

HealthforAnimals

GUIDELINES FOR APPLICATION OF GS1 MARKINGS TO ANIMAL HEALTH PRODUCTS

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1. Introduction

The first version of this document, published in 2005, has been a great success and led to the consistent use of Identification and bar coding throughout the Animal Health industry. Since the last update published in 2008 further small improvements have taken place, although all the core principles of using Data Matrix to encode Product ID, Expiry Date and Lot Number remain valid.

HealthforAnimals has agreed on a unique worldwide identification principle for Animal Health products production batches. Unique identification provides opportunity to differentiate with an optical machine readable marking the batch throughout the supply chain and is a pre-requisite for traceability of Animal Health products from production to application. It will increase products security and give logistic advantages in the warehouses.

This guideline is developed as a requirement, so that, when and where product identification is required, there will be consistency in the use of a data structure worldwide. This guideline specifies the use of GS1 application identifiers (AI's) within a Data Matrix symbology for encoding the data. As appropriate, this document is based on the General GS1 Specifications for Data Matrix.

Data Matrix has been accepted symbology in the GS1 system since 2005. The use of GS1 Data Matrix is now widespread, and still growing, on both Animal and Human health products. Data Matrix symbols are to be printed on all secondary packaging of the registered units of sale. The encoded information will contain the product number, lot number and the expiry date. The product number will be a 14 digit Global Trade Item Number (GTIN) or GS1-13.

Data Matrix was selected because of its small size, error correction, low contrast requirements and the amount of data that can be encoded compared to one-dimension codes.

Please note that the Data Matrix is not a retail point of sale bar code like GS1-13 or UPC. The purpose of the Data Matrix bar code is as an aid to record electronically Product ID, Expiry Date and Lot Number.

2. Scope

HealthforAnimals has agreed that all Veterinary Medicinal Products, are to be codified according to the present guidelines. It is recommended to apply this system to other AH products.

Use of this process, together with appropriate IT systems will allow accurate electronic tracking and tracing of products.

HealthforAnimals' prime objective is to ensure codification of each individual Product with a Product ID, an Expiry Date and a Batch Number. For higher packaging levels (e.g. bundles, shippers, pallets, etc.), the same core data of Product ID, an Expiry Date and a Batch Number

is recommended using linear GS1 128 or 2 dimensional symbols (out of GS1 standard) with the same GS1 syntax including the Quantity Application Identifier.

3. Normative references

The standards listed below are referenced in these guidelines. The relevant provisions contained in the referenced specifications constitute provisions of these guidelines.

- GS1 General Specifications (latest published version)
- ISO/IEC 15415 Bar Code Print Quality Test Specifications – 2D symbols
- ISO/IEC 15418 GS1 Application Identifiers and Fact Data Identifiers and Maintenance.
- ISO/IEC 15426-2 Bar Code Verifier Conformance Specification – Part II: 2-D
- ISO/IEC 16022 Information Technology – International Symbology Specification – Data Matrix

4. Symbols and Abbreviated Terms

1D	One dimensional or linear
2D	Two-dimensional
DM	Data Matrix
AI	GS1 Application Identifier
GS1	One Global Standard/System (former EAN International: European Article Numbering)
GTIN™	GS1 term for Global Trade Item Number™. A GTIN may be a 12 digits, 13 digits or a 14 digits number. For this document, the GTIN-14 is used to identify the product.
IFAH	International Federation for Animal Health YYMMDD Date expression of year, year month, month, day, day Note: the day (DD) is “00” if not applicable for expiry date.
UCC	GS1 US, formerly known as the Uniform Code Council
HRI	Human readable interpretation
ECC200	Error Check and Correction using the Reed Solomon algorithms. SSCC Serial shipment container code
GS1 128	Coding system using the Application Identifier standard (former EAN128)
UPC	Universal Product Code used for retailed items (12 characters)

5. Syntax requirements: GS1 128 Data Syntax

The coding of data will follow the GS1 128 syntax described in this paragraph. This data syntax can be used in a Data Matrix ECC200 symbol (described at § 6) as well as in a GS1-128 bar code (for higher packaging levels).

