



**GHTF Draft Proposal for**

**a draft guidance on**

**Unique Device Identification (UDI) System  
for Medical Devices**

**Authoring Group: GHTF SC UDI AHWG**

**Proposed by the Global Harmonization Task Force**

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## Preamble

This document 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.

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## Rationale for a UDI draft guidance document

The objective of the GHTF UDI ad-hoc working group is essentially to increase patient safety by:

- facilitating traceability of devices
- improving the identification of devices in adverse events
- facilitating field service corrective actions

It is anticipated that a UDI System may facilitate the reduction of medical errors.

The objectives pursued by the ad hoc working group were not:

- to find a solution to counterfeit devices
- to enable better control of purchasing and distribution

To be more specific the aim of traceability translates into the reduction of implication of medical devices in medical errors by:

- Providing a single, globally-accepted source for positive identification of medical devices. Health care professionals and patients will no longer have to access multiple, inconsistent, and incomplete sources in an attempt to identify a device, its key attributes, and a designated source for additional information.
- Ensuring the adequate identification of the device through its distribution and use.
- Providing rapid access to key attributes relating to the device. The UDI system will allow rapid retrieval of information from a dedicated data base system that focuses on the identification of devices.
- Simplifying integration of information on device use into medical records. The UDI system must ensure compatibility with electronic health records.

In addition the traceability capability can facilitate the resolution of device problems, by:

- Making it possible to more rapidly identify devices involved in adverse events. UDIs will be available for inclusion in adverse event reports, allowing greater accuracy in reporting, and more rapid aggregation of related reports.
- Providing for more rapid resolution of confirmed problems. UDIs will allow the Health Authorities to more rapidly collate and analyze problem reports and identify the most-

appropriate solution to a particular concern. UDIs will also allow more accurate target safety alerts, recalls, and other corrective actions on the specific devices that are of concern.

- Providing a single, globally-accepted “key” that can be used to link and integrate existing government, hospital, and corporate data bases that relate to medical devices. UDIs will allow for improved procurement, inventory management, and accounting. The existence of a “key” to link disparate data bases will allow creative new medical and business applications, and synergy among those applications.

### **Implementation issues of a global UDI**

Labelling requirements will be phased in over a period of some years.

The true benefit, in terms of patient safety, will only be achieved if all stakeholders (from manufacturer through to healthcare providers) use the globally harmonized UDI system.

Local deviations (regional or country) will have negative impact on the main objective to increase patient safety. The risk that the entire UDI concept would become inconsistent and unmanageable is very high. Therefore the GHTF Ad Hoc Working Group strongly recommends to avoid those deviations.

Due to the huge diversity of the medical device product portfolio a risk-based approach is essential. The ‘difficult to manage’ assortment needs to be divided into portions, which can be handled easily.

Medical devices are defined by different classes, according to their risk with regard to patient safety. Risk class systems are effectively used around the world and are therefore the basis for the UDI marking requirements.

Medical devices need to be marked on the different packaging levels according to their risk class. Also the data granularity varies. The decision tree in Annex II should serve as guidance. This decision tree describes the minimal requirements. To encode more data into the AIDC carriers or to mark more packaging levels is allowed.

The stepwise implementation process (for the UDI marking as well as the UDI Database), starting with medical devices belonging to the highest risk calls first, will help to reduce its complexity. All supply chain stakeholders will need sufficient time frames to prepare their systems, processes and staff, for the proper use of the UDI system. Between each implementation step it is planned to analyze the achieved results and make system adjustments, if necessary.

The UDI system by definition shall facilitate traceability. But it is not intended to administer any dynamic supply chain data (i.e. ePedigree information) within the UDI database. That has to be defined and organized outside the UDI guidance.

An important aspect regarding the effectiveness of the entire UDI system is the education of its users along the supply chain (from manufacturers to healthcare providers). Proper actions need to be planned and performed in time by the regional regulatory authorities.

The Ad Hoc Working Group realize that several other issues will have to be addressed by the Administrations in charge of the implementation phase, such as the UDI for capital equipments with multiple subassemblies, for kits...

The activities of this Ad Hoc Working Group were by nature 'open-ended'. It is clearly the involvement of the competent Administrations for the implementation which is important as the final design phase. The draft guidance proposed by the Ad Hoc Working Group ambition is to pave the way for a single and global Unique Device Identification of Medical Devices.

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## **1. Introduction**

In the interests of patient safety against a background of globalisation it is desirable to address traceability of medical devices at a global level. A key element in achieving global traceability of medical devices is the development of a Unique Device Identifier (UDI). The primary aim of a UDI System 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, in the fight against counterfeiting.

