

## Guide to Encode the Unique Identifier on Medicinal Products

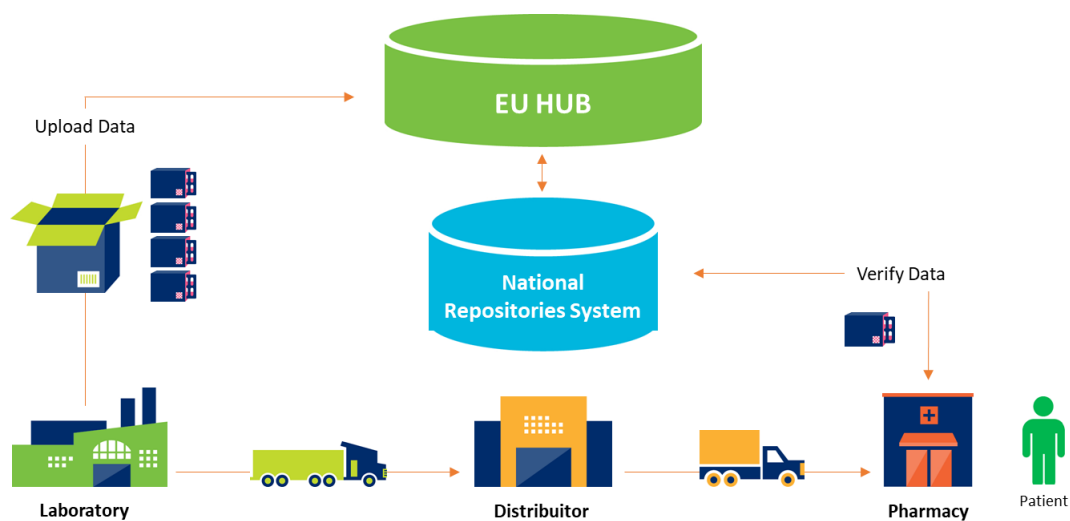


# Introduction

The Directive 2011/62/EU “Falsified Medicines Directive” aims to establish the safety features necessary to prevent the entry into the legal supply chain of falsified medicinal products within the European Union.

The safety features determined by the European Union consist of three different measures:

- An **anti-tampering device** that allows the verification if the packaging of a medicinal product has been tampered with;
- Development of a **central information and data router** (‘hub’) and a **national repositories system** that allow the traceability of medicinal products for human use within the European Union;
- A **unique identifier** placed on the packaging of a medicinal product enabling the verification of its authenticity and its identification throughout the entire supply chain.



# 1. The role of GS1 Standards in the implementation of the Falsified Medicines Directive

Any Standard GS1 is based on the following principle:

Each product has a unique, unambiguous and global identification

The GS1 Standards are present in two distinct aspects:

- A product code that unequivocally recognizes a medicinal product designated as GTIN (*Global Trade Item Number*)
- The symbol and structure of the data used to create the Unique Identifier: GS1 DataMatrix

## Steps to Implement GS1 Standards in the Falsified Medicines Directive:

### Step 1: Identification of Medicinal Products

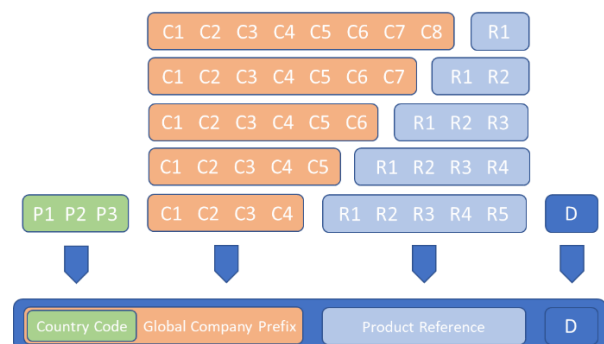
The first field of the Unique Identifier is the product code. Each code is assigned to a specific medicinal product identifying at least its active ingredient, common name, pharmaceutical form, dosage, size of secondary package and type of packaging withholding the unique identifier.

According to GS1 Standards, this product code is represented by a Global Trade Item Number or GTIN. The GTIN uniquely, unequivocally and globally identifies medicines along the supply chain. Any change to the product requires the assignment of a new GTIN code.

GTIN codes are unique, unambiguous, and global numbers that identify each product presentation and its respective associations at higher hierarchical levels.