5.1. Application identifiers in the GS1-128 syntax

The Application Identifier Standard used in the GS1-128 syntax allows data to be encoded in a standardized way recognized worldwide. The AI's are two three or four digit prefixes that are recognized by the bar code readers and give meaning to the data. The format can be of fixed or variable length, numeric or alphanumeric. The complete list is available at GS1 local organizations (www.gs1.org).

Three cases are envisaged:

- a) **Trade item:** it is an item upon which there is a need to retrieve pre-defined information and that may be priced, ordered, or invoiced at any point in the supply chain. In this case the content is homogenous (same product, same batch) and the item correspond to a described standard and is numbered as a selling unit described in a catalogue: single unit, group of 12 sold as a trade item, or a pallet of 900 units sold as a trade item.

Here after is given the list of codified Application Identifiers to be used according to the GS1 standard with the standardized formats.

AI	Description	Format of encoded data
01	Product Identification GTIN	14 digits
10	Batch Number	1-20 alphanumeric
17	Expiration Date	6 digits: YYMMDD

- b) **Logistic unit:** it is an item of any composition, established **for internal handling and storage that need to be managed for traceability records:**

- If the logistic unit is also a trade item (standard grouping described in a catalogue), the Application Identifiers mentioned in a) above are applicable.
- If the logistic unit is not standard (not described in a catalogue) and the content is homogenous (same product, same batch): e.g. pallet of 843 units, box with 7 units, then the following list of codified Application Identifiers will be used:

AI	Description	Format of encoded data
02	GTIN of trade item contained in a logistic unit	14 digits
10	Batch Number	1-20 alphanumeric
17	Expiration Date	6 digits: YYMMDD

37	Number of Units Contained	1-8 digits
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c) **Logistic unit:** it is any item of any composition, established for **transport and/or storage**

that needs to be managed throughout the supply chain.

- If this logistic unit is also a trade item (standard grouping described in a catalogue), the Application identifiers are applicable.

AI	Description	Format of encoded data
01	GTIN of trade item contained*	14 digits
10	Batch Number	1-20 alphanumeric
17	Expiry Date	6 digits: YYMMDD
00	Serial Shipping Container Code**	18 digits

- If the logistic unit is not standard (not described in a catalogue) and the content is homogenous (same product, same batch): e.g. a pallet of 843 units, box with 7 units then the following list of codified Application Identifiers is to be used.

AI	Description	Format of encoded data
02	GTIN of trade item contained*	14 digits
10	Batch Number	1-20 alphanumeric
17	Expiry Date	6 digits: YYMMDD
37	Number of Units Contained	1-8 digits
00	Serial Shipping Container Code**	18 digits

* *The GTIN of the trade items contained represents the identification number of the highest level of trade items contained in the logistic unit.*

** *The SSCC provides a unique reference number that can be used as the key to access information regarding the logistic unit in computer files. In principle the SSCC, when combined with EDI, can be used to meet all traceability requirements.*

5.2. Mandatory Data Elements

5.2.1. GTIN of the trade item AI(01)

The Global Trade Item Number is a 14 digits number that identifies a trade item in an unambiguous way. It is the Product ID, a number that is described in a catalogue. Orders and invoices can be linked to this GTIN.

The GTIN identifies the lowest trade item as well as standard groupings of trade items (described in a catalogue).

Two main structures are possible:

Numbering Structures	14-digit Global Trade Item Number (GTIN)													
	T ₁	T ₂	T ₃	T ₄	T ₅	T ₆	T ₇	T ₈	T ₉	T ₁₀	T ₁₁	T ₁₂	T ₁₃	T ₁₄
GTIN-14	N	N	N	N	N	N	N	N	N	N ₁	N ₁	N ₁	N ₁	N ₁₄
GTIN-13	0	N	N	N	N	N	N	N	N	N ₉	N ₁	N ₁	N ₁	N ₁₃

Check character

The code is composed of:

- Indicator digit (only for the GTIN-14 number) assigned by the user company. This digit can have a value from 1 to 8. The digit 9 is not to be used since it denotes a variable measure trade item.
- A GS1 Company Prefix allocated by the GS1 organization to the user company
- An unique item number assigned by the user company
- Check digit- (see algorithm below)

The code is not linked to the production location neither to the distribution location. The format of the string following AI (01) is 14 digits.

