

ANNEX B - UNICEF GUIDELINES FOR VACCINE BARCODE SPECIFICATIONS

UNICEF is supporting the general efforts to improve traceability of vaccines in the receiving countries. Barcodes on different packaging levels bear options to support supply chains and improve traceability of vaccines.

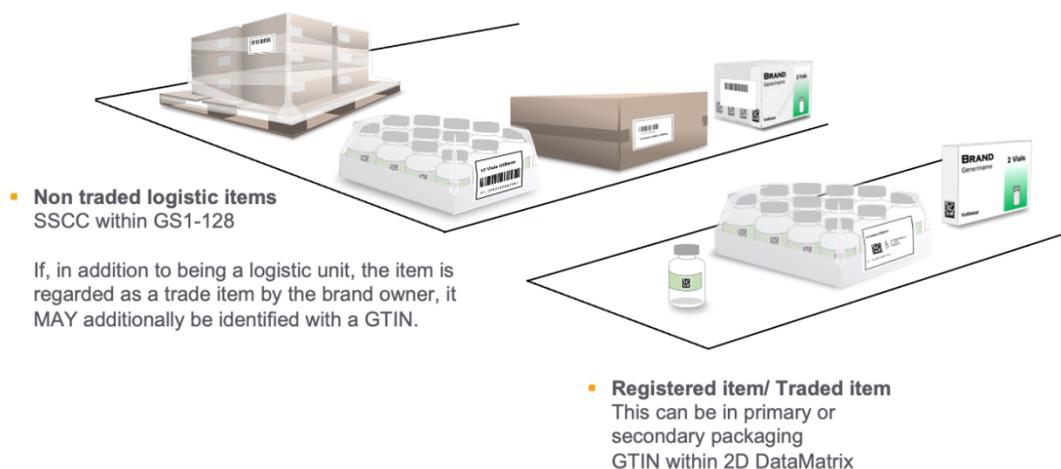
For UNICEF tenders issued after 1 October 2019, the application of barcodes on secondary packaging and higher levels is mandatory for the supply of vaccines from 1 January 2022 and onwards.

Whereas the application of GS1-barcodes on secondary packaging and higher level is considered as the minimum and **mandatory** requirement, GS1-serialised barcodes are considered a **preferred** characteristic.

The application of barcodes should not replace any information on the packaging or labels as currently required in accordance with the WHO guidelines for labelling.

A. GS1-Coding Specifications¹ to comply with mandatory characteristics

The illustration provides an overview of the mandatory coding specifications which are covered in detail through this document under section A.



A.1 Registered item/ Traded Item

Data Carrier Symbol: Data Matrix ISO version ECC 200

¹ At the time of writing version 20 of the GS1 General Specifications were published at <https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications> and form the basis of all references within this document

Data encoding: Data should be encoded using the GS1 system element strings and will utilize ASCII encoding according to ISO 16022.

Data:

Three data elements that are **required:**

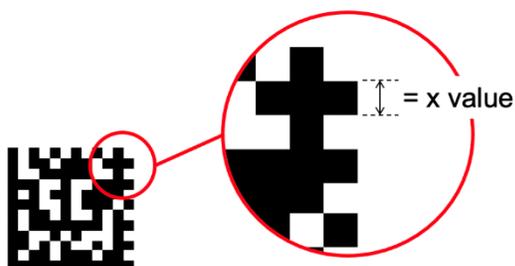
Data element	Application Identifier	Example
Global Trade Item Number	01	01234567890123
Expiry date	17	210131
Batch/ Lot	10	abc123

There is no guidance for the order in which the data elements should be encoded in the Data Matrix; however, it is more efficient to encode the fixed length fields first i.e., GTIN and Expiry date, followed by the variable length fields.

For full details of GS1 elements strings and application identifiers please refer to section 3 of the GS1 General Specifications.

Additional element strings: These may be included in the Data Matrix. An example of an additional element string could be a National Healthcare Reimbursement Number, used where GTIN alone does not meet the needs of the national systems.

Size and shape: There are no preferences regarding the use of square or rectangular symbols. The x dimension of each module should comply with recommendations made by GS1 for healthcare items, namely a minimum x value of 0.255mm and a maximum of 0.615mm.



Negative and positive symbols: The Data Matrix symbol may be produced either dark on a light background or light on a dark background, both are acceptable, as long as they meet the data carrier quality requirement.

