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Healthcare
User Group

Recommendations on Medical Device and IVD Field Safety Corrective Actions and Recalls using Unique Device Identifiers & GS1 Standards

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About the Healthcare User Group

The Healthcare User Group (HUG) is made up of invited senior representatives from healthcare trade associations, providers, suppliers, solution and service companies and other related organisations. The objectives of the group are:

- To actively support and accelerate the adoption of GS1 standards throughout healthcare, by sharing learnings and best-practice solutions from local implementations
- To help healthcare providers comply with Unique Device Identification (UDI) and Falsified Medicines Directive (FMD) regulations
- To identify and review opportunities that enhance efficiency and patient safety

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Recommendations for how GS1 Unique Device Identifiers (UDIs) should be used by manufacturers and healthcare providers in the process of field safety corrective actions and recalls for medical devices and in-vitro diagnostic medical devices.

1 Introduction

Unique Device Identification (UDI) of medical devices and in-vitro diagnostic medical devices is required or is being introduced in various parts of the world in recognition that using UDI systems based on international guidance [(1)] has the potential to significantly enhance the post-market safety of medical devices by:

- improving incident reporting
- improving targeting of recalls
- enhancing monitoring by competent authorities (such as MHRA)
- reducing medical errors
- protecting against counterfeit devices
- improving purchase-policy and stock-management by hospitals [(2)].

Forthcoming European regulations [(2)] [(3)] will require that UDIs must be placed on all of these products or their labels and that this information must be used for reporting serious incidents and to facilitate field safety corrective actions. Furthermore, the NHS in England is implementing the widespread use of GS1 standards in healthcare with the aim of improving patient safety and operational efficiency [(4)].

This document provides recommendations for how UDIs based on GS1 standards should be used by manufacturers and healthcare providers in field safety corrective actions (FSCAs) and recalls for medical devices and in-vitro diagnostic medical devices with the aim of improving the efficiency and effectiveness of the processes. Many of these recommendations could also be applied to any alerts issued by medical device competent authorities to healthcare providers.

The document has been prepared by a subgroup of the GS1 UK Healthcare User Group consisting of representatives from GS1 UK, ABHI, BIVDA, NHS Trusts, AIHO, suppliers and chaired by MHRA. It has been agreed by the Healthcare User Group as representing their views and it will be presented to the MHRA with a request that the recommendations are incorporated into official MHRA guidance. It will also to be put forward to the European Commission requesting incorporation into the European guidelines on the medical device vigilance system (MEDDEV 2.12-1) [(5)].

2 Scope

This document gives guidance on the use of GS1 Unique Device Identifiers (UDIs) in medical device and in-vitro diagnostic medical devices field safety corrective actions and product recalls including:

- how medical device and in-vitro diagnostic medical device manufacturers should include GS1 UDIs in their Field Safety Notices (FSNs) and how this information should be distributed in electronic (machine readable) form
- how GS1 UK could assist manufacturers in implementation
- how the EU MEDDEV 2.12 guidance [5] should be changed to require manufacturers to include UDI-Device Identifiers (DIs) and where appropriate UDI-Production Identifiers (PIs), such as batch or serial numbers in their FSNs
- how hospitals, distributors and points of sale, including retail pharmacies, can use the GS1 UDI information when it is included in FSNs.

3 Terms and Definitions

Medical device - Any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes of:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means [2].

In-vitro diagnostic medical device - Any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological process or state;
- concerning congenital physical or mental impairments;
- concerning the predisposition to a medical condition or a disease;
- to determine the safety and compatibility with potential recipients;
- to predict treatment response or reactions;
- to define or monitor therapeutic measures.

Specimen receptacles are considered to be in vitro diagnostic medical devices. "Specimen receptacle' means devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination [3].

Unique Device Identification (UDI) - A series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific device on the market. The UDI is comprised of a ***Device Identifier*** (UDI-DI) and a ***Production Identifier*** (UDI-PI).
Note: The word "Unique" does not imply serialisation of individual production units [1].

Device Identifier (UDI-DI) - A unique numeric or alphanumeric string specific to a model of medical device and that is also used as the "access key" to information stored in a UDI Database. Examples of the UDI-DI include GS1 GTIN (Global Trade Item Number), HIBC-LIC (Labeler Identification Code), ISBT 128-PPIC (Processor Product Identification Code) [1].