When to use a GTIN-13 versus a GTIN-14 number?

The company is free to choose between these two GTIN structures. But a good practice is, when having several levels of trade items of the same product, to start with a GTIN-13 number (indicator = 0) for the lowest trade item, then 1 for the next grouping (for instance the group of 10 units), 2 for the following group (for instance 10 groups of 10) etc.

The Indicator in a GTIN-14 Identification Number allows each user to increase the numbering capacity when identifying similar trade items in different packaging configurations.

5.2.2. GTIN & Count of trade item Contained: AI (02) and AI (37)

When having several levels of commercial groups of the same product, each level can be coded with a GTIN. For example this GTIN begins by the numbering of the level of group concerned: 0 is the single unit, 1 the next group (for instance the group of 10 units), 2 the next group (for instance 10 groups of 10) etc. In that case, the different groups must be defined and communicated to the customers as trade items. The interest of groups is to avoid scanning each individual item.

AI (01) is used for identifying this pre-defined groups as trade items.

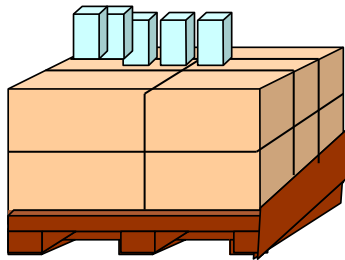
AI (02) identifies the GTIN of trade item contained in a standard logistic unit. The format of the string following (02) is 14 numeric characters.

It has a mandatory associated with AI (37) that indicates the count of trade items contained.

These Application Identifiers have normally a mandatory association with the SSCC. An SSCC provides a unique reference number that can be used as the key to access information regarding the logistic unit in computer files. In principle, the SSCC when combined with EDI can be used to meet all traceability requirements.

It means that only the single unit is a trade item

- Unit: 01234567890128 always with AI(01)
- Group of 12 (02)01234567890128(37)12
- Pallet (02)01234567890128(37)432 432 units of 01234567890128
- Incomplete pallet (02) 01234567890128(37)149 149 units of 01234567890128



Examples are given in § 13 below.

For shipments, and traceability of parcels, use of SSCC according to GS1 standards is recommended.

GTIN check digit Algorithm

GTIN - 13		N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₀	N ₁	N ₁	N ₁	N ₁
GTIN - 14	N ₁	N ₂	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₀	N ₁	N ₁	N ₁	N ₁	N ₁
Multiply value of each position by															
	x	x	x	x	x	x1	x3	x1	x3	x1	x3	x1	x3		
Accumulated results = <i>Sum</i>															
Subtract <i>sum</i> from the next highest multiple of ten = <i>Check digit</i>															

5.2.3. Batch number: AI(10)

The batch number is assigned at the point of manufacture. The code is alphanumeric and is variable up to 20 alphanumeric characters.

5.2.4. Expiry date: AI(17)

The expiry date is often referred to as "use by date" or "maximum durability date" and indicates the date by which the product should be used. It is always encoded as a fixed length 6 numeric characters: YYMMDD

If the day is not specified, the DD must be filled with two zeros. (e.g. (17)070500).

If there is no expiry date, it is required, for the homogeneity of the coded message to encode a 00 date as follows: 17000000.

5.2.5. Count AI(37)

Length is variable up to 8 numeric characters. It is compulsory to use it after AI (02).

5.2.6. Lead time in re-using a GTIN

Companies must ensure that GTINs allocated to Regulated Healthcare Trade Items shall never be reused.

