Title: CGS161 Printing BarCodes for Medical Devices

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Process Owner: Health Care Business Group - Quality Management Systems

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1.0 EXTERNAL REFERENCES

SCOPE: This Corporate General Specification defines requirements and responsibilities for the printing of Automatic Identification symbols (i.e. barcodes) on packaging supplies purchased by or for 3M Health Care.

GENERAL INFORMATION: This Corporate General Specification covers the Healthcare Automatic Identification Standard requirements as outlined in the documents referenced below.

Country/Region	External Regulation, Standard, or Guidance
International version	• ISO/IEC 15415 Information technology - Automatic identification and data capture techniques - Bar code symbol print quality test specification - Two-dimensional symbols: http://www.iso.org • ISO/IEC 15416 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Linear symbols: http://www.iso.org • ISO 15459 Information Technology – Automatic identification and data capture techniques – Unique Identification
Australia	NA
Brazil	NA
Canada	NA
European Union	NA
United States	• GS1 General Specifications: http://www.gs1.org: • Uniform Symbol Standard Code 39 and Uniform Symbol Standard Code 128: http://www.aim.org • ANSI INCITS 182-1990 (R2002) – formerly ANSI x3.182-1990 – Guideline for Bar Code Print Quality: http://web.ansi.org

Note: Each location is responsible for ensuring that any additional regulations or standards that apply to its country, in addition to those referenced above, are met.

1.0 PURPOSE

1.1 To assure the printing of Automatic Identification symbols (barcodes) which conform to the documents referenced above. This Corporate General Specification shall supplement the 3M individual item specification(s). Instructions in the 3M individual item specification(s) have precedence over any instructions contained in this Corporate General Specification.

This Corporate General Specification contains recommended sizes and printing requirements of bar code symbols using GS1 accepted data structures and symbologies. Decisions regarding appropriate data structure and barcode symbology to be used must be made by the business unit, depending on product type and distribution methods.

2.0 3M'S RESPONSIBILITY TO SUPPLIERS

2.1 Provide information to be encoded, bar code symbol location, orientation, size, and color of symbol printing.

2.2 Position bar code symbol on packaged products to conform with referenced standards, as well as 3M requirements.

3.0 SUPPLIER RESPONSIBILITY

3.1 Print the bar code symbol in conformance with the published 3M and industry quality standards, maintaining minimum ANSI/ISO grades as stated herein.

3.2 Supplier requirements – General:

- Understand the effect of print process on bar width and advise 3M if artwork needs to be modified.
- Use ANSI or ISO verifier. All printed bar codes must meet a C or better grade with regular verification audits
- Use correct aperture setting.
- Calibrate verifier and ensure NIST traceable.
- Train operators.
- Use appropriate sampling processes (see 4.4)
- Ensure that the human readables match the encoded data within the printed bar code symbol.

3.3 On new items, advise if unable to meet minimum bar code quality requirements **prior** to producing packaging supplies.

3.4 Develop and implement appropriate inspection procedures to ensure conformance to print quality requirements for each bar code symbol provided to 3M on an ongoing basis.

3.5 Maintain a record of all inspection results for each product produced.

4.0 BAR CODE SYMBOLOGY REQUIREMENTS

The following are definitions and recommended sizes of bar codes in the various options. **(It is the responsibility of the business unit to determine the appropriate data structure and symbology for each product.)**

See appropriate sections referenced below for definitions, appropriate data structure and bar code symbology combinations.

Section 4.1 Definitions
Section 4.2 GS1-128 (Preferred data structure and symbology for most health care products)
Section 4.3 2 Dimensional Barcode Symbols - GS1 Data Matrix (may be used for very small health care products/packages)
Section 4.4 UCC/EAN Data Structure – U.P.C./EAN Symbology
(Required for retail point of sale scanning. Refer to Corporate General Specification 138 for more details)

4.1 DEFINITIONS

For All Package Levels:

- Quiet Zone: This is "white space" that needs to exist both before and after the bar code symbol and represents a calculation that is 10 times (multiplier) the value of the defined X-Dimension.
- Barcode Human Readable (below barcode symbol): The human readable digits should be centered below the bar code symbol. Although there is no font style or font size specified for the human readable, it is recommended to use a san serif type font (Arial or equivalent) and minimum font size that will be clearly legible.
- Human Readable Interpretation (HRI): The actual printing of the Lot Number (with LOT symbol), the Expiration Date (with hourglass symbol) or Serial Number (with SN symbol) that is added to labeling for human translation. The day in the HRI must match the day printed in the bar code human readable.