In addition, the development of an international approach will make the medical device market more secure for all the stakeholders (health authorities, hospitals, manufacturers, distributors, etc).

This is why many regional regulatory authorities and industry at large see the introduction of UDI as an effective tool in the efficient protection of public health. It is mainly for patient safety reasons that all the actors in the sector support the development of 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. The design and construction of a UDI System should be addressed in a forum like GHTF, in order to encourage the use of a harmonised UDI System by all regulatory jurisdictions. Therefore the aim of this UDI Ad Hoc Working Group (AHWG), established at the Ottawa GHTF Steering Committee (SC), is to ensure the design of a globally acceptable UDI System.

The aim of this document is to pave the way for the establishment of a global UDI System in the medical device sector. It provides guidance to build a global UDI System. Further additional guidance may need to be developed once these core elements are accepted.



## **2. Rationale, purpose and scope**

### **2.1 Rationale**

There is currently no global definition of what constitutes a UDI System. As a consequence, discrepancies between different national approaches do exist and will most likely increase.

Common worldwide UDI requirements would offer significant benefits to manufacturers, users and/or patients, and Regulatory Authorities.

In addition, eliminating or reducing differences between jurisdictions decreases the cost of gaining regulatory compliance.

In order to achieve global traceability the UDI System 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 System is to improve patient safety by:

- facilitating traceability of devices**
- enhancing the identification of devices in case of adverse events,**
- assisting in the event of a field safety correction**

**It is anticipated that a UDI System may facilitate the reduction of medical errors.**

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

- create, use and maintain a unique "Device Identifier"**
- develop and apply a "UDI Carrier"**



- establish the "UDI Database" with a defined list of Data Elements

### 2.3 Scope

This document applies to all products to be placed on the market 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"*". Replacement components or spare parts (e.g. power cord, circuit board) used for servicing or maintenance of a Medical Device are exempt from the requirements of this document.

## 3. References

### GHTF final documents

- SG1/N29:2005      [Information Document Concerning the Definition of the Term "Medical Device"](#)
- SG1/N43:2005      [Labelling for Medical Devices](#)
- SG1/N055:2009      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

When considering International standards relevant to UDI, within the scope of work of ISO/IEC JTC 1/SC 31, the Sub-committee responsible for Automatic Identification and Data Capture Techniques standardization [http://www.iso.org/iso/iso\\_technical\\_committee.html?commid=45332](http://www.iso.org/iso/iso_technical_committee.html?commid=45332), there are many standards that may apply.

When considering the AIDC identification and marking aspects of UDI, attention should be directed to the scope of work and complete body of standards of this group for applicable



documents. Other healthcare related standards may also be relevant, e.g. those of GS1 Healthcare and Health Industry Business Communication Council (HIBCC).

## **4. Definitions**

### **UDI**

UDI means Unique Device Identifier. The UDI is a series of numeric or alphanumeric characters 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 related information stored in the UDI Database. The UDI comprises the Device Identifier and Production Identifier.

Note: The word "Unique" does not imply serialisation of every single device, e.g. those devices marketed in lots and batches.

### **UDI System**

The framework for the production of a Unique Device Identifier (UDI), the application of the UDI on the label or directly on product, and the storage of the UDI and additional device related information in a UDI Database.

#### **UDI - Device Identifier (static)**

Is a unique numeric or alphanumeric code specific to a medical device and that is also used as the "access key" to information stored in a UDI Database.

#### **UDI - Production Identifier (dynamic)**

Is a numeric or alphanumeric code providing information reflecting how the device is controlled. The different types of Production Identifier(s) can include any combination of serial number, lot/batch number, manufacturing or expiration date.



### **UDI Carrier**

UDI Carrier is the means to convey the UDI by using automatic identification and data capture (AIDC)<sup>1</sup> and if applicable human readable information (HRI).

### **UDI Database (UDID)**

The UDID is an organized collection of information associated with medical device identification and labelling.

### **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. GHTF/SG1/N43:2005

### **Labelling/ information supplied by the manufacturer**

Written, printed or graphic matter

- affixed to a medical device or any of its containers or wrappers, or,
- accompanying a medical device,

relating to identification, technical description, and use of the medical device, but excluding shipping documents.