Exception: Regulated Healthcare Trade Items that have been withdrawn from the market and are reintroduced may use the original GTIN if they are reintroduced without any modifications or changes which require a new GTIN as specified by the GTIN Allocation Rules. As an example:

“Product A”, a first generation injectable antibiotic, was withdrawn from the market by its manufacturer due to declining sales. After a 10 year absence from the market, “Product A” was reintroduced by the manufacturer, in its original form and package configuration, to treat infections resistant to newer antibiotics. In this example the original GTIN may be used.

5.3. Optional data elements using GS1 Application Identifiers

Other data elements are available according to GS1 AI list.(www.gs1.org). For example, a serial number, a weight, dimensions etc...

The following parts concentrate on the technical details of bar code printing and scanning. It forms a useful basis for the service provider to give them the necessary technical background. Once the appropriate equipment has been purchased and correct procedures established, the production of correct bar code may be largely automated.

6. Meaning of the FNC1 in the Data Matrix ECC200

Function Code 1 (FNC1) is a specific function used in the Data Matrix ECC200 as well as in the GS1 bar code. This FNC1 is used:

1. in the first character position
2. as a separator between data elements with variable length

6.1. In the first character position

When FNC1 (Codeword ASCII value 232) appears in the first character position, it shall signal that the bar code is a Data Matrix ECC 200 that applies the GS1 Application Identifier Standard.

The symbology identifier for GS1 Applications of Data Matrix ISO/IEC 15424 provides a uniform methodology for reporting the symbology read, options set in the reader and any special features of the symbology encountered. The symbology identifier for GS1 Data Matrix ECC200 is **]d2** where:

-]** is the symbology identifier flag (ASCII value 93)
- d** is the code character for Data Matrix symbology
- 2** is the modifier indicating: **ECC200 FNC1 in first position**

This code is often reported as the AIM code. It is accessible only with a specific programming of the reader.

6.2. As a separator

FNC1 in any other later position acts as a field separator. Transmission of symbology identifiers shall be enabled. When used as a field separator, FNC1 shall be represented in the transmitted message by the ASCII character <GS> (ASCII value 29). See also § 7.3.

The purpose of this code is to stop the variable length sub-strings and to indicate a new AI will immediately follow.

This code (<GS>) is not printed in a human readable form.

Although the use of this code is essential for decoding the message, it usually does not appear on visualisation on a screen reported by the reader.

To verify (<GS>) presence, reader software programming is necessary.

7. Representation of data: Data Matrix ECC200 symbol using GS1-128 syntax

7.1. Concatenation of data when represented in a Data Matrix ECC200 symbol

Using the Data Matrix ECC200 Symbol, it is possible to concatenate (chain together) the discrete element strings associated with the two digits of an Application Identifier.

7.2. Concatenation of the Pre-Defined Length Element Strings

Concatenated Element Strings constructed from Application Identifiers with a pre-defined length do not require a separator character. The next Application Identifier follows fixed length element strings up to the last one.

7.3. Concatenation of the Variable Length Element Strings

Concatenating Element Strings of variable length, e.g. Application Identifiers (10) and (37) involves the use of a Separator Character. The Separator Character used is the Function 1 Character (FNC1) with ASCII value 29 (<GS>). It is placed immediately after the last symbol character of a variable length data string and is followed by the Application Identifier of the next element string. There is no character after the last element string even if of variable length.

The FNC1 character is not shown in Human Readable Interpretation.

When concatenating a mixture of pre-defined and variable length Element Strings, place the pre-defined Element Strings before the Variable element Strings

Order of the strings

In order to facilitate decoding and use of data, (homogeneity for customers) the various strings will be encoded as follows according to GS1 rules to have fixed length strings before variable length strings:

For a single unit:

- 1 GTIN 17 expiry date 10 Batch number For a group:
- 2 GTIN 17 expiry date 10 Batch number <GS> 37 Quantity

8. Human readable information

For human readable information the recommended and minimum text character height are (type OCR-B font):

	Character Height (cm)	Character Height (in)	Character Height (points)
Recommend	0.2 cm	0.08 in	5.76 pts
Minimum	0.125 cm	0.05 in	3.6 pts

The data elements and corresponding Application Identifiers:

GTIN AI (01), batch number AI(10) and expiry date AI(17) are to be printed in human legible characters, as required by local regulatory authorities, nearby the Data Matrix code associated with the symbol while respecting the quiet zones. Application Identifiers when printed must always be represented between parentheses that are never encoded in the symbol.