### GTIN-13

Any base unit shall be identified by a GTIN-13 code, which has the following structure:



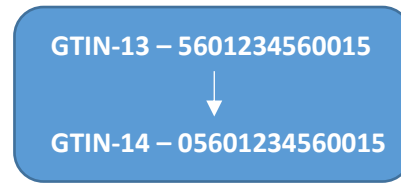
P = Country; C = Company; R = Product Reference

A GTIN-13 code is made up of 13 digits grouped in 4 fields:

1. Country Code – code that identifies the country in which the company has joined the GS1 System.

2. Global Company Prefix – Between 3 and 7 digits that uniquely identify the company that owns the brand.
3. Product Reference – Between 1 and 5 digits to identify the product reference.
4. Check Digit – Number that is calculated automatically using a mathematical algorithm based on the previous 12 digits.

The AI (01) is formatted for 14 numeric characters. In this case, the GTIN-13 takes the GTIN-14 format when a zero (0) is added to the left.



## Step 2: Designing the Unique Identifier

According to the Directive the unique identifier must be a GS1 DataMatrix symbol which shall contain the following information:

2011/62/EU Directive	GS1
Product Code	AI (01) GTIN
Serial number	AI (21) Serial Number
Batch number	AI (10) Batch Number
Expiration date	AI (17) YYMMDD
National Registration Number	AI (714) NHRN* – Portugal AIM

\*National Healthcare Reimbursement Number

### Application Identifiers

The Application Identifiers (AI) are numerical prefixes created to give unambiguous meaning to the encoded information sets. Each prefix is formed by 2, 3 or 4 characters in between parentheses and identifies the meaning and format of the data that is encoded immediately after the AI.

- **Application Identifier (01):**

It is used to identify units. This AI refers to the GTIN code assigned to the unit pack.

- **Application Identifier (10):**

This AI is used to identify lot numbers. A lot number can be built using up to 20 alphanumeric characters.

- **Application Identifier (17):**

AI (17) represents an expiry date that follows the numerical format “YYMMDD” (year, month and day) with a 6-digit fixed length.

- **Application Identifier (21):**

This identifier determines the package serial number that translates into a numeric or alphanumeric sequence with a maximum of 20 characters, generated by a deterministic or non-deterministic randomization algorithm.

- **Application Identifier (714):**

According to the requirements of the Portuguese Authorities, the medicinal products intended for the Portuguese market must include the national healthcare reimbursement number assigned by INFARMED, I.P. in the unique identifier. To comply with this requirement, GS1 Global Office assigned to Portugal the Application Identifier (714) to encode the 7-digit NHRN.

Therefore, to market medicinal products in Portugal, the DataMatrix code must include the product code in the AI (01) and the marketing authorization number (NHRN) in the AI (714).

The Application Identifier (714) is exclusively used for products intended to circulate in the Portuguese market.



(01) 05601234560015  
(21) 765E321  
(10) LV2001  
(17) 190213  
(714) 1234567



### **Step 3: The GS1 DataMatrix Symbology**

The GS1 DataMatrix is a GS1 two-dimensional symbology standard that can be printed using various printing techniques and on different types of surfaces: from label printing by thermal transfer to laser or inkjet card or even direct engraving on metal surfaces.

Most barcode design software allow the selection of:

- DataMatrix Symbology: free-to-use symbology and no predefined data structure. This symbology is usually used for internal systems.
- GS1 DataMatrix Symbology (version ECC 200): symbology based on a GS1 Standard structure and characterized by the presence of the FNC1, which signals the Barcode scanner and its software that it is a standard symbol. Its use can be applied both on internal systems and with any agent along a supply chain. This is the symbology indicated by the Directive to code the Unique Identifier.

### The design of the GS1 DataMatrix code

When designing a GS1 DataMatrix code it is necessary to consider three factors: size, contrast and location.

