactions per day. Built on a foundation of identification keys (such as the Global Trade Item Number or GTIN) and attributes (such as a batch/lot number, expiry date, unique serial number etc.), it is uniquely suited to meet the needs of the healthcare industry.

Pharmaceutical and medical device identification & marking can have very **specific needs,** including:
- **Encoding large amounts of variable or dynamic data** (batch/lot number, expiry date, serial number, etc.) at high production speeds
- **Direct part marking** (e.g. marking on surgical instruments, etc.)
- **Global legal and regulatory requirements** that may dictate the placement of, and data encoded in a bar code symbol as well as the specific data carrier (bar code symbology) to be used
- **Traceability requirements** for both pharmaceuticals and medical devices

There can be no visibility of an item or asset until there is a standard way for all stakeholders in the supply chain to identify it, capture and share information about it

Some of these needs are being met, and will continue to be met, through the use of 'traditional' linear bar code data carriers, such as GS1-128 or GS1 DataBar. However, for applications where they are not, GS1 Healthcare has adopted the use of GS1 DataMatrix as the GS1 Data Carrier (bar code symbology) solution.

The healthcare industry faces major challenges like counterfeiting, ineffective product recall, medication errors and lack of inventory costs and supply chain inefficiencies. Some countries like France have already a regulation in place to improve patient safety through better traceability.

The EU Falsified Medicines Directive (FMD) constitutes an important step in protecting patients from counterfeit medicines. As a result, European pharmaceutical supply chain actors, amongst others EFPIA (European Federation of Pharmaceutical Industry Associations) supported by GIRP (Pharmaceutical full-line wholesalers in Europe), PGEU (Pharmaceutical Group of the European Union) and EAEPC (European Association of Euro-Pharmaceutical Companies) are developing systems enabling medicine packs to be verified at the point of dispensing, with the objective to meet the requirements of the FMD.

The EFPIA solution is an end-to-end point-of-dispense coding and serialisation system which allows pharmacists to check a unique identification code on each individual pack when it is dispensed to the patient. These codes are generated and applied by manufacturers using a simple 2D data matrix barcode, which contains the GTIN (Global Trade Item Number), a unique serial number and additional attributes. The scan will reveal any duplication of data on packs and will trigger the system to immediately alert the pharmacist to the possibility of a counterfeit product. *www.efpia.eu*

In France, as from the 1st of January 2011, new regulation on the traceability of human pharmaceutical products requires a GS1 DataMatrix to be placed on all pharmaceutical packs.

This system will identify products with the **GS1 Standards using the 2D GS1 DataMatrix as the data carrier of choice.**
www.gs1.org/docs/healthcare/GS1-EFPIA_product_identification_vision.pdf

The Council of Europe and its EDQM (European Directorate for the Quality of Medicines and HealthCare) have also adopted a multi-level, anti-counterfeiting strategy. Part of this strategy is the eTACT system: the EDQM anti-counterfeiting traceability service for medicines. The aim of eTACT is to ensure the traceability of individual packs of medicines using mass serialisation. With interoperability in mind, eTACT will follow the main standards of GS1, namely GTIN (Global Trade Item Number) for product numbering and EPCIS (Electronic Product Code Information System) for interfacing systems. The eTACT project envisages placing a Unique Medicine Identifier (UMI), containing GTIN plus additional attributes on the secondary packaging of medicinal products in the form of a 2D datamatrix barcode
www.edqm.eu

GS1 DataMatrix – A tool to improve patient safety through visibility in the supply chain

What is GS1 DataMatrix?

A GS1 DataMatrix bar code symbol is a two-dimensional (2D) matrix bar code, consisting of black and white "cells" or modules, that can be arranged in a square or rectangular matrix. GS1 DataMatrix is the preferred two-dimensional (2D) matrix bar code symbology that efficiently meets all of the needs of the pharmaceutical and medical device industry, by:

- **Allowing the encoding and marking of a greater amount of data within a smaller space**

- **Enabling direct part marking** of trade items where labels may not be practical (small medical / surgical instruments)
- **Allowing the printing of variable information in a bar code data carrier, at high production rates**
- **Providing error detection and correction capabilities** to improve the readability of bar code symbols despite irregular packaging or physical damage to a label

Structure of GS1 DataMatrix

The GS1 DataMatrix may be printed as a square or rectangular symbol made up of individual dots or squares. This representation is an ordered grid of dark and light modules bordered by a finder pattern. The data is encoded using a series of dark or light modules based upon a pre-determined module size, grid size and mathematical formula.