- Print Quality: Refer to section titled "Print Quality Requirements" of this document for specific requirements associated with barcode quality.
- Application Identifiers are included only for the bar code symbology and the application to identify the data and should not be included in a data base situation. Function 1 (FNC1) character also must follow the start character and come before AI's
- Symbol Width: Maximum symbol width (including required quiet zone spacing) is 165 mm (6.5").
- Encoding: The maximum number of characters that can be encoded is 48 (includes the Application Identifier(s) and Function Code 1 (FNC1) when it is used as a data separator). **Note**: Use {CODE C} for encoding data that consists of an even number of digits as it may be possible to use an "Auto-Switching" setting in the label software to systematically control code type (Code A, B, or C) for data encoding. **Note**: GS1-128 requires the use of a Function 1 character at the beginning (right after the start pattern) which indicates the use of globally defined application identifiers (see details related to each application identifier below).

Application Identifier (AI) Definitions:

Application Identifier	Description		Application Identifier	Description
(01)	GTIN			
(17)	Expiration Date			
(10)	Batch/Lot Number	**OR**	(21)	Serial Number

Notes for Suppliers:

1. 3M will assign the product GTIN (Global Trade Identification Number) for each applicable package level.
2. With the exception of Application Identifier (01): Global Trade Identification Number (GTIN), all GS1-128 barcodes containing multiple Application Identifiers **must** be concatenated (joined together in one barcode)

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Application Identifier AI (01): Global Trade Identification Number

	Formatting Requirements AI(01) – GTIN				Example
Application Identifier	**GTIN**				
(01)	Indicator Digit N1	GS1 Company Prefix N2-N8	Item Reference N9-N13	Modulus 10 Check N14	**00707387123451**

Application Identifier AI (17): Expiration Date

The Application Identifier (17) indicates that the data field contains an Expiration Date. The Expiration Date is used to capture data that is relevant **only** to products that possess a certain shelf life that will cause them to expire. The data may **only** be numeric and **must** comply with the formatting requirements outlined below.

Formatting Requirements AI(17) – Expiration Date				Example
Application Identifier	**Expiration Date**			**030128**
(17)	Year $N_1 N_2$	Month $N_3 N_4$	Date 28	

Notes – Six total digits required YYMMDD:

1. Year: Defined as the tens and units of the year (e.g., 2003 = 03), which is mandatory
2. Month: Defined as the number of the month (e.g., January = 01), which is mandatory
3. Date: Defined as the number of the day of the relevant month

Application Identifier AI (10): Identifier Batch or Lot Number

The Application Identifier (10) indicates that the data field contains a Batch or Lot Number. The Batch or Lot Number is used to capture data that is considered relevant to the manufacturer. The data may be alphanumeric and can support a maximum of 20 characters. Examples of Batch or Lot Number definitions include, but are not limited to: a production lot number, a shift number, a machine number, a time, or an internal production code.

Formatting Requirements AI(10) – Batch or Lot Number		**Example**
Application Identifier	**Batch or Lot Number**	**2010AB125**
(10)	# Characters → X_1 … X_{20}	

Application Identifier AI (21): Serial Number

The Application Identifier (21) indicates that the data field contains a Serial Number. A Serial Number is used to capture data that is typically assigned to an entity for its lifetime. The data may be alphanumeric and can support up to a maximum of 20 characters. The manufacturer determines the Serial Number. **Note**: When Serial Number is combined with a product Global Trade Identification Number (GTIN), a Serial Number uniquely identifies an individual item.

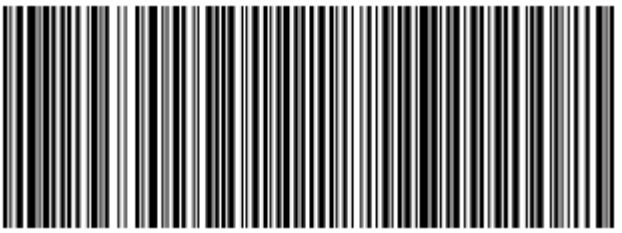
Formatting Requirements AI(21) – Serial Number		**Example**
Application Identifier	**Serial Number**	**A1234578901**
(21)	# Characters → X_1 … X_{20}	

4.2 Linear Bar Code GS1-128

4.2.1 Bar code Specifications - Outlined below are design specifications for the GS1-128 barcode (formerly known as UCC/EAN-128 barcode).

	X-Dimension		Bar Height		Quiet Zone	
Package Level	**Target**	**Minimum**	**Target**	**Minimum**	**Target**	**Minimum**
Inner[1]	0,495 mm 0.019 inches	0,495 mm 0.019 inches	32 mm 1.250 inches	32 mm 1.250 inches	6,35 mm 0.250 inches	6,35 mm 0.250 inches
Inner[2]	0,254 mm 0.010 inches	0,254 mm 0.010 inches	12,7 mm 0.500 inches	12,7 mm 0.500 inches	2,54 mm 0.100 inches	2,54 mm 0.100 inches
Shipping Container[1]	0,495 mm 0.019 inches	0,495 mm 0.019 inches	32 mm 1.250 inches	32 mm 1.250 inches	6,35 mm 0.250 inches	6,35 mm 0.250 inches

[1] Default specification.
[2] Alternative specification that is to be used only for inner packaging and in situations where the default inner specification will not work due to space constraints associated with label placement.