Data Carrier Quality: The quality of the Data Matrix code printing/ marking should be 1.5 (C) or better in accordance with ISO/TEC 15415:2011.

Overprint headings: This tender does not specify the overprint headings to be used or the physical location of these, as these are typically defined within national labelling regulations/ requirements and may include local language variations. In GS1 terms this text is referred to a non-HRI (human readable information).

It is however generally good practice to display this information adjacent to the Data Matrix, taking into consideration the quiet zone around the symbol. The following is for illustration purposes only and does not form part of the specifications of the tender (the 2D Data Matrix will not scan).



PC 01234567890123
EXP 11.2020
Lot 7654321D

In addition to the overprint headings human readable interpretation (HRI) may be applied, subject to physical and technical constraints. For further information on HRI please see section 4.15.1 of the GS1 General Specifications.

A.2 Non-traded logistic items (also referred to a tertiary packaging)

This an item established for the purposes of transport and storage and therefore needs to be managed through the supply chain.

Data Carrier Symbol and encoding: GS1-128 linear barcode symbology.

Full details and specifications for the GS1-128 can be found in section 5.4 of the GS1 General Specifications document.

Data: Serial Shipping Container Code (SSCC).

Human readable interpretation: Should the GS1-128 barcode fail to scan for example, through the result of damage, it is necessary that the SSCC is still available to be captured. The use of HRI (Human readable interpretation) is included on the packaging. For HRI rules refer to section 4.15.1 of the GS1 General Specifications.

The following is an example of a GS1-128 shown with HRI, it is not reproduced to size.



Additional element strings: These may be included within the GS1-128.

Data Carrier Quality: 128 linear barcode symbols must be evaluated in accordance with ISO/IEC 15416 which defines a standardized methodology for measuring and grading barcodes.

B. GS1-Coding Specifications² to comply with preferred characteristics

The illustration provides an overview of the preferred coding specifications which are covered in detail through this document under section B.

² At the time of writing version 20 of the GS1 General Specifications were published at <https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications> and form the basis of all references within this document



B.1 Registered item/ Traded Item

Data Carrier Symbol: Data Matrix ISO version ECC 200

Data encoding: Data should be encoded using the GS1 system element strings and will utilize ASCII encoding according to ISO 16022.

Data:

The data elements for the preferred barcode specifications/characteristics:

Data element	Application Identifier	Example
Global Trade Item Number	01	01234567890123
Expiry date	17	210131
Batch/ Lot	10	abc123
Serial number	21	a1b2c3000987654

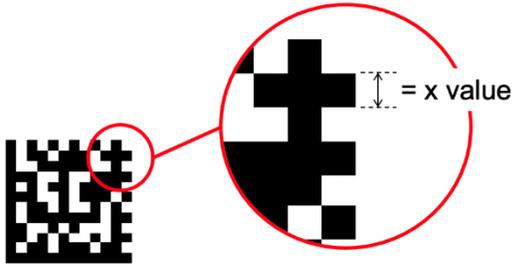
There is no guidance for the order in which the data elements should be encoded in the Data Matrix, however it is more efficient to encode the fixed length fields first i.e. GTIN and Expiry date, followed by the variable length fields.

For full details of GS1 elements strings and application identifiers please refer to section 3 of the GS1 General Specifications.

Additional element strings: These may be included in the Data Matrix. An example of an additional element string could be a National Healthcare Reimbursement Number, used where GTIN alone does not meet the needs of the national systems.

Serial number randomization: The serial number, if included, must be randomized to reduce the ability to guess the next serial number in a sequence. The probability of guessing a valid serial number must be less than 1 in 10,000. Consideration must also be given for large sets of serial numbers and the use of fixed patterns or algorithms which can be worked out given a set of serial numbers.

Size and shape: There are no preferences regarding the use of square or rectangular symbols. The x dimension of each module should comply with recommendations made by GS1 for healthcare items, namely a minimum x value of 0.255mm and a maximum of 0.615mm.

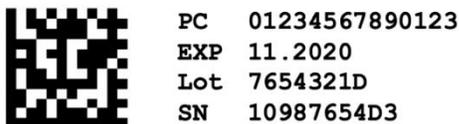


Negative and positive symbols: The Data Matrix symbol may be produced either dark on a light background or light on a dark background, both are acceptable, as long as they meet the data carrier quality requirement.

