RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES FOR IDENTIFICATION AND LABELLING OF PHARMACEUTICAL PRODUCTS

AUGUST, 2022

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FOREWORD

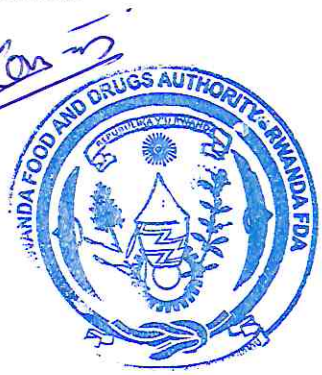
Rwanda Food and Drugs Authority (Rwanda FDA) is a regulatory body established by the Law N° 003/2018 of 09/02/2018 with the mandate to ensure the quality, safety and efficacy of the pharmaceutical products to support the implementation of various public health programs, improve the health status of the population and the socio-economic development of the Country.

Reference to the Regulations No. DFAR/HMDAR/TRG/003 Governing the Implementation of Identification, Data Capture, and Data Sharing for Traceability of Pharmaceutical Products and the Rwanda National Vision & Strategy for Pharmaceutical Traceability Leveraging GS1 Global Standards;

Rwanda FDA has developed this document to guide Market Authorisation Holders and other stakeholders in the supply chain on the use of global standards in identification, sharing and capturing of data labelled on pharmaceutical products.

The Authority acknowledges all the efforts of key stakeholders who participated in the development and validation of these guidelines.

Dr. Emile BIENVENU
Director General



GUIDELINES DEVELOPMENT HISTORY

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05/07/2022	Rev_0	First version

TABLE OF CONTENTS

ACRONYMS AND ABBREVIATIONS

FDA	Food and Drug Authority
GDD	Global Data Dictionary
GDSN	GS1 Global Data Synchronization Network
GLN	Global Location Number
GPC	Global Product Classification
GTIN	Global Trade Item Number
MAH	marketing authorization holder
MOH	Ministry of Health
NPC	National Product Catalogue
SF	substandard and falsified

DEFINITIONS

1. **Aggregation:** The hierarchy relationship between the unique identifiers for parent and child packaging hierarchies, where each packaging level will carry a unique identifier encoded in a data carrier. uniquely identified allowing the receiver of the product to scan one code and understand exactly what is in the whole shipment—every case, bundle, or individual carton.

2. **Automatic Identification and Data Capture (AIDC)**: a technology used to automatically capture data. aidc technologies include barcodes, smart cards, biometrics, and radio frequency identification devices.

3. **Barcode:** a symbol that encodes data into a machine-readable pattern of adjacent, varying width, parallel, rectangular dark bars and pale spaces.

4. **Batch/lot:** the batch or lot number associates an item with production information that the manufacturer considers relevant for traceability of the trade item. the data may refer to the trade item itself or to items contained in it.

5. **Data carrier**: any type of physical media (e.g. barcode, QR code, data matrix, or RFID) that encodes machine readable data.

6. **Data matrix**: a standalone, two-dimensional (2d) matrix symbology that is made up of square modules arranged within a perimeter finder pattern. data matrix symbols are read by two-dimensional imaging scanners or vision systems.

7. **Expiration date**: the date up until which the drug manufacturer can guarantee that the medicine is fully potent and safe to take based on scientifically-sound product testing.

8. **Function 1 symbol character (fnc1)**: When used as the first character, a function 1 symbol character (fnc1) indicates that the barcode follows the gs1 standard allowing the scanner to properly decode it. It is also used as a separator in between specific application

9. **Identifiers** that do not have a fixed character count (e.g., AI (10) Batch/Lot, AI (21) Serial Number

10. **Global trade item number (GTIN)**: The gs1 identification key used to identify trade items. The key comprises a gs1 company prefix, an item reference and check digit.

11. **Gs1**: A neutral, not-for-profit, global organization that develops and maintains the most widely used supply chain data standards in the world.

12. **Gs1 application identifier**: The field of two or more digits at the beginning of an element string that uniquely defines its format and meaning.