Production Identifier (UDI-PI) - A numeric or alphanumeric string that identifies the unit of device production. The different types of ***Production Identifier(s)*** include serial number, Batch/Lot number, software identification, date of manufacture and/or use-by date [1].

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 [6].

NOTE: GTINs are widely used as ***Device Identifiers (UDI-DI).***

Global Location Number (GLN) - The GS1 identification key used to identify physical locations or parties. The key comprises a GS1 Company Prefix, location reference, and check digit [6]. **Note:** GLNs may be used to identify both physical locations and legal entities.

Batch/Lot number - The batch or lot number associates an item with information 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 [6].

Serial number - A code, numeric or alphanumeric, assigned to an individual instance of an entity for its lifetime. Example: microscope model AC-2 with serial number 1234568 and microscope model AC-2 with serial number 1234569. A unique individual item may be identified with the combined Global Trade Item Number (GTIN) and serial number [6].

Field Safety Corrective Action (FSCA) - An action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a ***medical device*** or ***in-vitro diagnostic medical device*** that is already placed on the market.

NOTE: The FSCA may include:

- the return of a medical device or in-vitro diagnostic medical device to the supplier;
- device modification;
- device exchange;
- device destruction;
- retrofit by purchaser of manufacturer's modification or design change;
- advice given by the manufacturer regarding the use of the device and/or the follow up of patients, users or others (e.g. where the device is no longer on the market or has been withdrawn but could still possibly be in use e.g. implants or change in analytical sensitivity or specificity for diagnostic devices) [5].

Field Safety Notice (FSN) - A communication to customers and/or users sent out by a manufacturer or its representative in relation to a ***Field Safety Corrective Action*** [5].

Manufacturer - The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party [2].

Distributor - The natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a device available on the market, up until the point of putting into service [2].

Single Registration Number (SRN) – the number which identifies the manufacturer in the future European electronic system on registration of economic operators [2,3].

4 Guidance / Recommendations

4.1 Manufacturers

1. In addition, to their own catalogue numbers (product codes), manufacturers should reference Unique Device identifiers (UDIs) in their Field Safety Notices (FSNs). FSNs should always include the Device Identifiers (UDI-DIs) of all of the products affected by the Field Safety Corrective Action (FSCA) and where necessary they should also include relevant Production Identifiers (UDI-PIs).

2. In addition, manufacturers should send their customers and distributors, electronically, a list of all the products affected by the FSCA in an EXCEL spreadsheet using EXCEL 97-2003 Workbook .xls format. The spreadsheet should be structured as specified in table 1 below. The list of products should include

all products affected within the appropriate country, region or geographical area. The list should not be restricted to only those products thought to have been supplied to a single healthcare provider.

3. Distributors should pass on manufacturer FSNs unchanged to any customers which have received any of the products affected by the FSN.

4. Manufacturers/distributors may, in addition, provide healthcare providers with a list of products that have been supplied to them.

5. The EXCEL spreadsheet should consist of two worksheets whose cells and formatting should be protected to avoid data or formats being changed accidentally.

Worksheet 1 should contain the following information:

i. The manufacturer's European Single Registration Number (SRN).

Note: European SRNs will not be available until the revised European medical device regulations are implemented.

ii. The manufacturer's company name.

iii. The manufacturer's GS1 Global Location Number (GLN).

iv. The unique FSN number allocated by the manufacturer as required in MEDDEV 2.12-1 rev 8 [(5)].

v. The issue date of the FSN.

vi. The text FSN should be embedded in the spreadsheet so that it is both readable and printable for example as a PDF file.

Worksheet 2 should contain the following information:

Column Heading/Title	Description of the data	Required/Optional
Device Identifier (UDI-DI)	The device identifier(s) of all of the products affected by the FSCA as printed on the product label and included in the product barcode. This may be either a GS1 GTIN or a HIBCC product UPN. In England this should be a GS1 GTIN in text format. **Note:** The GTIN should be prepended by zeros, if necessary, to make up to 14 digits.	Required
Catalogue number	The manufacturer's product code in text format.	Required