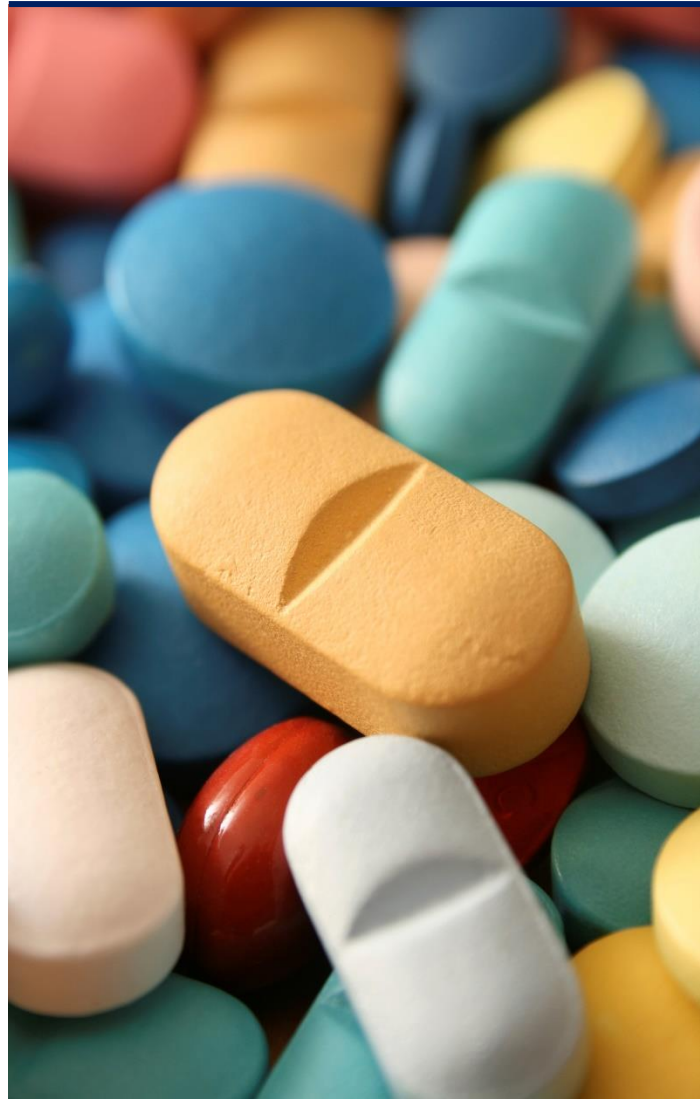
- The overall **size** of the GS1 DataMatrix is determined by the magnitude of a module and the character storage capacity.

The magnitude of a module (X-Dimension of the module) is the value in [mm] or [ $\mu$ m] of the width or height of the module. It is between 0.255 mm (minimum) and 0.615 mm (maximum).

It is advised to choose an X-Dimension value depending on the resolution of the printing equipment.

The following table shows the different character storage capacities to be encoded according to the number of modules that make up the GS1 DataMatrix.

It is recommended to use the optimal number of modules depending on the number of characters to encode.



Number of Modules		Data Capability	
Rows x Columns		Numerical	Alphanumeric
10 x 10		6	3
12 x 12		10	6
14 x 14		16	10
16 x 16		24	16
18 x 18		36	25
20 x 20		44	31
22 x 22		60	43
24 x 24		72	52
26 x 26		88	64



- The **contrast** between the background colour and the colour of the modules must be sufficient for the reader to detect the difference between the modules and the spaces. One of the features of the GS1 DataMatrix symbology is the ability to be printed in "negative", i.e. instead of the normal print of a light-coloured background with dark modules it can be printed with a dark coloured background and light modules.

Negative Printing:  
Dark background with light modules



Normal Print:  
Light background with dark modules



It is recommended to avoid glossy surfaces and inks so as not to interfere with the scanner's ability to decode. Care should also be taken with transparent printing surfaces since the scanner always needs a good contrast between the modules and the background to be able to read the code.

- The **location** of the symbol considers its physical positioning on the packaging and the elements of packaging that can cover it or make it difficult to read. This location refers to the symbol itself and to the human readable information accompanying it. The human readable information must follow the recommendations of positioning according to the current legislation.