13. **Gs1 member organization**: A member of gs1 that is responsible for administering the gs1 system in its country (or assigned area). This task includes, but is not restricted to, ensuring user companies make correct use of the gs1 system; have access to education, training,

promotion, and implementation support; and have opportunity to play an active role in the global standards management process.

14. **Gs1-128 linear barcode:** A barcode symbology using bars and spaces in one dimension that leverages a subset of code 128 which uses the function that allows the encoding of element strings.

15. **Primary packaging**: The first level of packaging for the product marked with an aidc data carrier either on the packaging or on a label affixed to the packaging. For non-sterile packaging, the first level of packaging can be in direct contact with the product. For sterile packaging, the first level of packaging can be any combination of the sterile packaging system and may consist of a single item or group of items for a single therapy such as a kit. For packaging configurations that include a retail consumer trade item, primary packaging is a packaging level below the retail consumer trade item.

16. **Secondary packaging**: A level of packaging marked with an aidc carrier that may contain one or more primary packages or a group of primary packages containing a single item.

17. **Human readable interpretation (hri)**: Characters, such as letters and numbers, which can be read by persons and are encoded in gs1 aidc data carriers confined to a gs1 standard structure and format. The human readable interpretation is a one-to-one illustration of the data encoded in a data carrier. However, start, stop, shift and function characters, as well as the symbol check character, are not shown in the human readable interpretation.

18. **Logistic unit:** An item of any composition established for transport and/or storage of pharmaceuticals that needs to be managed through the supply chain. It is identified with an sscc.

19. **Package:** Any article that may be used for filling, inserting or wrapping or packing regulated products and includes the immediate container and other wrapping materials;

20. **Pharmaceutical:** Any substance or mixture of substance:

    a) Used in the diagnosis, treatment, mitigation or prevention of human disease, disorder, abnormal physical or mental state, or the symptoms thereof;

    b) Used in restoring, correcting or beneficial modification of organic or mental functions in humans;

    c) Which are articles other than food, intended to affect the structure or any function of the body of humans; and

    d) Which includes articles intended for use as a component of any articles specified in clause (a), (b) or (c).

21. **Serial number**: A numeric or alphanumeric sequence of maximum 20 characters, generated by a deterministic or a non-deterministic randomization algorithm.

22. **SSCC**: The gs1 identification key used to identify logistics units. The key comprises an extension digit, gs1 company prefix, serial reference, and check digit.

23. **Tertiary homogenous pack**: A tertiary pack that consists entirely of the same trade item with the same batch number and expiration date.

24. **Tertiary mixed pack**: A tertiary pack that contains either more than one unique trade item or entirely the same trade item with different batch numbers or expiration dates.

25. **Tertiary packaging**: The highest level of packaging that may include a pallet that contains (one or usually) several cases or a case that contains (one or usually) several items in its primary or secondary packaging. Tertiary packaging may refer to either a logistic unit or a trade item.

26. **Tertiary partial pack**: A homogenous pack of products that is not to be considered a trade item because it is less than full.

27. **Trade item**: Any item (product or service) upon which there is a need to retrieve predefined information and that may be priced, ordered, or invoiced at any point in any supply chain.

28. **Unique identifier**: A numeric or alphanumeric string captured in a machine-readable data carrier and human-readable form on the label of the pharmaceutical package that is associated with a single product or product group. In this instance, unique identifier refers to the combination of GTIN with expiration date, batch/lot and serial number.