The GS1 DataMatrix is readable omni-directionally (in a 360-degree orientation).

A GS1 DataMatrix can contain the following attributes :

Manufacturer Product Code (GTIN) - 14 digits
Expiry Date - 6 digits (YYMMDD)
Batch / lot Number - up to 20 alpha-numeric characters
Unique Serial Number (randomized) - up to 20 alpha-numeric characters

Example: Use of GS1 Standards for the identification of products using a GS1 DataMatrix

|	
GTIN:	(01) 07046261398572
Expiry:	(17) 130331
Batch / lot:	(10) TEST5632
S/N:	(21) 19067811811

Where is it used and placed?

Because of its small size and high information capacity, GS1 DataMatrix is used in multiple industry sectors including electronics, automotive, aerospace and is particularly suited to healthcare. You can find it on a medication or medical device package as well as directly on medical devices.

The exact location of a GS1 DataMatrix symbol on a product is determined by the manufacturer who will need to consider:

- The available space on the product package
- The type of product and printing substrate (packaging material)
- The intended usage of the GS1 DataMatrix (for example, will the symbol be read in an automated environment or by hand)

GS1 DataMatrix – A tool to improve patient safety through visibility in the supply chain
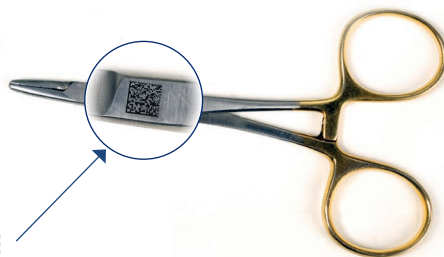
How to read it?

To read the GS1 DataMatrix symbology, camera-based bar code scanners are required. Laser bar code scanners cannot read data matrix bar codes but camera-based bar code scanners can read both linear and 2D bar codes.

This is the reason GS1 Healthcare published a specific position paper on camera-based scanners. For more information, please read at:
www.gs1.org/docs/healthcare/GS1_HUG_ps_Camera_Based_Scanners.pdf

Advantages of GS1 DataMatrix

GS1 DataMatrix contains much more information than a classic linear bar code symbol such as the GTIN (Global Trade Item Number), lot number, expiry date and even a unique serial number which allows better traceability. Indeed, 2D matrix bar code symbols capture the largest amount of data in by far the smallest footprint.

The symbols **can also be printed directly on the products themselves,** providing serial numbers that track them throughout their entire lifetime. That can be extremely important if recalls arise.

It has a **sophisticated error correction algorithm**, which can compensate for lost or missing data due to extraneous marks or partial symbol damage. With error correction, GS1 DataMatrix bar code symbols can recover from various types of physical damage. A GS1 DataMatrix symbol can be scanned even if damaged, torn or printed poorly provided the amount of damage does not exceed the available error correction.

The GS1 System, the world's most accepted standards system in Healthcare, provides globally unique identification numbers and bar code marking for trade items.

GS1 DataMatrix and mobile Health

Having more than one symbol on a product creates challenges in the care-giving environment, for example: the time taken to identify which symbol to scan, the impact of the wrong symbol being scanned, the ability of the scanner to scan and decode only one symbol when in close proximity to another etc., these have potential to impact patient safety.

This is why **GS1 Healthcare advocates for ONE bar code symbol to be placed on product packaging** as a long term objective.

In order to fulfil various needs, GS1 is enabling a GS1 DataMatrix that can not only contain the GTIN, batch/lot number, expiry date and unique serial number, but **will also offer the possibility to hold a URL link** pointing to a website that could contain the following information:

- Packaging leaflets from medicines in electronic format
- IFU (instruction for use) for medical devices – allowed in electronic format in the EU
- A product video
- Other product related information

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 please visit :

www.gs1.org/healthcare

GS1 AISBL
Blue Tower
Avenue Louise, 326, b10
B-1050 Brussels, Belgium
T +32 (0)2 788 78 00
F +32 (0)2 788 78 99
contactus@gs1.org

www.gs1.org

GS1 DataMatrix – A tool to improve patient safety through visibility in the supply chain