Data Carrier Quality: The quality of the Data Matrix code printing/ marking should be 1.5 (C) or better in accordance with ISO/TEC 15415:2011.

Overprint headings: This tender does not specify the overprint headings to be used or the physical location of these, as these are typically defined within national labelling regulations/ requirements and may include local language variations. In GS1 terms this text is referred to a non-HRI (human readable information).

It is however generally good practice to display this information adjacent to the Data Matrix, taking into consideration the quiet zone around the symbol. The following is for illustration purposes only and does not form part of the specifications of the tender (the 2D data Matrix will not scan).



In addition to the overprint headings human readable interpretation (HRI) may be applied, subject to physical and technical constraints. For further information on HRI please see section 4.15.1 of the GS1 General Specifications.

Tamper Sealed: To prevent the contents being separated from the stock keeping unit/serialized registered item, it is preferred that a tamper seal should be applied. The primary function is to ensure the integrity of the pack is maintained.

B.2 Non-traded logistic items (also referred to a tertiary packaging)

This an item established for the purposes of transport and storage and therefore needs to be managed through the supply chain.

Data Carrier Symbol and encoding: GS1-128 linear barcode symbology.

Full details and specifications for the GS1-128 can be found in section 5.4 of the GS1 General Specifications document.

Data: Serial Shipping Container Code (SSCC).

Human readable interpretation: Should the GS1-128 barcode fail to scan for example, through the result of damage, it is necessary that the SSCC is still available to be captured. The use of HRI (Human readable interpretation) is included on the packaging. For HRI rules refer to section 4.15.1 of the GS1 General Specifications.

The following is an example of a GS1-128 shown with HRI, it is not reproduced to size.



Additional element strings: These may be included within the GS1-128.

Data Carrier Quality: 128 linear barcode symbols must be evaluated in accordance with ISO/IEC 15416 which defines a standardized methodology for measuring and grading barcodes.

B.3 Serialization and Batch data

Although there is no traceability system currently in place to upload the serialization and batch data, the data must be stored and made available for upload on request for at least the shelf life of the product.

The following is a list of the data for the preferred barcode specification:

- GTIN
- Batch/ Lot
- Expiry date
- **Date of manufacture**
- **Serial numbers**

Aggregation

For the purposes of this preferred tender requirement on serialization, aggregation is determined to be a relationship created between two items, one which is packed inside the other.

An example would be 10 cartons packed in a shipping case, a relationship is made between the individual serial numbers on the 10 cartons and the SSCC on the shipping case. By capturing aggregation data and storing this, it is possible to scan the SSCC and then look up the specific serial numbers on the cartons contained inside, without opening up the shipping case.



To facilitate the potential future tracing of physical products through the supply chain, aggregation should be implemented where possible.

Aggregation relationships need to be made between the highest level of packaging e.g. the pallet, all the way down to the stock keeping unit. If a bundle is produced but is not handled as a logistics item (it has no label and SSCC), then it can be excluded from the aggregation.

When aggregation relationships have been made this data must be stored and made available for upload on request, for at least the shelf life of the product.

The manufacturer must keep a record of which batches have aggregation applied and which have not and be able to produce this information on request.

Master Data

The following master data items must be made available on request for each stock keeping unit.

GTIN, Product name, MAH Name

There are no master data requirements for the SSCC.

UNICEF is supporting the general efforts to improve traceability of vaccines in the receiving countries. For this tender the application of barcodes is considered a preferred characteristic. The application of barcodes should not replace any information on the packaging or labels as currently required in accordance with the WHO guidelines for labelling.

Coding Specifications³ to comply with preferred characteristics

The illustration provides an overview of the coding specifications which are covered in detail through this document.

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Registered item/ stock keeping unit

Data Carrier Symbol: Data Matrix ISO version ECC 200

Data encoding: Data should be encoded using the GS1 system element strings and will utilise ASCII encoding according to ISO 16022.

Data: Four data elements are preferred.

Data element	Application Identifier	Example
Global Trade Item Number	01	01234567890123
Expiry date	17	210131
Batch/ Lot	10	abc123
Serial number	21	a1b2c3000987654

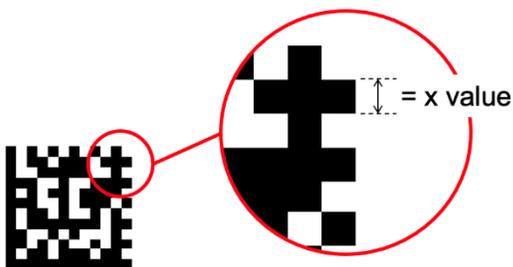
There is no guidance for the order in which these should be encoded in the Data Matrix, however it is more efficient to encode the fixed length fields first i.e. GTIN and Expiry date, followed by the variable length fields.

