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GHTF Discussion Paper

(in view of preparation of a draft guidance on)

UDI for Medical Devices

Title: **Unique Device Identification (UDI) System**

Authoring Group: **GHTF SC UDI AHWG**
Proposed by the Global Harmonization Task Force for Public Consultation
Deadline for comments: 31 March 2010
Address for submitting comments: mail box: entr-cosm-med-dev@ec.europa.eu

Expectations from this consultation phase/invitation for public comments:
Part A: Comments on the UDI system:
Comments/suggestions are invited on the chapters of this discussion paper; in particular the UDI system including the UDI code, carrier and placement, the UDI Database; How such a system would or could be used by manufacturers, regulators, purchasers, and/or final users? More globally, what could be the governance and economic model of a single UDI system worldwide?

Part B: Comments on the concept of UDI Database(s):
- What is your vision on how (a) UDI Database(s) could be designed and implemented in the short term worldwide? Who are the different types of users?
- What are the key elements of UDI Database(s) administration?
- How will the UDI Database(s) articulate/interact with other existing entities or international standardisation organizations.

Disclaimer: No prejudice/preference towards a single global physical database versus the interconnection of regional data bases is anticipated in this consultation document.

Date: November 12, 2009

Roland Rotter, GHTF Chair

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0. Preface

The document herein was produced by the Global Harmonization Task Force, a voluntary group of representatives from medical device regulatory agencies and the regulated industry. The document is intended to provide non-binding guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development.

1. Introduction

For the sake of patient safety, in the era of global economy it is desirable to address tracking and tracing of medical devices at a global level. One reliable way to achieve track and trace of medical devices is to develop a Unique Device Identifier (UDI). The primary aim of a UDI mechanism is to increase patient safety.

It will also improve the work of market surveillance authorities in case of field safety corrective actions, and for instance the fight against counterfeiting. In addition, the development of an international approach will make the trade of medical devices more secure for all the stakeholders (health authorities, hospitals, manufacturers, distributors, etc).

This is why the introduction of a UDI system appears to many regional regulatory authorities and to industry at large as an effective tool to protect more efficiently public health. It is mainly for patient safety reasons that all the actors of the sector advise to develop UDI for medical devices.

For the GHTF regional jurisdictions, it is of great importance that a globally applicable UDI system without regional adaptations is developed. Therefore, the design and construction of a UDI mechanism should be addressed in a forum like GHTF, in order to encourage the use of a harmonised UDI system by all regulatory jurisdictions. Hence the creation of this UDI Ad Hoc Working Group (AHWG), established at the Ottawa GHTF Steering Committee (SC), in order to ensure that the design and the implementation of the UDI will be accepted globally.

This document aims to pave the way for the establishment of a UDI in the medical device sector. It develops the common and essential principles necessary to build a global UDI. Further additional points will need to be developed once these core elements are accepted.

2. Rationale, purpose and scope

2.1 Rationale

First, there is currently no such a definition of what is a UDI mechanism at the worldwide level. As a consequence, discrepancies between different national approaches do exist.
Therefore, common worldwide UDI requirements would offer significant benefits to the manufacturer, user and/or patient, and Regulatory Authorities. In addition, eliminating or reducing differences between jurisdictions decreases the cost of gaining regulatory compliance.

Second, while developing a UDI system, one important consideration which shall be taken into account is the risk associated to the device. The UDI mechanism shall be implemented stepwise according to the risk of the device – starting with the highest risk first (e.g., implants) and staggering implementation, with the lowest risk class (e.g., most disposables) implemented last. Further, the introduction of UDI shall allow sufficient implementation timeframes to let manufacturers comply with the requirements

Finally, in order to achieve all the positive elements of a UDI mechanism, the use of UDI should be promoted among all stakeholders, including regulatory agencies, medical device manufacturers, distributors, hospitals, and medical professionals.

2.2 Purpose

The main goal of a UDI is to improve patient safety by:

- **reducing device related medical errors,**

- **enhancing the identification of devices in case of adverse events,**

- **facilitating traceability**

In addition, this guidance aims to avoid prescriptive country-specific requirements regarding the core elements of the UDI mechanism by developing common guidance to:

- **create, use and maintain according to its level of competence a unique identification code**

- **develop a global and unique code**

- **establish the UDI Database with a defined list of attributes**

2.3 Scope

This document applies to all products that fall within the definition of a medical device that appears within the GHTF document "*Information Document Concerning the Definition of the Term "Medical Device"*".

3. References

GHTF final documents

SG1/N29R16:2005	Information Document Concerning the Definition of the Term "Medical Device"
SG1/N43:2005	Labeling for Medical Devices
SG1/N55:2009	Definitions of the Terms Manufacturer, Authorized Representative, Distributor and Importer Registration and Listing
SG1 (PD)/N65	Registration of Manufacturers and other Parties and Listing of Medical Devices

International standards

ISO/IEC 15415	Information technology -- Automatic identification and data capture techniques - Bar code print quality test specification -- Two-dimensional symbols
ISO/IEC 15416	Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Linear symbols
ISO/IEC 24720	Information technology -- Automatic identification and data capture techniques -- Guidelines for direct part marking (DPM)
ISO/IEC 29158	Information technology -- Automatic identification and data capture techniques -- Direct Part Mark (DPM) Quality Guideline

Remark: That is only a selection of AIDC specific ISO-Standards. All the others are valid as well.