1. INTRODUCTION

The Ministry of Health (MOH) is undertaking a number of supply chain and health information system investments and governance interventions to improve efficiency in sharing data across the supply chain and in the health sector, strengthen data quality, extend data visibility, and reduce costs of data capture and transformation. In a time where the country seeks to achieve greater health benefits and reduced operational costs, implementation of global standards serves as an enabler in achieving these goals through ensuring consistency in how health commodities are identified, how data can be captured about these commodities as they move through the supply chain, and how this data can be shared across disparate systems in a consistent and streamlined manner across industries, countries, and trading partners. These interventions together create an enabling environment for pharmaceutical traceability, which aims to:

a) Decrease the presence of substandard and falsified (SF) medications

b) Ensure the quality and desired efficacy of pharmaceutical products

c) Promote trust in the pharmaceutical sector and healthcare system

d) Provide visibility of product status across the supply chain

e) Create supply chain efficiencies from manufacturers to the end consumer

f) Increase patient safety

As mandated by Rwanda FDA in Regulations CBD/TRG/030, these guidelines apply to the use of global standards in identification, sharing and capturing of data labelled on pharmaceutical products. This document is intended to provide trading partners with further information on how to implement this mandate as required to distribute pharmaceutical products in the Rwandan market. This document is not intended to address in any further detail requirements around sharing of associated master, transaction, and event / traceability data. More direction will be provided on these topics in additional guidance in the future.

2. PRODUCT IDENTIFICATION AND LABELLING REQUIREMENTS FOR PHARMACEUTICALS

This section describes how to implement the product identification and labelling requirements as mandated in the referenced FDA Regulations CBD/TRG/030 Readers should consult the *GS1 General Specifications*[1] and the *GS1 AIDC Healthcare Implementation Guideline*[2], or their GS1 Member Organization for additional information.

2.1 Secondary Pack Trade Item

All secondary trade item packaging must include a GS1 DataMatrix encoded with the following information and printed adjacent to the data carrier in Human Readable Interpretation (HRI):

AI	Description	Recommended timeframe
01	GTIN	No later than 3.0 year after the entry into force of the guideline
17	Expiration Date	No later than 3.0 year after the entry into force of the guideline
10	Batch/Lot	No later than 3.0 year after the entry into force of the guideline
21	Serial Number	No later than 4.0 years after the entry into force of the guideline

An example of this in practice:

(01) 10857674002017
(17) 251231
(10) NYFUL01
(21) 192A837H7

Encoded in the data carrier, this example will take on the following format:

FNC Opening Character	AI	GTIN	AI	Expiration Date	AI	Batch/Lot Number	FNC Separator	AI	Serial Number
FNC1	01	10857674002017	17	251231	10	NYFUL01	<GS>	21	21192A837H7

Read via AIDC technology, this example will take on the following format:

]d2011085767400201717251231 10NYFUL01<GS>21192A837H7

The probability that the serial number can be guessed shall be negligible and, in any case, lower than one in ten thousand. The character sequence resulting from the combination of the product identifier and the serial number shall be unique to a given pack of a medicinal product.

Rwanda FDA does not mandate the order in which data is encoded into the data carrier. However, for the most efficient encoding, it is recommended to have fixed-length data elements precede variable-length elements.

[1] For more information, see https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications
[2] For more information, see https://www.gs1.org/docs/healthcare/GS1_Healthcare_Implementation_Guideline.pdf

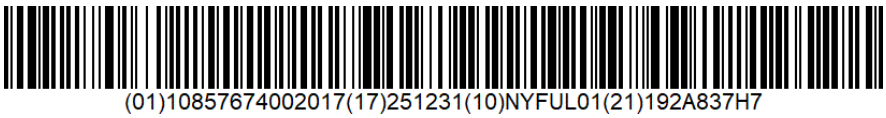
2.2 Tertiary Pack Trade Item

All tertiary pack trade item packages must include a GS1-128 barcode or a GS1 Data Matrix encoded with the following information and printed adjacent to the data carrier in HRI:

AI	Description	Recommended timeframe
01	GTIN	No later than 3.0 years after the entry into force of the guidelines
10	Batch/Lot	No later than 3.0 years after the entry into force of the guidelines
17	Expiration Date	No later than 3.0 years after the entry into force of the guidelines
21	Serial Number	No later than 4.0 years after the entry into force of the guidelines

An example of this in practice:

(01) 10857674002017
(17) 251231
(10) NYFUL01
(21) 192A837H7



Encoded in the data carrier, these examples will take on the following format:

FNC Opening Character	AI	GTIN	AI	Expiration Date	AI	Batch/Lot Number	FNC Separator	AI	Serial Number
FNC1	01	10857674002017	17	251231	10	NYFUL01	<GS>	21	21192A837H7

Read via AIDC technology, this example will take on the following format:

]d2011085767400201717251231 10NYFUL01<GS>21192A837H7

The probability that the serial number can be guessed shall be negligible and, in any case, lower than one in ten thousand. The character sequence resulting from the combination of the product identifier and the serial number shall be unique to a given pack of a medicinal product.

Rwanda FDA does not mandate the order in which data is encoded into the data carrier. However, for the most efficient encoding, it is recommended to have fixed-length data elements precede variable-length elements. In this instance where a tertiary pack trade item is also considered a logistic unit, the SSCC can be applied in lieu of the serialized GTIN.

2.3 Tertiary Pack Logistic Unit

All tertiary pack logistic units must include a GS1-128 barcode[3] encoded with the following information and printed adjacent to the data carrier in HRI:

AI	Description	Required by
00	Serial Shipping Container Code (SSCC)	No later than 5.0 years after the entry into force of the guideline

An example of this in practice:

Encoded in the data carrier, this example will take on the following format:

FNC Opening Character	AI	SSCC
FNC1	00	006141411234567890

Read via AIDC technology, this example will take on the following format:
]c100006141411234567890

3. DESCRIPTION OF PACKAGING LEVELS

This section includes descriptions of each level of the packaging hierarchy. Readers should consult the *GS1 General Specifications*[4] and the *GS1 AIDC Healthcare Implementation Guideline*[5], or their GS1 Member Organization for additional information.

3.1 Tertiary Packaging

Tertiary packaging refers to upper levels of the packaging hierarchy. A tertiary pack may be:

i. A pallet that contains (one or usually) several cases[6]
ii. A case that contains (one or usually) several items in the items' primary or secondary packaging

Tertiary packaging may be used as either a logistic unit or as a trade item. Tertiary packages can be homogenous (i.e., consisting entirely of the same trade item, batch/lot, and expiry), partial (i.e., consisting of a homogenous pack of items that is not to be considered a trade item because it is less

[3] Per the GS1 General Specifications (Release 19.1), trading partners have the option to include a GS1DataMatrix in addition to the GS1-128 barcode on the logistic unit.
[4] For more information, see https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications
[5] For more information, see https://www.gs1.org/docs/healthcare/GS1_Healthcare_Implementation_Guideline.pdf
[6] For more information, see GS1 AIDC Healthcare Implementation Guideline, Section 3.5.4, Case / Shipper and Pallet.

than full), or mixed (i.e., either more than one unique trade item or entirely the same trade item with different batch numbers or expiration dates).

It is recommended that labels containing the barcode symbols, with associated HRI, be positioned on two faces of the tertiary packaging to enable ready access for scanning when the item is stored, stocked on shelves, or handled.

3.1.1 Logistic Unit

A logistic unit is an item of any composition established for transport and/or storage that needs to be managed through the supply chain. In many instances, the tertiary package logistic unit is a pallet but may also be an export carton.

The logistic unit is identified using the serial shipping container code (SSCC). This packaging level is marked with a GS1-128 barcode, either on the packaging itself or on a label affixed to the packaging.

A GS1 Data Matrix or GS1 QR Code symbol MAY be included in addition to the GS1-128 symbol. When used, the GS1 2D symbol SHALL include all element strings included in the GS1-128 symbol(s), and MAY include additional element strings. If a logistic unit does not have at least one surface area greater than an A6 or 4” x 6” logistic label, a GS1 Data Matrix or GS1 QR Code MAY be used by itself on a logistic label, though a GS1-128 containing a SSCC is still recommended. If a logistic label is used with only a GS1 Data Matrix or GS1 QR Code, care must be taken to ensure trading partners are able to scan this barcode.