For full details of GS1 elements strings and application identifiers please refer to section 3 of the GS1 General Specifications.

Additional element strings: These may be included in the Data Matrix. An example of an additional element string could be a National Healthcare Reimbursement Number, used where GTIN alone does not meet the needs of the national systems.

Serial number randomisation: The serial number must be randomised to reduce the ability to guess the next serial number in a sequence. The probability of guessing a valid serial number must be less than 1 in 10,000. Consideration must also be given for large sets of serial numbers and the use of fixed patterns or algorithms which can be worked out given a set of serial numbers.

Size and shape: There are no preferences regarding the use of square or rectangular symbols. The x dimension of each module should comply with recommendations made by GS1 for healthcare items, namely a minimum x value of 0.255mm and a maximum of 0.615mm.

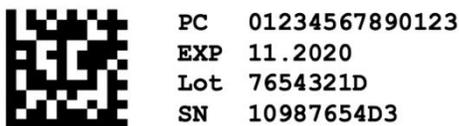


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Data Carrier Quality: The quality of the Data Matrix code printing/ marking should be 1.5 (C) or better in accordance with ISO/TEC 15415:2011.

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In addition to the overprint headings human readable interpretation (HRI) may be applied, subject to physical and technical constraints. For further information on HRI please see section 4.15.1 of the GS1 General Specifications.

Tamper Sealed: To prevent the contents being separated from the serialised registered item/ stock keeping unit, it is preferred that a tamper seal should be applied. The primary function is to ensure the integrity of the pack is maintained.

Non-traded logistic items (also referred to a tertiary packaging)

This an item established for the purposes of transport and storage and therefore needs to be managed through the supply chain.

Data Carrier Symbol and encoding: GS1-128 linear barcode symbology.

Full details and specifications for the GS1-128 can be found in section 5.4 of the GS1 General Specifications document.

Data: Serial Shipping Container Code (SSCC).

Human readable interpretation: Should the GS1-128 barcode fail to scan for example, through the result of damage, it is necessary that the SSCC is still available to be captured. The use of HRI (Human readable interpretation) is included on the packaging. For HRI rules refer to section 4.15.1 of the GS1 General Specifications.

The following is an example of a GS1-128 shown with HRI, it is not reproduced to size.



Additional element strings: These may be included within the GS1-128.

Data Carrier Quality: 128 linear barcode symbols must be evaluated in accordance with ISO/IEC 15416 which defines a standardised methodology for measuring and grading barcodes.

Batch and serialisation data

Although there is no traceability system currently in place to upload the batch and serialisation data, the data must be stored and made available for upload on request for at least the shelf life of the product.

The following is a list of the preferred data:

- GTIN
- Batch/ Lot
- Expiry date
- Date of manufacture (please refer to Annex D as this is under consideration by WHO)
- Serial numbers

Aggregation

For the purposes of this tender, aggregation is determined to be a relationship created between two items, one which is packed inside the other.

An example would be 10 cartons packed in a shipping case, a relationship is made between the individual serial numbers on the 10 cartons and the SSCC on the shipping case. By capturing aggregation data and

storing this, it is possible to scan the SSCC and then look up the specific serial numbers on the cartons contained inside, without opening up the shipping case.



To facilitate the potential future tracing of physical products through the supply chain, aggregation should be implemented where possible.

Aggregation relationships need to be made between the highest level of packaging e.g. the pallet, all the way down to the stock keeping unit. If a bundle is produced but is not handled as a logistics item (it has no label and SSCC), then it can be excluded from the aggregation.

When aggregation relationships have been made this data must be stored and made available for upload on request, for at least the shelf life of the product.

The manufacturer must keep a record of which batches have aggregation applied and which have not and be able to produce this information on request.

Master Data

The following master data items must be made available on request for each stock keeping unit.

GTIN, Product name, MAH Name

There are no master data requirements for the SSCC.

Electronic leaflets

There is no specific requirement however, it is possible to utilise the GS1 Digital Link standards to link the data in the 2D DataMatrix with online leaflets and other digital information.