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DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

Harmonizing Unique Device Identifiers: Issues and Solutions

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The Intent of the use of Unique Device Identifiers

- Serve important regulatory and supply chain functions for medical devices
- They allow for tracking of devices throughout the global supply chain to the patient
- UDI provides global visibility to device adverse event reporting and a better means to perform post-market surveillance, thereby enhancing patient safety

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Issues affecting the adoption of UDI

- Lack of harmonization within jurisdictional UDI databases leading to additional administrative burden

Grouper	Source	Data Element	Description
Latex	EU	Containing Latex	An indication of whether the device or packaging is labelled as containing natural rubber that comes in contact with humans
Latex	IMDRF	Critical warnings or contraindications	a. [e.g.: Labeled as containing latex? (Yes/No),
Latex	US	Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437).	Indicates that the device or packaging contains natural rubber that contacts humans as described under 21 CFR 801.437. Choosing 'Yes' indicates that the device label or packaging contains one of the following statements: (1) "Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions", (2) This Product Contains Dry Natural Rubber", (3) Caution: The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions" or (4) "The Packaging of This Product Contains Dry Natural Rubber". ¶ ¶ Choose Yes/No from the drop down list.

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Issues affecting the adoption of UDI

- Rules built into the regional databases that cause creation of new device identifiers when a data element is changed

	FDA	GS1	EU	IMDRF	KR
Change in the Issuing Agency (e.g., GS1 or HIBCC)	X				
Change in the Device Count (quantity)	X	X	X	X	
Change in the Brand Name (this is the "family" name for a product)	X	X	X	X	X
Change in the version or model number on the device label or accompanying packaging used to identify a category or design of a device.	X		X	X	
Change in the device classification of a kit (e.g., Class III to Class II)	X				
Change in the Single Use status of a device or accessory	X		X	X	
Change in the Latex Content (i.e., required to be labeled as containing Latex)	X				
Change in the MRI Safety Status	X				
Change in the Device Packaged as Sterile Status (i.e., device/accessory is packaged sterile or if a device/accessory requires sterilization prior to use)	X		X	X	

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Issues affecting the adoption of UDI

- Lack of direct “translation” between different Issuing Entities

GS1 – Global Trade Identification Number: GTINs may be eight, 12, 13, or 14 digits long, and each of these four numbering structures are constructed in a similar fashion, combining Company Prefix, Item Reference and a calculated Check Digit (GTIN-14 adds another component- the Indicator Digit, which can be 1-8). GTIN-8s will be encoded in an EAN-8 barcode. GTIN-12s may be shown in UPC-A, ITF-14, or GS1-128 barcodes. GTIN-13s may be encoded in EAN-13, ITF-14 or GS1-128 barcodes, and GTIN-14s may be encoded in ITF-14 or GS1-128 barcodes. The choice of barcode will depend on the application; for example, items to be sold at a retail establishment could be marked with EAN-8, EAN-13, UPC-A or UPC-E barcodes.

HIBC - The HIBC LIC Primary Data Structure format encodes a “+” identifier of the HIBC Supplier Data Structure, a 4 character Labeler Identification Code (LIC), a 1 to 18 character Product or Catalog Number (PCN), a one-digit Unit of Measure Identifier (U/M), and a single-digit Check Character (C).

ICCBBA - Data structures generally comprise two elements: • Data identifier: a two or three-character code that identifies the data structure)and • Data content: the data characters that provide the information to be conveyed (e.g., coded information that conveys the unit is A, RhD positive).

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Issues affecting the adoption of UDI

- Varying definitions of terms and concepts between jurisdictions causes creation of new UDI-DIs to accommodate different rules

> The term model/brand is of particular concern because these terms differ between jurisdictions. For example, in the US, this term comes from the information found on the device label or accompanying packaging used to identify a category or design of a device. The version or model identifies all devices that have specifications, performance, size, and composition within limits set by the labeler. In the US this is a required term, whereas in the EU, this term is optional, if applicable, and is used to describe the device model, reference, or catalogue number. There are a number of terms that follow this logic of one jurisdiction making the data element mandatory whereas other jurisdictions make the data element as optional (or applicable).

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Issues affecting the adoption of UDI

- UDI AIDC Symbology requirements emerging w/o regard for the UDI issuing entity standards or the ability to read these symbols in the global supply chain

Established Standard:	For Identification of:	Barcode Symbology:
UPC-A or UPC-E	items for sale in the USA and Canada	UPC/EAN
EAN-8 or EAN-13	items for sale worldwide	UPC/EAN
ISBN, ISSN & Bookland	books and periodicals	EAN-13 with UPC/EAN
UCC-128, EAN-128 or SSCC-18	shipping cartons	Code 128
SCC-14	shipping cartons	Interleaved 2 of 5 or Code 128
EAN-14	shipping cartons	Interleaved 2 of 5 or Code 128
SSCC-18	shipping cartons	Code 128
SISAC	serial numbers for serial publications	Code 128
SICI Code	serial numbers for serial publications	Code 128
POSTNET	US mail addresses for the US Post Office	POSTNET
USPS Special Services	US mail return receipts and registered mail	Interleaved 2 of 5 or Code 128
MICR	bank checks	MICR E-13B or CMC-7
LOGMARS	United States Department of Defense standard	Code 39

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Issues affecting the adoption of UDI

- Direct marking of devices is not consistently defined; implementation is being delayed until there is a better understanding

The concept of direct marking is also inconsistent jurisdiction to jurisdiction. Various means of permanent marking may be selected by industry to meet the requirements for direct marking. These may include, but is not limited to a label, indelible label, a placard, etching, etc. The concept of when to direct mark is also not aligned as indicated below:

US	EU	KR
High level disinfection & sterilization	High level Cleaning, High level disinfection & sterilization	Reusable product – this was defined to mean the same as the EU

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Issues affecting the adoption of UDI

- Lack of focused education for healthcare delivery organizations and system preparation

As stated in the IMDRF document **IMDRF/UDI WG/N54 FINAL:2019,** the benefits of UDI strongly rely on effective integration of the UDI to support various regulatory activities during the lifecycle of medical devices[1] and uptake of UDI across the whole healthcare sector.

Those benefits are more likely be achieved when the UDI is recorded in real world electronic health systems (e.g. electronic health records (EHRs), device registries, material management systems, and reimbursement data) and used as part of real world evidence to improve clinical and regulatory decision making.

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Current Concerns from the Regulators, Industry and HealthCare

- These issues are contradictory to the spirit of UNIQUE Device Identification and potentially hamper the global interoperability of the UDI system – Industry has been slow to adopt the use of UDI for a global purchasing process and continues to use REF as the identifier for purchasing
- These issues affect traceability of medical devices, adverse event reporting, global data sharing and transparency, and ultimately result in inefficient processes, higher cost and a decrease of patient safety

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Proposed Solutions to address the Issues

- Jurisdictions should adopt the IMDRF UDI guidance documents N7: 2016 Common Data Elements for Medical Device Identification & N48:2019 Unique Device Identifier (UDI) Application Guide
- Jurisdictions should consider the guidance from IMDRF N53:2019 Use of Data Elements Across IMDRF Jurisdictions
- Actively participate in this DITTA workshop to discuss these concerns
- Submit a NWIP for the update to N48 and N53 to support a globally harmonized approach to the implementation of a UDI system
- Implement according to UDI Issuing Entities together with relevant IEC and ISO standards

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