3.1.2 Trade Item

Trade items are products and services for which there is a need to retrieve predefined information and that may be priced, ordered, or invoiced at any point in the supply chain. The tertiary package trade item will typically be a case or carton but may also be a shrink-wrapped tray or other configuration.

A homogenous pack trade item is identified with a GTIN, batch/lot number, expiration date, and serial number. This packaging level can be marked with a GS1-128 barcode or a GS1 Data Matrix either on the packaging itself or on a label affixed to the packaging.

Examples of tertiary packaging include, but are not limited to:

3.2 Secondary Packaging

Secondary packaging is a level of packaging that may contain one or more primary packages, or a group of primary packages containing a single item.[7] The secondary pack is always a trade item. This

packaging level is marked with a GS1 DataMatrix, either on the packaging itself or on a label affixed to the packaging.

Examples of secondary packaging include, but are not limited to:

In-scope commodities can have more than one level of secondary packaging, such as an inner pack (bundles) and intermediate packs (inner case). **Identification and marking of inner and intermediate secondary packaging levels are considered to be required.** Examples of inner or intermediary secondary packaging include, but are not limited to:

3.3 Primary Packaging

Primary packaging is the first level of packaging that is in direct contact with the item.[8] This packaging level is marked with a GS1 Data Matrix, either on the packaging itself or on a label affixed to the packaging.

Identification and labeling of trade items at this level is optional unless the supplier is providing items in "carton less packaging", i.e., without a secondary packaging level. Marking trade items at this level is also recommended where the secondary package will likely be opened or removed before being dispensed to one or several patients (e.g., a display carton is opened, and individual or split blister packs are distributed to patients).

Examples of primary packaging include, but are not limited to:

[7] For more information, see GS1 AIDC Healthcare Implementation Guideline, Section 3.5.3, Secondary Package.
[8] For more information, see GS1 AIDC Healthcare Implementation Guideline, Section 3.5.2, Primary Package.

4. OVERVIEW OF RELEVANT GLOBAL STANDARDS

A summary of the GS1 standards relevant to these regulations are described in this section. This document is based on the use of the *GS1 General Specifications*[9] as the primary reference document for technical specifications to implement in accordance with GS1 global standards. A point to note the GS1 General Specifications are published annually, the latest version of the *GS1 General Specifications* should always be considered.

4.1 Identify

The GS1 Application Identifiers (AI) referenced in this section are used for identifying items and locations.

4.1.1 AI (00) Serial Shipping Container Code

The GS1 (AI) (00) indicates that the data field contains an SSCC. The SSCC is used to uniquely identify a logistic unit. The SSCC must remain unique and not be reallocated for a minimum of one year from the shipment date of the logistic unit from the SSCC assignor to the trading partner, in accordance with *GS1 General Specifications*.

The SSCC format is as follows:

GS1 Application Identifier	Serial Shipping Container Code (SSCC)		
	Extension digit	GS1 Company Prefix → ← Serial Reference	Extension digit
0 0	N_1	N_2 N_3 N_4 N_5 N_6 N_7 N_8 N_9 N_{10} N_{11} N_{12} N_{13} N_{14} N_{15} N_{16} N_{17}	N_{18}

For more information on how to generate an SSCC and apply it to a logistics label, please refer to the *GS1 General Specifications* and the following resources:

- http://www.gs1.org/barcodes/technical/idkeys/sscc
- https://www.gs1.org/docs/tl/GS1_Logistic_Label_Guideline.pdf

[9] For more information, https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications

4.1.2 AI (01) Global Trade Item Number (GTIN)[10]

The GS1 AI (01) indicates that the data field contains a GTIN. The GTIN is the globally unique GS1 identification number used to identify trade items (i.e., items that may be priced, ordered, or invoiced). GTINs are assigned by the brand owner of the item and are used to identify items as they move through the global supply chain to the hospital or ultimate end user. Reuse of a GTIN is not permitted.