9. Print Quality for Data Matrix Symbols

It is highly recommended to procure the ISO/IEC 15415 standard that gives all details regarding the print quality. The aim of the following is to give the acceptable levels of the measurement criteria.

Minimum cell size will be in the range of 0.0075 inch (0.19 mm) to 0.015 inch (0.38 mm).

GS1 recommends a minimum of X dimension of 10 mils (.010")

The International Standard *ISO/IEC 15415 Information technology - Automatic identification and data capture techniques - Bar code symbol print quality test specification - Two-dimensional symbols* methodology shall be used for measuring and grading Data Matrix. Verifiers that comply with the standard measure the print quality grade. The grade includes a grade level, measuring aperture, the wavelength of light used for the measurement, and the illumination angle relative to the symbol.

A symbol grade is only meaningful if it is reported in conjunction with the illumination and aperture used. It should be shown in the format *grade/aperture/light/angle*, where:

- "*grade*" is the overall symbol grade as defined in *ISO/IEC 15415 Information technology - Automatic identification and data capture techniques - Bar code symbol print quality test specification - Two-dimensional symbols*, i.e. the arithmetic mean to one decimal place of the scan reflectance profile or scan grades,
- "*aperture*" is the diameter in thousandths of an inch (to the nearest thousandth) of the synthetic aperture defined in *ISO/IEC 15415 Information technology - Automatic identification and data capture techniques - Bar code symbol print quality test specification - Two-dimensional symbols*.
- "*light*" defines the illumination: a numeric value indicates the peak light wavelength in nanometres (for narrow band illumination); the alphabetic character W indicates that the symbol has been measured with broadband illumination ("white light") the spectral response characteristics of which must imperatively be defined or have their source specification clearly referenced,
- "*angle*" is an additional parameter defining the angle of incidence (relative to the plane of the symbol) of the illumination. It shall be included in the reporting of the overall symbol grade when the angle of incidence is other than 45°. Its absence indicates that the angle of incidence is 45°.

Note: This International Standard provides for 30° and 90° illumination in addition to the default 45°.

An asterisk following the value for "grade", in the case of a two-dimensional matrix symbol, indicates that the surroundings of the symbol contain extremes of reflectance that may interfere with reading – see *ISO/IEC 15415 Information technology - Automatic identification and data capture techniques - Bar code symbol print quality test specification - Two-dimensional symbols*.

Aperture Diameter (in 0.001")/Aperture ref	Aperture Diameter	“X” dimension range (in	“X” dimension range (in
03	0.075	0.004 to 0.007	0.100 to 0.180
05	0.150	0.0071 to 0.013	0.180 to 0.330
10	0.250	0.0131 to 0.025	0.330 to 0.635
20	0.500	0.0251 and larger	0.635 and larger

Examples:

- 2,8/05/660 would indicate that the average of the grades of the scan reflectance profiles, or of the scan grades, was 2,8 when these were obtained with the use of a 0,125 mm aperture (ref. no. 05) and a 660 nm light source, incident at 45°.
- 2,8/10/W/30 would indicate the grade of a symbol intended to be read in broadband light, measured with light incident at 30° and using a 0,250 mm aperture (ref. no. 10), but would need to be accompanied either by a reference to the application specification defining the reference spectral characteristics used for measurement or a definition of the spectral characteristics themselves.
- 2,8*/10/670 would indicate the grade of a symbol measured using a 0,250 mm aperture (ref. no. 10), and a 670 nm light source, and indicates the presence of a potentially interfering extreme reflectance value in the surroundings of the symbol.