Note: Some regional and national regulations refer to 'Labelling' as 'Information supplied by the manufacturer' (Source – ISO 13485) GHTF SG1/N43:2005

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<sup>1</sup> See Annex I (list of AIDC)



## **Manufacturer**

“Manufacturer” means any natural or legal person<sup>2</sup> with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s). GHTF SG1/N055

## **Primary packaging**

Primary packaging is the material that first envelops the product and holds it. For sterile packaging, the primary package can be any combination of the sterile packaging system.

## **5. Guidance for the UDI System**

A UDI System for medical devices shall 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 Carrier should be technology neutral. National or regional regulatory requirements shall not restrict methods of AIDC as this will hinder the establishment of a global UDI System.

5.1 The marking of the device with its UDI shall be an additional labelling requirement.

5.2 The manufacturer shall be responsible for creating and maintaining the uniqueness of its medical device UDI throughout all jurisdictions world-wide. All along the supply chain the UDI created by manufacturer shall not be altered.

5.3 Internationally accepted coding systems such as GS1 and HIBCC, meet the criteria of the UDI and manufacturers shall be permitted to choose which system to use. It is imperative that these coding systems be adopted and implemented, without national deviations or changes to these otherwise global standards.

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<sup>2</sup> The term “person” that appears here includes legal entities such as a corporation, a partnership or an association



5.4 Globally accepted AIDC methods based on ISO standards shall be used.

5.5 The UDI Carrier shall be on the label of the device or on the device itself.

5.6 The manufacturer is responsible for maintaining the accessibility of their UDI and the related information (UDI Database).

5.7 The National/Regional regulation for UDI System shall include a robust process for evaluating and adjudicating applications for UDI exemptions.

## **6. UDI**

6.1 The assignment of a UDI to a device shall follow international medical device identification standards allocation rules. A significant change to device characteristics requires in any case that a new UDI must be allocated to the product.

6.2 Reprocessors of single use devices (SUD) shall create a new UDI. All requirements of this document shall apply to the reprocessed SUD. The reprocessor is responsible for ensuring that the reprocessed device cannot be confused with the original SUD.

6.3 Remanufacturers shall create a new UDI. All requirements of this document shall apply to the remanufactured device. In addition the remanufacturer shall retain record of the OEM's UDI.

6.4 The UDI contains two parts the Device Identifier and the Production Identifier.

6.5 The two parts and their elements must be individually identifiable.

6.6 The UDI shall be based on international medical device identification standards.

6.7 The Device Identifier part of the UDI identifies the specific device.

6.8 The Device Identifier is a series of numeric or alphanumeric characters that has no inherent meaning, i.e. information should not be directly extracted from the UDI. The Device Identifier is globally unique and is the primary key used to access information about the device stored in the UDI Database (UDID).



6.9 The Production Identifier specifies the particular production unit i.e. serial number, and/or batch, or lot number. If the label has an expiry date, it shall be part of the UDI Production Identifier. If the device does not have a serial and/or batch or lot number, the manufacture date shall be used.

6.10 The different types of Production Identifiers (see 6.9) included in the UDI will depend on the risks associated with the distribution and use of the device. Based on this risk assessment certain devices do not require Production Identifiers as part of the UDI. (see annex II: decision tree).

## **7. UDI Carrier and placement**

7.1 When AIDC carriers other than the UDI Carrier are part of the product labelling, the UDI Carrier shall be readily identifiable. Carriers not intended to be part of the UDI System, but which serve other purposes, are not subject to the specific UDI requirements/standards.

7.2 No particular AIDC methods should be required. Any type of data carrier is acceptable, that is based on ISO and recognized by the organisations that produce international medical device identification standards such as: GS1 and HIBCC.

7.3 If linear bar codes are used, the Device Identifier and the Production Identifier(s) can be concatenated or non-concatenated in two or more bar codes. All parts and elements of the UDI bar code shall be distinguishable and identifiable.

7.4 The UDI should be human readable and encoded in an AIDC format.

7.5 If there are significant space constraints limiting the use of both forms on the label, the AIDC format shall be favoured. However, certain environments or use situations, such as home care, may warrant the use of human readable over AIDC.

7.6 In case of RFID, human readable information and bar code shall also be provided.

7.7 The UDI Carrier should be readable at least throughout the intended use of the carrier.



7.8 If the UDI Carrier is readable through the primary packaging then UDI Carrier does not need to be also on the primary package.

7.9 Durable devices, devices that are not packaged, or devices that require reprocessing, cleaning, sterilization or adjustment between patients' use should be directly marked with a permanent UDI Carrier, in addition to marking on the primary package if applicable.

The directly marked UDI Carrier shall survive reprocessing in line with manufacturer instructions.