The GTIN can be 8, 12, 13, or 14 digits in length. The format of the GTIN-14 is as follows:

GS1 Application Identifier	Global Trade Item Number (GTIN)													
	GS1-8 Prefix or GS1 Company Prefix →							← Item Reference						Check digit
0 1	N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8	N_9	N_{10}	N_{11}	N_{12}	N_{13}	N_{14}

For more information on how to generate and maintain a GTIN, please refer to the *GS1 General Specifications* and the following resources:

- http://www.gs1.org/gtin
- https://www.gs1.org/1/gtinrules/en/healthcare

4.1.3 AI (10) Batch/lot[11]

The GS1 AI (10) indicates that the data field contains a batch or lot number. The batch/lot number field is alphanumeric.

The format of the batch/lot number is as follows:

GS1 Application Identifier	Batch or Lot Number
1 0	X_1 → variable length → X_{20}

4.1.4 AI (17) Expiration date[12]

The GS1 AI (17) indicates that the data field contains an expiration date. The structure of the expiration date should be as follows:

Year: the tens and units of the year (e.g., 2003 = 03), which is mandatory
Month: the number of the month (e.g., January = 01), which is mandatory

[10] For more information, see GS1 General Specifications, Section 3.3.2, Identification of a trade item (GTIN): AI (01).
[11] For more information, see GS1 General Specifications, Section 3.4.1, Batch or Lot Number: AI (10).
[12] For more information, see GS1 General Specifications, Section 3.4.7, Expiration Date: AI (17).

Day: the number of the day of the relevant month (e.g., second day = 02); if it is not necessary to specify the day, the field must be filled with two zeros[13]

The format of the expiration date is as follows:

GS1 Application Identifier	Expiration Date					
	Year		Month		Day	
1 7	N_1	N_2	N_3	N_4	N_5	N_6

4.1.5 AI (21) Serial number[14]

The GS1 AI (21) indicates that the data field contains a serial number. When combined with a GTIN, a serial number uniquely identifies an individual item. The manufacturer who assigns the GTIN determines the serial number.

The serial number field is alphanumeric. The probability that the serial number can be guessed shall be negligible and, in any case, lower than one in ten thousand. The character sequence resulting from the combination of the GTIN and the serial number will be unique to a given pack of a pharmaceutical until at least one year after the pack's expiration date or five years after the pack has been released for sale or distribution, whichever is the longer period.

The format of the serial number is as follows:

GS1 Application Identifier	Serial Number
2 1	X_1 ⟶ variable length ⟶ X_{20}

4.2 Capture

All tertiary and secondary packages are required to be labelled in accordance with the specified barcode requirement, with relevant GS1 Application Identifiers encoded and printed in their human readable form.[15]

As part of the regular manufacturing/production process, barcode symbol print quality and data content must be verified and graded in accordance with the appropriate sections within the *GS1 General Specifications* to ensure printing quality across packages and to verify that the data carrier

[13] A General Specification Change Notification (GSCN) has been issued that will change the structure of the Expiration date for Healthcare in the next release of the GS1 General Specification. This GSCN will state: "How the day of the month is expressed for regulated healthcare products will change starting 1 January 2025. As of that date, the day of the month SHALL NOT be expressed as two zeros. A valid day of the month (e.g., last day of July = 31) SHALL be include. For more information, see GS1 General Specifications, Section 3.4.7, Expiration Date: AI (17).
[14] For more information, see GS1 General Specifications, Section 3.5.2, Serial Number: AI (21).
[15] For more information, see Ten Steps to GS1 Barcode Implementation User Manual.

can stand moisture, abrasion and other external factors possibly influencing the data carrier quality. Many GS1 Member Organizations provide comprehensive barcode verification services to ensure companies are implementing barcode labelling requirements to specification based on optical and data structure requirements.

The data carrier shall:

1. be printed on the label of the product in a good visible manner.
2. be printed on a flat surface.
3. not be covered by anything which prevents scanning of the data carrier.
4. be placed on the same side of each package of the same product.