For acceptance (as per ISO/IEC 16022 and 15415):

Minimum print quality of **1.5/aperture/670** and (0,8X is the absolute maximum aperture to use)

Decode: **passes** and

Symbol Contrast **SC ≥ 40%** (6 to 10mil aperture, 660nm wavelength)



Symbol contrast is the value difference between light and dark symbol elements and between the quiet zone and perimeter elements.

and

Modulation: Grade 2



Modulation refers to the reflectance uniformity of a symbol light and dark elements.

and

Fixed Pattern Damage: Grade 2



Fixed pattern damage refers to finder pattern and clock pattern damage.

and

Axial non uniformity $AN \leq 0.10$ (spacing of mapping centre)



Axial non-uniformity is the amount of deviation along the symbol's major axes. The inconsistency of X, Y dimensions indicates movement of the object as it is being marked.

and

Grid non uniformity ≤ 0.63



rs to a symbol's cell deviation from the ideal grid of a theoretical perfect symbol. The greatest distance from an actual to a theoretical grid intersection determines the grid non-uniformity grade.

and

Print Growth $-0.85 \leq D' \leq 0.85$ (filling boundary volume compared to nominal)



Print growth refers to the deviation (larger or smaller) of actual element size from intended element due to printing problems. When a symbol is printed, the ink may "bleed" causing an

overprint. If there is not enough ink, or if there is some other problem with printing equipment, the result may be an underprint.

and

Unused Error Correction ≥ 0.37 , tests to measure to which extent damage has eroded the safety margin of error correction. Error correction is a method of reconstructing or replacing data that is lost through symbol damage. 100% unused error correction is ideal.

Minimum quality grade = 2.0 (equivalent to Grade C on ANSI grading scale)

10. Other marks

Other fixed local barcodes (e.g. linked to the registration number) in other symbols than Data Matrix ECC200 may be kept preprinted on the packaging if and when required by local regulatory authorities.

11. Scanners

It is imperative that the correct scanner be used.

Some CCD or 2D Imaging technology such as array scanners and vision systems are capable of scanning all symbols in the GS1 System, including Data Matrix. **Note that linear imagers, like laser scanners, cannot scan Data Matrix;** only 2D or array imaging scanners can scan Data Matrix, as well as camera based or vision systems.

The imaging and camera based systems offer many advantages over the linear imagers most notably the elimination of the need to orientate the bar code and the ability to read all types of bar codes. The Data Matrix code can be scanned in any orientation. Many imaging scanners also offer the option of being able to take photographs which could have value in recording additional information i.e. signatures.

12. Samples of acceptable formats

Locations, formats and layouts are left free, to be organized according to the available space.

Example of the preferred method of the DATA Matrix Symbol with the HRI GTIN, Lot Number and Expiry.

The code below represents:

Lot Number: ABCD1234

Expiration Date: October 25, 2009

GTIN: 01234567890123

Qty: 10



Alternative Format: Example of the optional Data Matrix Symbol Encoded with HRI GTIN and AI's for Lot and Expiry



GTIN: 01234567890123
Exp. Date: 25 Oct. 2009
Batch: ABCD1234

Alternative Format: including Lot Number, GTIN and Expiry



For a group of products:



13. Examples of concatenated strings

FNC1(01)01234567890128 (17)YYMMDD(10)ABC123
 FNC1(02)01234567890128 (17)YYMMDD(10)ABC123FNC1(37)12

FNC1(02)01234567890128 (17)YYMMDD(10)ABC123FNC1(37)432
 if

FNC1(01)01234567890142 (17)YYMMDD(10)ABC123

FNC1(01)21234567890122 (17)YYMMDD(10)ABC123

for a single unit.
 for a bundle not being a trade item of 12 units
 of 01234567890128 (**only for internal
 traceability purpose**)
 for a pallet of 432 units of 01234567890128

pallet is not a trade item (**only for internal
 traceability purpose**)

for a pallet of 36 units of 01234567890135 if
 the pallet is a trade item and numbered with a
 specific GTIN.

for a pallet of 432 units if the pallet is
 identified as a trade item using the indicator 2.

The parenthesis are never encoded in the symbol. They are only shown to ease understanding.