4. Definitions

UDI
Unique Device Identification (Identifier)
Nb: The word "Unique" does not imply necessarily serialisation of every single device.

UDI System
The framework for the production of a UDI Code, the application of the UDI code on the label[1] or directly on product, and the storage of the UDI Code and additional device identification information in a UDI database.

UDI Code
The UDI code is a numerical or alphanumerical code that is created through a coding system.
It allows the unambiguous identification of a specific product on the market and represents the "access key" to device identification information stored in the UDI-database.
The UDI Code is comprised of static and dynamic information.

UDI Code Static part (device identifier)
A unique numeric or alphanumeric code that is used as the unique "access key" to information stored in a UDI database.

[1] GHTF/SG1/N43:2005 Label "Written, printed or graphic information provided upon the medical device itself. Where physical constraints prevent this happening, this term includes information provided on the packaging of each unit or on the packaging of multiple devices".

UDI Code Dynamic part (production identifier)
Information which identifies a specific device (e.g. serial number) and/or a batch/lot of devices (depending of the type of devices), and, as appropriate, expiration or manufacture date.

UDI Coding System
The algorithm through which a UDI Code is created and allocated to a device. Coding systems applicable for a global UDI System will be maintained and/or created by international standard organisations.

UDI Carrier
It is the means to carry the UDI Code by using automatic-identification and/or human readable

- Human readable:
The UDI-Carrier preferably includes human readable information (HRI).

- Automatic identification
Data capture (AIDC) technologies includes linear or two-dimensional bar codes, RFID…

The UDI Carrier may be integrated with, but does not replace any labelling obligation.

UDI Database (UDID)
The UDID contains device information accessible through the static part of the UDI Code.

5. Essential Principles: Guidance for the UDI System

General introduction

A UDI for medical devices will consist of a unique identification code using a globally accepted standard format. In order to accommodate most methods of labelling, marking, and identifying products, UDI should be technology neutral, that is, it should not be restricted to a particular method of Automatic Identification and Data Capture (AIDC)[2].

The UDI database shall allow the use of an existing globally accepted data exchange process to harmonize the exchange of device information for safety purposes. It shall utilize a globally accepted nomenclature such as the Global Medical Device Nomenclature (GMDN).

The UDI system shall be implemented stepwise according to the risk of the device – starting with the highest risk first (e.g., implants) and staggering implementation, with the lowest risk class

[2] Radio Frequency Identification (RFID) is a developing AIDC technology which may provide significant advantages as a UDI Carrier. At this time, however, the use of RFID in healthcare raises specific concerns.

(e.g., most disposables) implemented last. Further, that the introduction of UDI shall allow sufficient implementation time for manufacturers to maintain compliance with quality system requirements. This will need to be determined in a way that is globally translatable. The use of UDI shall be promoted among all stakeholders, including regulatory agencies, medical device manufacturers, distributors, medical facilities, and medical professionals.

5.1 The UDI shall be an additional essential principle that may be integrated with existing labeling, which, through UDI carrier, improves patient safety through global device tracking. The UDI is not an alternative to the existing labeling/marking requirements set out in the GHTF Essential Principles.

5.2 Every manufacturer shall maintain the uniqueness of its UDI code for a medical device throughout all jurisdictions world-wide.

5.3 Currently available globally accepted device auto-identification techniques based on ISO standards shall be used.

5.5 Coding systems internationally accepted such as GS1 and HIBCC meet the criteria of the UDI Code and shall be used. It is imperative that these coding systems be adopted and implemented, without national deviations or changes to these otherwise global standards.

5.6 The UDI carrier shall be on the label of the device or on the device itself. If a new entity / company replaces the original equipment manufacturer (OEM) the UDI carrier of the new entity / company3 shall be on the label or on the device itself in replacement of the OEM UDI carrier. The company removing a UDI in order to place its own UDI, on the label or on the device, shall keep record of the previous UDI.

5.7 The manufacturer is responsible for creating and maintaining the uniqueness and the accessibility of the UDI code throughout the intended lifetime of the device or five years after the production of the last device.

6. UDI Code

6.1 The UDI code is the combination of static information (device identifier) and dynamic information (production identifier).

6.2 The static part of the UDI code uniquely identifies the specific device (manufacturer, type of device, including model number, and other characteristics of the device such as sizes or quantities per pack). A significant change to device characteristics requires that a new UDI Code be allocated to the product.

[3] Re-manufactured or re-processed by any entity other than the original equipment manufacturer.

6.3 The UDI code static part (device identifier) is a “non-intelligent” alpha-numeric number that has no inherent meaning, i.e. information cannot be directly extracted from the UDI Code. The device identifier is globally unique and is the primary key used to access “intelligible” information about the device stored in the UDI Database (UDID).