The possibility to use stickers to implement the barcoding requirements is allowed as a temporary measure and must be officially requested by the manufacturer/importer/MAH to Rwanda FDA at least 30 days before the deadline for implementation. Together with such a request, the manufacturer/importer/MAH must provide a plan and timeframe for transition and implementation of on-pack printing.

Placing the unique identifier on the secondary package by means of stickers is acceptable under the following conditions:

a. During the grace period of the implementation of the unique identifier.
b. When no legal and/or technically feasible alternative exists, as agreed between the supplier and the Authority.

When placing the unique identifier on a sticker the following conditions should be met:

a. The sticker shall be tamper-evident and not possible to remove without damaging the package, the sticker itself, or otherwise leaving visible signs.
b. The sticker on which the unique identifier is printed should be placed by a manufacturer under Good Manufacturing Practice conditions.

4.2.1 GS1-128 barcode[16]

A GS1-128 barcode is a linear barcode symbology using bars and spaces in one dimension. It is a subset of the Code 128 barcode symbology. A linear barcode can be concatenated (i.e., represent all elements of a data string in a single barcode) or non-concatenated (i.e., represent individual elements of a data string over two or more barcodes).

Example of a GS1-128 barcode for a logistic unit

Example of a GS1-128 barcode for a trade item

[16] For more information, see GS1 General Specifications, Section 5.4, Linear Barcodes — GS1-128 Symbology Specifications.

Concatenated (preferred)

Non-concatenated (only if necessary)

4.2.2 GS1 Data Matrix[17]

A GS1 Data Matrix is a two-dimensional matrix symbology that is made up of square modules arranged within a perimeter finder pattern. Two-dimensional imaging scanners or vision systems read GS1 Data Matrix symbols.

Example of a GS1 Data Matrix for a logistic unit

a)  (00) 0 0614141 123452

If a logistic label is used with only a GS1 Data Matrix, care must be taken to ensure trading partners are able to scan this barcode. See the GS1 General Specifications for further information.

Example of a GS1 Data Matrix for a trade item

(01) 10857674002017
(17) 251231
(10) NYFUL01
(21) 192A837H7

[17] For more information, see GS1 General Specifications, Section 5.7, Two-dimensional barcodes — GS1 DataMatrix symbology.

5. SUPPORTING RESOURCES

Find a GS1 Member Organization

Use this resource to find a GS1 Member Organization to register your company.
https://www.gs1.org/contact/overview

GS1 General Specification

This resource is the primary document that details the foundational GS1 standards that defines how identification keys, data attributes and barcodes must be used in business applications.
https://www.gs1.org/docs/barcodes/GS1_General_Specifications.pdf

10 Steps to Barcode Your Product

This resource provides a step-by-step instruction for implementing AIDC on your products.
http://www.gs1.org/barcodes/implementation

GS1 GTIN Healthcare Allocation Rules

This resource provides the rules for assigning GTINs to trade items in the health sector.
https://www.gs1.org/docs/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf

AIDC Healthcare Implementation Guideline

This resource provides information on the more technical aspects of implementing AIDC for healthcare on various levels of packaging.
https://www.gs1.org/docs/healthcare/GS1_Healthcare_Implementation_Guideline.pdf

Global Standards Technical Implementation Guideline for Global Health Commodities

This resource was developed by a set of international procurement agents in the global health community to support suppliers in meeting their AIDC requirements. It includes a number of technical references and a Frequently Asked Questions section that may be useful to trading partners in their implementation.
http://ghsupplychain.org/global-standards-technical-implementation-guideline-global-health-commodities-v21.

ENDORSEMENT OF THE GUIDELINES

	Author	Checked by		Approved by
Title	**Human Medicines and Device Assessment Division Manager**	**Head of Department**	**Quality Assurance Analyst**	**Director General**
Names	IRASABWA Clarisse	Dr. HABYALIMANA Vedasté	NDAYAMBAJE Théogène	Dr. Emile BIENVENU
Signature				
Date	16/08/2022	16/08/2022	16/08/2022	16/08/2022

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