Product Description	The manufacturer's product description in text format.	Required
Batch/Lot number (UDI-PI)	The batch/lot number of the affected products as printed on the product label and included in the product barcode. **Note:** If all batches are affected then this column may be left blank.	Optional
Serial number (UDI-PI)	The serial number of the affected products as printed on the product label and included in the product barcode. **Note:** If all serial numbers are affected then this column may be left blank.	Optional
Use-by date (UDI-PI)	The date when the product is due to expire as included in the product barcode. The date should be formatted in Excel date format and displayed as *yymmdd*. **Note:** This column may be left blank.	Optional
Date of manufacture (UDI-PI)	The date when the product was manufactured as included in the product barcode. The date should be formatted in Excel date format and displayed as *yymmdd*. **Note:** This column may be left blank.	Optional

Normally either the Batch/Lot number column or the Serial number column of the spreadsheet will be left blank. If the affected products have both Batch/Lot number and Serial number, then the Serial number should always be provided and optionally the Batch/Lot number.

Note:

(i) Where Serial number is the main UDI-PI, the spreadsheet should include one row of information for each affected Serial number, rather than listing Serial number ranges in a single row.

(ii) Where Batch/Lot number is the main UDI-PI, the spreadsheet should include one row of information for each affected Batch/Lot, rather than listing Batch/Lot number ranges in a single row.

(iii) Where all batches or serial numbers of a product are affected Batch/Lot or Serial number should not be listed.

6. Manufacturers and distributors should send FSNs to a central point designated by the healthcare provider (see 4.2) in addition to any other contacts.

7. Manufacturers and distributors should continue to use their existing processes to ensure that FSNs have been received and acted on appropriately.

4.2 Healthcare providers

Healthcare providers should create a central point, (e.g. within the Risk Department) if not already in place to receive, record and report FSNs and to ensure that FSCAs are fully implemented.

They should inform relevant manufacturers, suppliers and distributors of their contact details for this central point and ensure that this information is kept up to date. This may be done by providing a dedicated email address (for example *FSNcontrol@healthcareprovider.uk*) and phone number that will remain valid when staff changes occur.

Healthcare providers should create a policy, if not already in place, which clearly defines the process by which they ensure that there is an effective, systematic, auditable approach to the distribution of the information received about field safety corrective actions and that the information is acted upon within the defined timescales. This will include initially running product data provided through internal systems, such as the Purchasing and/or Inventory Management systems to check whether the product(s) have ever been purchased. If affected product(s) have been purchased, then establishing where any remaining inventory is located will be essential, as it may require removal and returning to the Supplier or other corrective actions. If affected product(s) have already been used on, prescribed to, or implanted into a patient, and if remedial action involving the patient is required then it will be necessary to identify which patients have been affected so the necessary remedial action can take place.

The data search should always be in the first instance by the device identifier and then by the batch/lot number and or serial number as per this example:

Device Identifier	Catalogue number (Manufacturer product code)	Product Description	Batch/Lot number	Serial number	Use-by Date	Date of Manufacture
08714729863847	H74939277545110	Guiding Sheath 5F, 45 cm, ST, CC	17966591		180531	180220
08714729863847	H74939277545110	Guiding Sheath 5F, 45 cm, ST, CC	17971123		180531	180220
08714729863847	H74939277545110	Guiding Sheath 5F, 45 cm, ST, CC	18003862		180531	180220
08714729863847	H74939277545110	Guiding Sheath 5F, 45 cm, ST, CC	18044434		180531	180220

5 References

(1) IMDRF/UDI WG/N7FINAL:2013 - Unique Device Identification (UDI) of Medical Devices – 9 December 2013 - *http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-udi-guidance-140901.pdf*

(2) Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 – 27 June 2016 - *http://data.consilium.europa.eu/doc/document/ST-10617-2016-REV-1/en/pdf*

(3) Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices – 27 June 2016 - *http://data.consilium.europa.eu/doc/document/ST-10618-2016-REV-1/en/pdf*

(4) NHS eProcurement Strategy – April 2014 - *www.gov.uk/government/uploads/system/uploads/attachment_data/file/344574/NHS_eProcurement_Strategy.pdf*

(5) MEDDEV 2.12-1 rev 8 – Guidelines on a medical devices vigilance system – January 2013 - *http://ec.europa.eu/DocsRoom/documents/15506/attachments/1/translations/en/renditions/native*

(6) GS1 General Specifications Version 16 - *http://www.gs1.org/genspecs*

The above links were correct at the time of publication.

6 Annex – Example electronic document

An example machine excel spreadsheet is attached. It is protected using password "GS1UK".

Example machine readable FSN.xls