6.4 The UDI code dynamic part (production identifier) specifies the particular production unit i.e. serial number, and/or batch, or lot. Where appropriate the product expiration date shall also be part of the UDI production identifier.

7. UDI Carrier and placement

7.1 No particular format of AIDC technology should be required. Any type of data carrier is acceptable, e.g. linear or two-dimensional bar code or RFID if based on ISO standards.

7.2 The static and dynamic parts of the UDI Code may be expressed as concatenated or non-concatenated linear bar codes, or two dimensional bar code. If non-concatenated the bar codes should be proximal.

7.3 In most cases, the UDI Carrier should be both human readable and encoded in an AIDC format that facilitates its use at least throughout the intended life of the device.

7.4 The human readable information and the AIDC format should both be placed on the label of the device. If there are significant space constraints limiting the use of both forms, the AIDC format shall be favoured. However, certain use situations, such as home care, may warrant the use of human readable over AIDC.

7.5 In case of RFID, human readable information and AIDC should be provided.

7.6 Durable devices or devices that require reprocessing, cleaning, sterilization or adjustment between patients' use should be considered for direct part marking, in addition to marking on the primary package.
Direct part marking may not be possible on some devices due to materials, processing, or performance issues. Any regulatory requirement related to the marking of higher packaging's level shall insure that the marking is unique and inference should not be prohibited.
The placement of the UDI Carrier shall be done in a way that AIDC technology can be used during normal operation or storage. The UDI Carrier shall be accessible / visible for the user.

7.7 Regarding consumable product, the UDI Carrier shall be placed on the package or on the device itself.
In case of sterile implants, the UDI Carrier shall be placed on the primary and secondary sterile package of the device.

7.8 The UDI Carrier for most low risk devices packaged and labeled individually does not need to be on the unit of use level but rather on a higher level of packaging, e.g. “shelf pack”.

7.9 Kits shall have a UDI Carrier. Individual devices within the kit do not need to have a UDI Carrier as long as the manufacturer has the means to identify individual devices.

7.10 For devices sold only at retail POS (Point of Sale), the packaging should only be marked with the appropriate point of sale data carrier (linear bar code symbol). The production identifier does not need to be encoded in this instance.

8. UDI Data Base (UDID)

General introduction

In order to increase patient safety, the UDI Database is intended to support regulators' efforts to track devices globally.
No product pricing or classified information shall be included in the database.

Different types of systems can be developed. In addition, they might evolve. The aim of developing UDID essential principles at a global level is to ensure as much interoperability as possible.

Each jurisdiction shall establish its Unique Device Identification Database (UDID) utilizing the same “core identification attributes” as presented in the UDID Attributes section. Furthermore, a globally harmonized method of UDI data exchange should be utilized to facilitate the global exchange of UDI information. These attributes will evolve over time and GHTF could take responsibility of maintaining a worldwide compatibility.

These core identification attributes cannot add new requirements to existing "labeling" requirements.

8.1 Global attributes and their definitions for the UDID are listed below. These global attributes should comply with applicable international standards.

8.2 The manufacturer (or organization otherwise responsible for placing the device on the market) shall be responsible for submitting and maintaining the identifying information and other device attributes in the UDID.

8.3 The data in the UDID is publically available and shall be free of charge.

8.4 The UDID by definition contains all the core identification attributes. The regulators in all jurisdictions shall use these attributes on a mandatory basis in the database.

8.5 UDID Attributes are the following:

- Unique Device Identification Code
This is the static part (device identifier) of UDI code.

- Manufacturer Name

- Manufacturer Contact Information
Address, including Country Name and Contact Point information.

- Nomenclature
Global Nomenclature code (e.g.: GMDN).

- Device Name (generic name)

- Trade Name (Brand Name)

- Device model number (or reference number)

- Controlled by serial and/or lot/batch number and/or manufacturing and/or expiration date - check box [ ]

- Quantity and Packaging level
E.g. Box of ten items, kit of 100 tests

- Size including units of measures (volume / …)
Device size when it is needed clinically, (e.g. 8F catheter).

- Storage conditions (as labeled on the product and/or the IFU) (e.g. needs to be refrigerated)

- Labeled as single use - check box [ ]

- Sterility

Package Sterile – Yes/No

If Yes: Sustainability of the sterile package (Use cases)

- Need to be sterilized before use – Yes/No

- Restricted number of use (number)
Only if the device's label indicates a limited number of use.

- Labeled and /or IFU as containing allergens/materials of concern - Yes/No

If YES
Indicate the name of the allergens/materials of concern (e.g. Latex) (limited list to be defined and managed by the GHTF)

- Regional authorised representatives as labelled (list of countries)
Information about the regional representatives information such as the address or telephone number, when applicable.

- URL for additional information – Web address

- Special Instruction for use
If it is necessary to inform to the user about special indication for the device, such as: “Not to use to the certain Patient”, “Intended Use or Part of Use”…

9. Annex: Outlook of a prospective UDI system fully implemented