GS1 DataMatrix

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

Visibility enabled by use of Data Matrix 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.

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 directly on surgical instruments, etc.)

- **Global legal and regulatory requirements** that may dictate the placement of, and data encoded in a barcode symbol, as well as the specific data carrier barcode symbology to be used

- **Traceability requirements** for both pharmaceuticals and medical devices

The healthcare industry faces major challenges like counterfeiting, ineffective product recalls, medication errors and lack of inventory as well as inventory costs and supply chain inefficiencies.

Some countries like France already have 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 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 European Medicines Verification Organisation (EMVO) 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 / matrix barcode, which contains the GTIN, a unique serial number and additional attributes. A scan of the barcode 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.emvo-medicines.eu

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 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 GS1 DataMatrix barcode.
www.edqm.eu/en/FAQ-eTACT-1482.html

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

Data Matrix meets the needs of the industry

A Data Matrix barcode symbol is a two-dimensional (2D) matrix barcode, consisting of black and white "cells" or modules that can be arranged in a square or rectangular matrix.

A Data Matrix 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 barcode data carrier, at high production rates**

- **Providing error detection and correction capabilities** to improve the readability of barcode symbols despite irregular packaging or physical damage to a label.
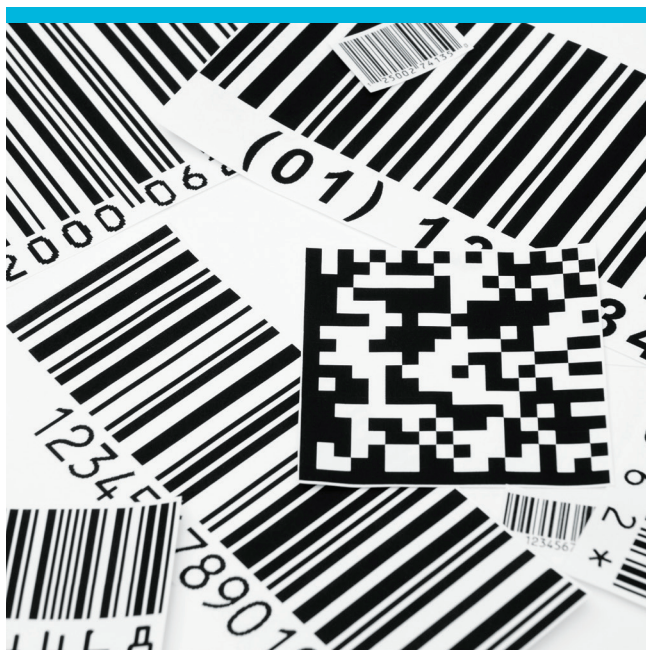
Structure of a Data Matrix

A Data Matrix may be printed as a square or rectangular symbol made up of individual modules (dots or squares). This representation is an ordered grid of dark and light modules which include a finder pattern and is bordered by a clear area or "quiet zone". The data is encoded using a series of dark or light modules based upon a pre-determined module size, grid size and mathematical formula.

A Data Matrix is readable omni-directionally (in a 360-degree orientation).

Where is it used and placed?

Because of its small size and high information capacity, the Data Matrix barcode 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 Data Matrix 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 Data Matrix (for example, will the symbol be read in an automated environment or by hand).

How to read it?

To read a Data Matrix symbol, camera-based barcode scanners are required. Laser or linear barcode scanners cannot read Data Matrix barcodes but camera-based barcode scanners can read both 1D / linear and 2D / matrix barcodes.

Advantages of a Data Matrix over a a traditional 1D / linear barcode

A Data Matrix can contain much more information than a traditional 1D / linear barcode symbol such as a product code with lot number, expiry date and even a unique serial number, which allows better traceability. Indeed, 2D / matrix barcode 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 to track them throughout their entire lifetime. That can be extremely important if recalls arise.

A Data Matrix 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, Data Matrix barcode symbols can recover from various types of physical damage. A Data Matrix symbol can be scanned even if damaged, torn or printed poorly provided the amount of damage does not exceed the available error correction.

GS1 DataMatrix

The GS1 system, globally endorsed by the healthcare community, is the most widely used identification system worldwide with more than 6 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, serial number, etc.), it is uniquely suited to meet the needs of the healthcare industry.

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., have the potential to impact patient safety.

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

Pharmaceutical and medical device identification & marking can have very specific needs as mentioned above. Some of these needs are being met, and will continue to be met, through the use of traditional 1D / linear barcode 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 (barcode symbology) solution.

The GS1 DataMatrix cannot only contain the GTIN, batch/lot number, expiry date and unique serial number, but also offers the possibility to hold a URL link pointing to a website that could contain information such as the following:

- 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.

Structure of a GS1 DataMatrix

A GS1 DataMatrix can easily 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 - up to 20 alpha-numeric characters

(01)09504000059101
(21)19067811811
(10)563GS1
(17)200331

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

GTIN: (01)09504000059101

Expiry: (21)19067811811

Batch / lot: (10) 563GS1

S/N: (17) 200331

A GS1 DataMatrix can be read by camera-based scanners. GS1 Healthcare has published a specific position paper in this regard. For more information, please read: www.gs1.org/docs/healthcare/GS1_HUG_ps_Camera_Based_Scanners.pdf

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 70 leading Healthcare organisations worldwide.

For more information about GS1 Healthcare, please visit: **www.gs1.org/healthcare**