Guidance Document for EHIMA labelling of hearing aids and accessories in accordance with UDI

1. Scope

This EHIMA guidance document is intended to provide guidance to hearing aid manufacturers on a common industry format for UDI labels. The document covers hearing aids and accessories, including standalone software classified as a medical device or accessory to a medical device. The guidance document will allow the common use of bar-code and 2D matrix scanners when handling hearing aids and accessories.

2. Identification attributes on product packaging

The following shall be labeled on the packaging according to GS1 specifications [1] and corresponding Human Readable Interpretation (HRI) text. The manufacturer can apply either a GS 1 2D Data matrix or a 128 1D concatenated barcode. Alternatively, both can be applied if required.

DI = Device Identifier (01) GTIN (13 digits)

- GS1 Country Code (2 digits)
- GS1 company code (5 digits)
- Product reference (5 digits)
- Control number (1 digit)

PI = Production identifier

The production identifier shall include the following:

- (21) Serial Number (optional for standalone SW)
- (10) Batch or Lot (if applicable)
- (11) Production Date (in the format YYYY-MM-DD)
- (17) Expiration date (if applicable)
- (20) Product Variant (if applicable)
- (30) Quantity (optional)
- (240) Model (optional)
- (422) Country of Origin (optional)

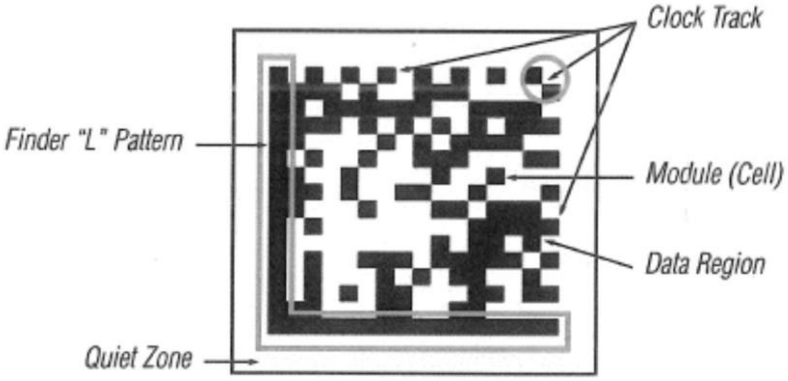
Note: FDA does not require that model data on each price point or color is uploaded to the FDA GUDID. Manufacturers can define variants in line with FDA rules [3] and GS1 specifications [1].

3. Identification attributes on further packaging levels

Further packaging levels following should be labeled in the same manner as above with the following additions.

- Revision (optional)
- GTIN of Contained Trade Items (must be different to the GTIN on the base packaging)
- Count of Trade Items (optional)

4. GS1 2D Data matrix



The 2D Data Matrix should be in accordance with the GS1 guideline [2], ISO/IEC 15415 [10] & ANSI x3.182 [12].

5. GS1 1D Barcode

If applied, the 1D barcode should be displayed below the 2D Data matrix.

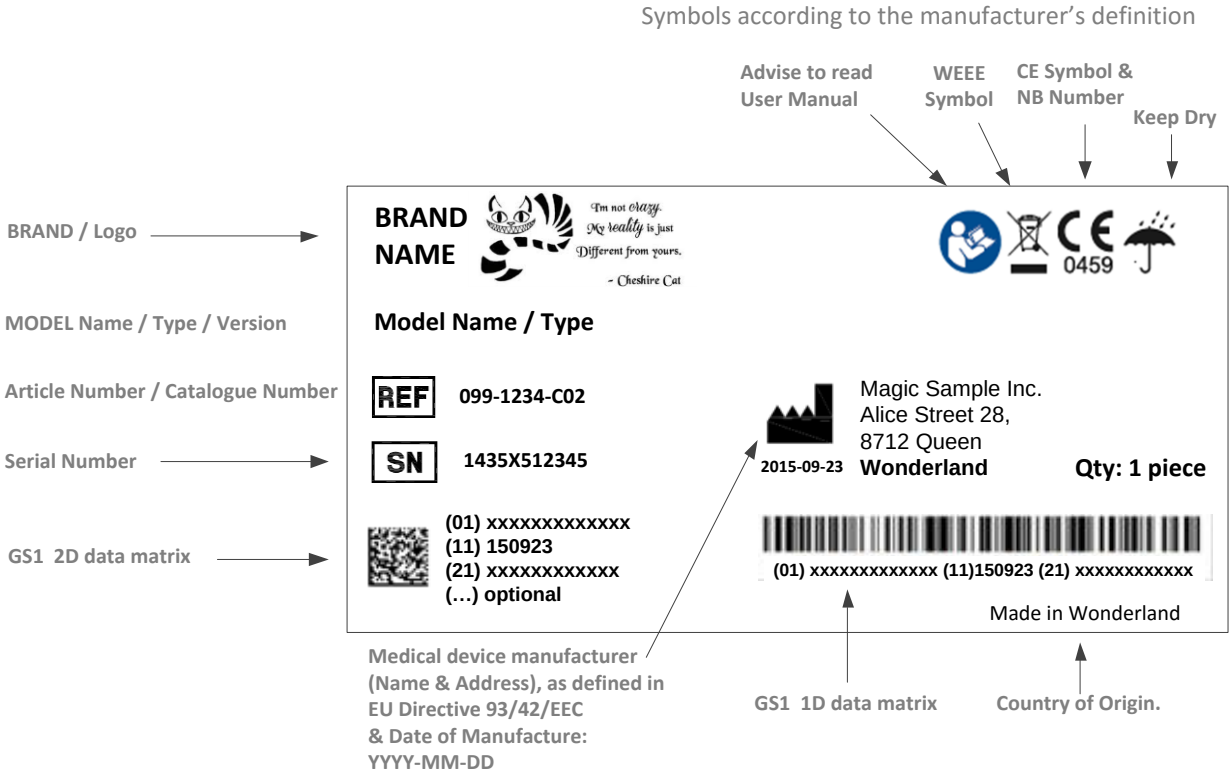
The bar code should be in accordance with GS1 specification [1], ANSI X3.182 [12] & ISO/IEC 15416 [11].

