

# **PROCEDURE for 2D DataMatrix String Validation**

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# History Changes

Date	Version	Description	Author
2022-04-08	1.0	Initial version	Mariana Dilova
2025-03-04	1.0	Revised, no changes needed	Pavlina Gyamcheva

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## 1. Purpose

The purpose of this procedure aims to define rules for verification of 2D DataMatrix code. This document intends to facilitate this process by offering predefined steps of verification execution and predefined requirements for 2D DataMatrix code for the European, Russian and Brazilian markets.

The current procedure aims to further assist the pharmaceutical manufacturers to define internal rules and SOPs for 2D DataMatrix verification that have to be applied for each created template containing 2D barcode.

This document is not meant to be all inclusive and is not a replacement for GS1 standard including 2D DataMatrix verification. The GS1 General Specifications should always be referred to for all details on GS1 System rules and recommendations.

## 2. Scope

The scope of this procedure is to cover the processes of 2D DataMatrix content verification into the following cases:

- Serialization machine - initial validation (for templates containing 2D DataMatrix code)
- Newly created templates (after validation) containing 2D DataMatrix code

## 3. Abbreviations

Abbreviation	Description
SaTT	Serialization and Track &Trace
AI	GS1 Application Identifier
GTIN	Global Trade Identification Number
PC	Product Code
NHRN – ANVISA Medicine Registry Number	National Health Reimbursement Number
BN	Batch Number/LOT
2D	Two-dimensional DataMatrix Barcode
SN	Serial Number
GS1	GS1 or Global Standards One is a not-for-profit organization that develops and maintains global standards for business communication. The best known of these standards is the barcode, a symbol printed on products that can be scanned electronically.
DataMatrix	DataMatrix is a two-dimensional code consisting of black and white "cells" or dots arranged in either a square or rectangular pattern, also known as a matrix. The information to be encoded can be text or numeric data
UI	Unique Identifier

## 4. Verification Acceptance Criteria

The GS1 DataMatrix barcode should encode at least the data mentioned below that makes up the UI (Unique Identifier). According to the specific market, the 2D DataMatrix has different requirements for coding and verification. The 2D DataMatrix code is determined on the basis of a string (sequence of elements) for the concrete destination.

- For European market regulation, the barcode should present:

**(01)1235467890123(17)171031(10)9N8767(21)1234567890**

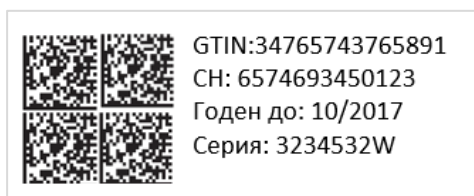
- (01) – GTIN
- (17) – Expiration date
- (10) – Lot/Batch number
- (21) – Serial number



- For Crypto markets regulation, the barcode should present:

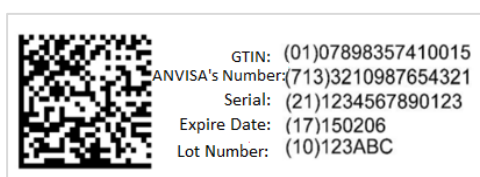
**(01)34765743765891(21)6574693450123(91)0bad(92)  
5Nv2wDyxpEPMiaNhsluui8CP5KTQXMOhWat3LQjzEnDU**

- (01) – GTIN
- (21) – Serial number
- (91) – Crypto code
- (92) – Crypto signature



- For Brazilian market regulation, the barcode should present:

- (01) – GTIN
- (713) – NHRN
- (21) – Serial number
- (17) – Expiration date
- (10) – Lot/Batch number



**Notes:** It is possible to add additional elements to the barcode string in case of specific customer requirements.

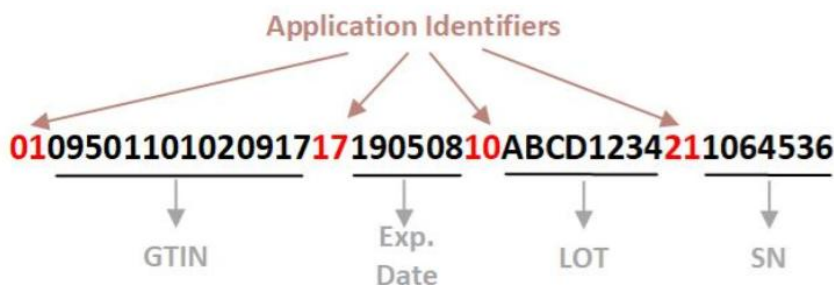
For example: Manufacture/Production date - AI (11).