7.10 If there are multiple parts or components to the finished assembled devices the UDI is required only on one part.

7.11 Direct part marking may not be possible or warranted on some devices due to size, design, materials, processing, or performance issues.

7.12 The placement of the UDI Carrier shall be done in a way that AIDC method can be used during normal operation or storage. The UDI Carrier shall be accessible / visible for the user.

7.13 The UDI Carrier for low risk devices packaged and labelled individually does not need to be on the primary package but rather on a higher level of packaging<sup>3</sup>, e.g. "shelf pack". However, when it is intended by the manufacturer that the user does not have access to the higher level of packaging, the UDI should be on the primary packaging and at the minimum being human readable.

7.14 Kits shall have their own UDI. 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. Note: Jurisdictions may differ in their definition of kit. UDI requirements pertaining to kits should follow the definition of kit in the jurisdiction where the product is being distributed.

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<sup>3</sup> Primary packaging usually is the smallest unit of distribution or use and may be the package which is in direct contact with the contents. For sterile packaging, the primary package can be any combination of the sterile packaging system. Secondary packaging is outside the primary packaging, perhaps used to group primary packages together, e.g. "shelf-pack".



7.15 For devices sold only at retail POS (Point of Sale), the Production Identifier does not need to be encoded in all instances.

7.16 Marking of the higher level packaging shall be different from the UDI of the devices inside.

## **8. UDI Database**

In this document, the wording UDI Database (UDID) refers to a global conceptual Database which in practice may consist of a single internationally accessible database or a network of Regional UDI Databases which should be able to communicate with each other. As a matter of consequence, for the manufacturer, only one unique submission into a regional Database should be required. All UDID data elements are required, unless indicated otherwise. “If applicable” means the information shall be in the UDID when it appears on the label.

8.1 No product commercial confidential information shall be included in the UDID.

8.2 The UDID data elements should not be used to create new national regulatory requirements.

8.3 Global data elements and their definitions for the UDID are listed below. Data field attributes, such as alphanumeric and field length should be harmonized with internationally accepted standards (e.g.: Date format, field syntax ...).

8.4 The manufacturer shall be responsible for submitting and maintaining the identifying information and other device data elements in the UDID.

8.5 The data in the UDID is publicly available and shall be free of charge.

8.6 The presence of the device on the UDID does not mean that the device is approved for use in all jurisdictions.

8.7 The database should allow for the linking for all the packaging levels of the product.

8.8 In case the UDI Carrier is not on the primary package, a specific code should be allocated to the product in the database, which will serve as an additional identifier.



8.9 UDI Data Elements are the following:

**- Device Identifier**

**- Manufacturer Name (as represented on the label and/or instruction for use)**

**- Manufacturer address structure**

Street

Town

Country

Phone

Email

**- Contact Information (if different from manufacturer)**

Address, including Country and point of contact

**- Nomenclature**

Global Nomenclature code (such as GMDN).

**- Nomenclature term**

Such as generic (GMDN term)



- **Trade Name** (Brand Name) **if applicable**

- **Device model number** (or reference or catalogue number) **if applicable**

- **Controlled by: check all that apply**

serial

lot/batch number

manufacturing

expiration date

- **The Device Identifier can be found on:**

Unit of measure: (e.g. each, box, pack...)

Quantity per unit of measure: (e.g. 10, ...)

- **In case of different levels of packaging, parent/child relationship shall be provided**

- **Other alternative Device Identifiers (if applicable)**

E.g. GTIN and HIBC been concurrently used



**- Size, Volume, Length, Gauge, Diameter (if applicable)**

E.g.: Should include clinically relevant characteristics such as measurement, size appropriate to the product (e.g. 8F catheter).

**- Additional product Description (optional)**

Additional clinically relevant information: Free text

**- Storage and handling conditions (as labelled on the product and/or in the IFU)**

Temperature range

Relative humidity range

Pressure range

Avoid direct sunlight

[Yes /No]

**- Labelled as single use**

[Yes/No]

**- Sterility**

Sterile package

[Yes/No]



If "No": Need to be sterilized before use

[Yes/No]

**- Restricted number of reuses (if applicable)**

[ ]

**- Labelled as Containing Latex**

[Yes/No]

**- Authorised Representatives (list of countries) (if required by the local / regional regulatory authority)**

Information about the regional representative's information such as the address or telephone number, when applicable.

Name

Address

Email

Telephone

**- License or marketing authorization or registration number / code (if required by the local regulatory authority)**



**- URL for additional information – Web address (optional)**

e.g.: Electronic IFU

**- Critical Warnings or Contraindication (if applicable)**

As on the label, if a particular regulation requires that the label of the device contains critical warnings or contraindications associated with the use of the device.