6. Information on the Product Packaging Identification Label

The following information shall be on the product packaging or on the identification label:

- Corporate Logo or brand name
- Legal Manufacturer address
- Identification attributes, e.g. model name
- Applicable regulatory marks e.g. CE-marking
- Year, month, day of manufacture in the format YYYY-MM-DD
- Made in [Country of Origin] (optional)

7. Sample 2D Matrix + 1D Barcode label



Symbols for "Keep dry", "Advice to read User Manual" and "Quantity" are optional

8. Dates on Labels

All dates displayed on the labels for medical devices (not just dates contained in the UDI information) shall be displayed per the ISO 8601:2004 requirements:

Standard: YYYY-MM-DD

Example of acceptable format:

- 2013-06-14

Note: It is not necessary to specify the day (the Day field should be filled with two zeros), the resultant data string shall be interpreted as the last day of the noted month including any adjustment for leap years (e.g. "130200" is "2013 February 28", "160200" is "2016 February 29", etc.). [1]

Date format exceptions that do not fall under the UDI date formatting:

- Dates contained in the UDI AIDC (2D matrix, barcode) should be encoded according to the GS1 specification: <YYMMDD>. The associated HRI text displayed next to the AIDC should also follow the GS1 specification since the displayed information is intended to accurately represent the encoded information. Note: If only year and month are available, DD must be filled with two zeroes. [1]

9. References:

[1] GS1 General Specifications

[2] GS1 DataMatrix Guideline - Overview and technical introduction to the use of GS1 DataMatrix

[3] Federal Register / Vol. 78, No. 185 / Tuesday, September 24, 2013 – FDA Unique Device Identification System, Final Rule.

[4] EN 980 Symbols for use in the labelling of medical devices

[5] ISO 15233 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements

[6] ISO 7000 Graphical symbols for use on equipment -- Registered symbols

[7] ISO 8601:2004 Data elements and interchange formats -- Information interchange -- Representation of dates and times

[8] FDA guidance document - Global Unique Device Identification Database (GUDID), Guidance for Industry, issued on: June 27, 2014.

[9] FDA guidance document - Unique Device Identification System: Small Entity Compliance Guide, Guidance for Industry and Food and Drug Administration Staff, issued on August 13, 2014.

[10] ISO/IEC 15415 Bar code symbol print quality test specification - Two-dimensional symbols

[11] ISO/IEC 15416 Bar code print quality test specification - Linear symbols

[12] ANSI X3.182 Bar Code Print Quality Guideline

For Symbols refer to [4, 5, 6]

10. Definitions

AIDC - Automatic identification and data capture
Any technology that conveys the unique device identifier or the device identifier of a device in a form that can be entered into an electronic patient record or other computer system via an automated process, e.g. 2D matrix, barcode, RFID etc.

GTIN
Global Trade Identification Number - a family of GS1 (EAN.UCC) global data structures that employ 14 digits and can be encoded into various types of data carriers such as in bar codes or radio frequency identification (RFID).

GS1
Organization that manages barcode standards used by retailers, manufacturers and suppliers. (http://www.gs1.org/)

HRI
Human Readable Interpretation, e.g. human readable text

DI - device identifier
A mandatory fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device.

PI - Production Identifier
Precisely identifies the specific device by providing variable information, such as the lot or batch, the serial number, expiration date, the date of manufacture.

RFID - radio frequency identification
The wireless use of electromagnetic fields to transfer data, for the purposes of automatically identifying and tracking tags attached to objects.

11. History

Draft V01 2014-07-30; initial draft

Draft V02 2015-01-29

- Combination of the black and white factory icons for manufacturing date and manufacturer name to the black symbol only.
- Introduction of the symbols for Serial number and Catalogue number

Draft V03 2015-09-20;

- GN ReSound updates.
- Addition of clarification from FDA on model definitions
- Document formatted on EHIMA document template.

Draft V04 2015-09-24

- Updated following review at EHIMA Q-Manager meeting 23-09-15.

V05 2016-01-25

- Updated based on input from EHIMA TC committee members