### Printing the GS1 DataMatrix code

Maintenance of the printing equipment is as important as the correct setting of the printing parameters. The following recommendations should be considered:

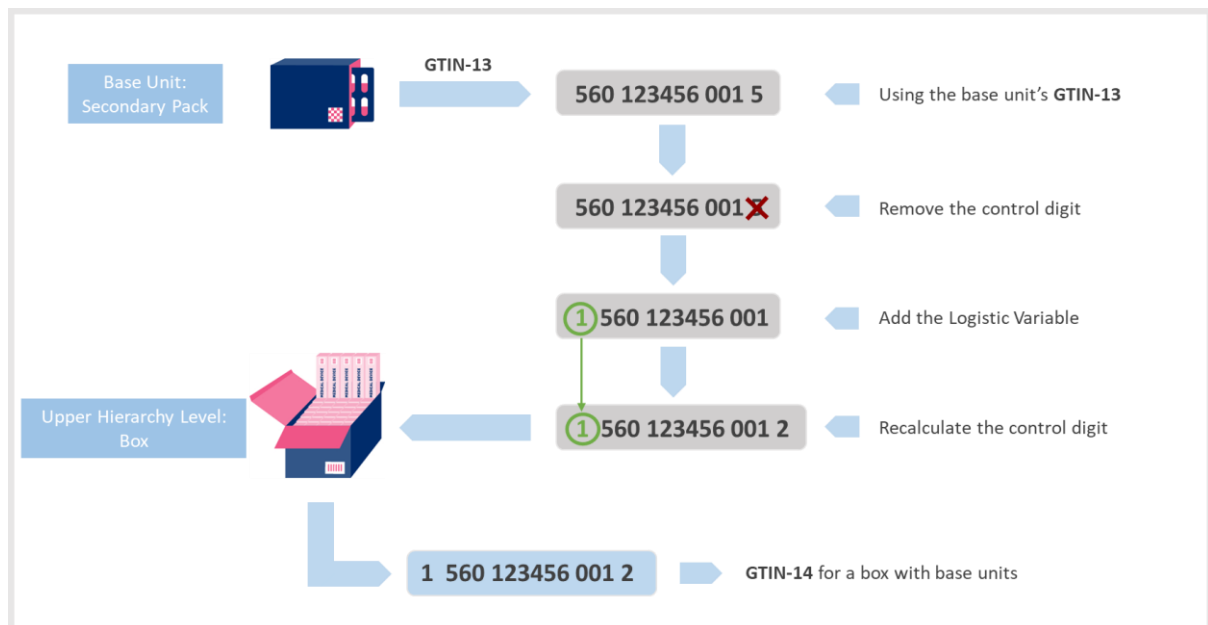
- Avoid printhead failure
- Avoid dirt or incompatibilities between consumables
- Pay attention to print detours from the pre-set print position.
- Avoid print deformation.  
Note that the GS1 DataMatrix code is a square, non-rectangular or trapezoid symbology. When the GS1 DataMatrix code presents itself as a rectangle it results from the joining of two simple GS1 DataMatrix square codes side-by-side.
- Avoid sharpening or thickening of the modules when printing considering the determined X-dimension.

## 2. Box Encoding: a hierarchical level higher than the unit

By "upper hierarchical level" we mean any set of several identical base units whose purpose is to facilitate its handling and transport along the supply chain.

As a good practice GS1 Portugal advises the identification of the upper hierarchical levels using GTIN-14 codes that derive from the GTIN-13 code of the base unit. The GTIN-14 is obtained by adding a logistic variable to the GTIN-13 of the base unit.

The **logistic variable** is a digit that is placed to the left of the base unit's GTIN-13 code to identify specific sets of base units. In the Health Sector, this digit may vary between 1 and 8.



In this example, the logistic variable 1 may represent a box containing 20 base units.

The GTIN-14 is encoded onto boxes using ITF-14 or GS1-128 symbology.

**GTIN-14 encoded on an ITF-14**



15601234560012

**GTIN-14 encoded on a GS1-128**



(01) 1 5601234 56001 2

For more information on ITF-14 and GS1-128 symbology, see GS1 Portugal's document "GS1 Logistics Label - National Market Standards and Specifications".



#### **ABOUT GS1 PORTUGAL**

Founded in 1985 by the Retail Industry, GS1 Portugal is one of 112-member organizations of GS1 and the entity authorized to manage the GS1 Standards System in Portugal – develops, adopts and implements standards that revolutionize the way we do business. More than 8.000 companies from different sectors of activity have joined GS1 Portugal and believe in the GS1 System to transform the way we work and live.

More information on [www.gs1pt.org](http://www.gs1pt.org)

#### **GS1 Portugal**

Estrada do Paço do Lumiar, Campus do Lumiar, Edifício K3

1649-038 Lisboa

Portugal

**T** +351 21 752 07 40

**E** [info@gs1pt.org](mailto:info@gs1pt.org)

[www.gs1pt.org](http://www.gs1pt.org)