## 5. Verification Steps

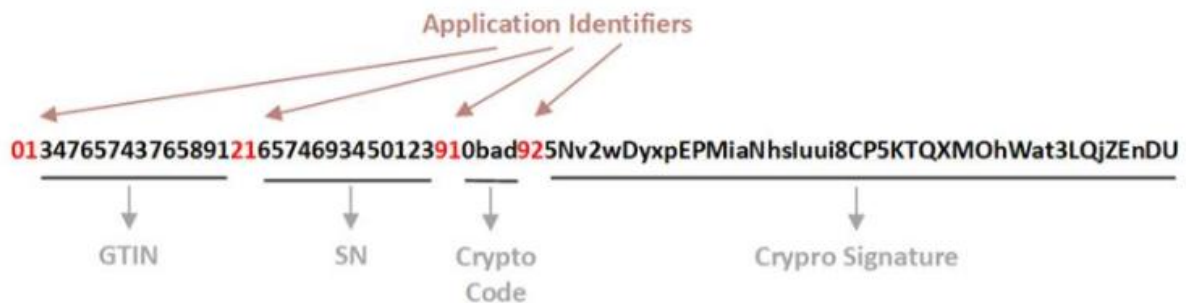
- Open SoftGroup® SaTT Line Controller application
- Select a batch with serialization and start production process
- Take the first accepted carton, produced in “Production mode”
- Open SoftGroup® SaTT Reworking Station application
- Scan the 2D DataMatrix code printed on the selected carton
- Verify that the serial number is presented on the working screen and the barcode string is visualized in “Barcode string” column
- Check the results of the scanned 2D DataMatrix code:
  - ✓ The visualised string elements correspond to the elements set in the batch
  - ✓ The 2D coding component types (GTIN, LOT, etc.) are correctly presented according to GS1
  - ✓ The AI separators are correctly coded
  - ✓ The information (value) after each AI separator is correctly coded

For example:

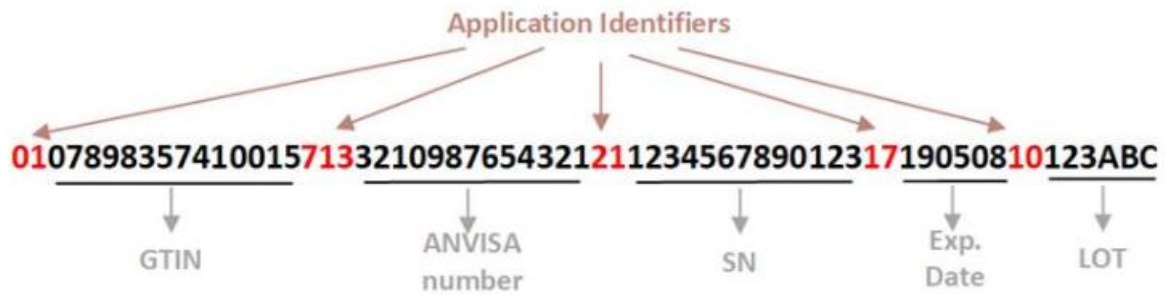
1. The main information in the string for European market should contain the following information:



2. The main information in the string for Russian market should contain the following information:



3. The main information in the string for Brazilian market should contain the following information:



## 6. Recommendations

In order to improve 2D DataMatrix barcode string verification process SoftGroup recommends:

1. The 2D DataMatrix barcode string verification process should be executed **for the first accepted carton**, produced during the “Production” mode and **it has to be repeated in the middle and in the end of the produced batch**. This should be done by authorized user on the line (e.g. Super User)
2. The taken samples from each batch should be stored (by QA/QC/QP – responsible people) as an evidence to prove that the printed 2D DataMatrix code corresponds to the respective regulations and requirements.