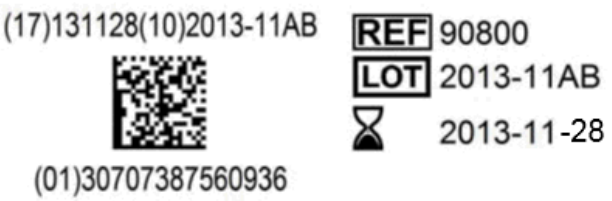


4.3 2 Dimensional Barcode Symbol – GS1 Data Matrix

4.3.1 GS1 Data Matrix is acceptable where space on packaging is limited

4.3.2 For Quality requirements for GS1-Data Matrix barcode symbols, refer to GS1 General Specification document and ISO document: *ISO/IEC 15415* Information technology - Automatic identification and data capture techniques - Bar code symbol print quality test specification - Two-dimensional symbols.

4.3.3 Here is an example of a GS1 Data Matrix barcode symbol:



4.4 Alternate Bar Code Symbologies

4.4.1 Standards do allow the use of alternate bar code symbologies and data structures, such as UPC Versions A or E, EAN-13 and ITF-14 symbologies. There are other 3M Corporate General Specification in existence, covering requirements for these symbologies. Please refer to these documents for more details.

Corporate General Specification 138: Point of Sale Bar Code Symbols - UPC – A and EAN-13 Symbols

Corporate General Specification 158: ITF-14 (Interleaved Two of Five) Bar Code Symbols

NOTE: It is the business unit's decision to determine appropriate bar code data structure and symbology to be used for a specific product.

Appendix

Recommended sizes and suggested print substrate/method of bar code symbols using GS1-128. These options shown below only cover barcode symbols which encode only the GTIN (AI of 01). The left to right dimensions given only include that AI and no additional pieces of concatenated data

#301
NBar 0.0100" (0.254 mm) BHgt 0.50" (12.7 mm) BBar N/A
Left-Right 1.540" (3.912 Cm) Top-Bottom 0.628" (1.595 cm) QZone 0.10" (2.54 mm)
Print Tolerance: +/- 0.0035" (0.0889 mm)
Minimum ANSI Grade: C/05/670 (1.5/05/670)

1.1 OFFSET

#302
Bar 0.0110" (0.2794 mm) BHgt 0.50" (12.7 mm) BBar N/A
Left-Right 1.704" (4.328 cm) Top-Bottom 0.628" (4.328 cm) QZone 0.11" (2.794 mm)
Print Tolerance: +/- 0.0039" (0.0991 mm)
Minimum ANSI Grade: C/05/670 (1.5/05/670)
Flexo - Narrow Web, 7" (17.8 cm) or less

#303
NBar 0.0140" (0.356 mm) BHgt 0.60" (15.24 mm) BBar N/A
Left-Right 2.166" (5.501 cm) Top-Bottom 0.772" (1.961 cm) QZone 0.14" (3.556 mm)
Print Tolerance: +/- 0.0051" (0.130 mm)
Minimum ANSI Grade: C/10/670 (1.5/10/670)

1.1.1.2 Flexo - Wide Web, 8" (20.3 cm) or larger

#304
NBar .0160" (4.064 mm) BHgt 0.60" (15.24 mm) BBar N/A
Left-Right 2.474" (6.284 cm) Top-Bottom 0.790" (2.001 cm) QZone 0.16" (4.064 mm)
Print Tolerance: +/- 0.0059" (0.15 mm)
Minimum ANSI Grade: C/10/670 (1.5/10/670)
Flexo – Porous Pouch Substrate

#306
NBar 0.020” (0.508 mm) BHgt 1.25” (3.175 cm) BBar N/A
Left-Right 3.180” (5.077 cm) Top-Bottom 1.479” (3.756 cm) QZone 0.25” (6.35 mm)
Print Tolerance: +/- 0.0075” (0.191 mm)
Minimum ANSI Grade: C/10/670 (1.5/10/670)
Shipper Label – Paper

#305 – direct print on Corrugated. Note that special printing processes must be used to ensure C or better grade with verification
NBar 0.020” (0.508 mm) BHgt 1.25” (3.175 cm) BBar 0.20” (5.08 mm)
Left-Right 3.580” (9.093 cm) Top-Bottom 1.869” (4.747 cm) QZone 0.25” (6.35 mm)

Print Tolerance: +/- 0.0075” (0.191 mm)
Minimum ANSI Grade: C/10/670 (1.5/10/670)
Corrugated – Preprinted

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