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## 9. Annexes

### 9.1 Annex I

## Data Carrier Illustrations (samples)

GS1-128 nonconcatenated



(01) 2 081019001 002 4



(17)080100(10)1Q34

GS1-128 concatenated



(01)00681490024464(17)090115(10)H612

EAN13



4 022495 212825

EAN13 Composite



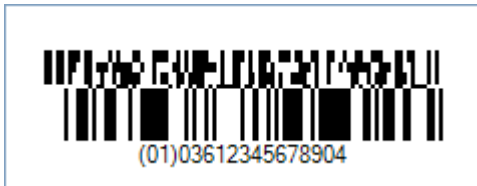
3 312345 678903



GS1-DataMatrix



GS1-DataBar Truncated Composite



Codablock F



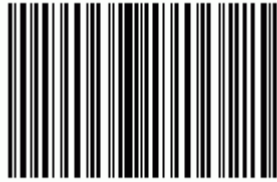
QR Code



PDF417

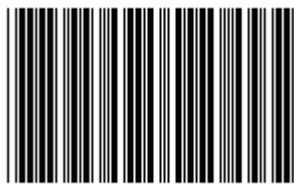


Code128



123456789012345678

Code39



C O D E 3 9

Code39 (HIBC – primary + secondary)



\*+A123B123450/\*



\*+\$\$810494121523SN6543D\*

Codes128 (HIBC – primary + secondary)



\*+A123PROD789053\*

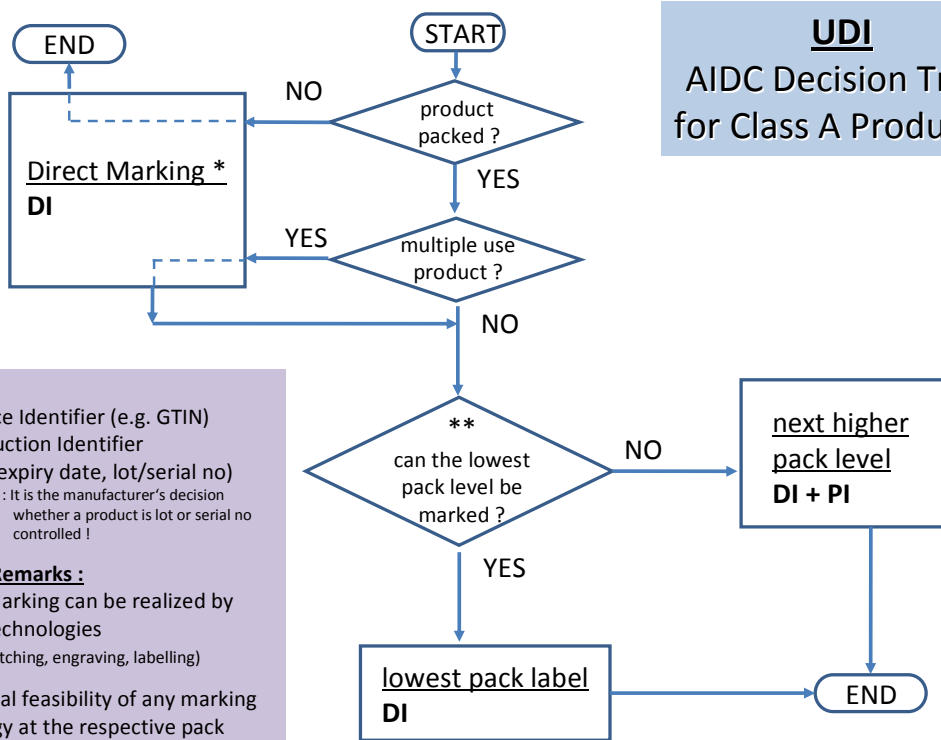


\*+\$\$810494121523SN6543D\*



9.2 Annex II

**UDI**  
AIDC Decision Tree  
for Class A Products



**Legend**  
 DI = Device Identifier (e.g. GTIN)  
 PI = Production Identifier  
 (e.g. expiry date, lot/serial no)  
 remark : It is the manufacturer's decision whether a product is lot or serial no controlled !

**General Remarks :**  
 \*Direct Marking can be realized by various technologies  
 (e.g. laser etching, engraving, labelling)

\*\*technical feasibility of any marking technology at the respective pack level (or prod. itself) is a prerequisite (e.g. sufficient space, substrate or packaging material suitable etc.)

