



*DITTA White Paper on Unique Device Identification:*

***Challenges with Implementing Global Unique Device Identification Requirements and Solutions***

## Executive Summary

### Purpose

*Challenges with Implementing Global Unique Device Identification Requirements* describes the current variability of unique device identification (UDI) requirements and implementation globally. While many expectations remain harmonized, there are elements of the global UDI system that are starting to deviate from its original intended harmonization, causing challenges for medical device manufacturer supply chain compliance. This is contrary to the purpose of the UDI system implementation, which is to increase transparency and standardization (among other elements). This is also leading to an inefficient and ineffective process with potential impact on patient safety.

This document describes some of these challenges and inconsistencies that industry has experienced as well as provides recommendations on improvements that can standardize and enable regulators implement global strategies which will improve adoption, usage and benefits of UDI requirements. , implementation and usage – in line with the expectations of the collaborative approach seen by the IMDRF working group and related documents.

The recommendations described in this document focus on people, processes, and master data management.

DITTA recommends that

The International Medical Device Regulators Forum (IMDRF):

- Update N48 UDI System Application Guide, N53 Use of UDI Data Elements Across Different IMDRF Jurisdictions, and N7 UDI Guidance: Unique Device Identification of Medical Devices to support a globally harmonized approach to the implementation of a UDI system (consider expanding this bullet to include specific “what” and “why” for each of the documents)
- Support manufacturers and regulators through continued educational seminars and workshops
- Regulators:
  - Ensure regional regulations and standards align with wording in the IMDRF guiding documentation. Eliminate the introduction of region-specific requirements or processes, when possible.
  - Consider adopting the IMDRF UDI guidance documents N7: 2016 Common Data Elements for Medical Device Identification & N48:2019 Unique Device Identifier (UDI) Application Guide
  - Adhere to processes set forth by UDI Issuing Entities and other recognized standards such as IEC and ISO standards.
- Medical device manufacturers:
  - Enable digitized, machine-to-machine publication (consider cost of implementing a digitized solution vs. cost of sustaining manual labor)
  - Develop global product structures (consider implementing a global, cross-functional strategy for product management vs. sustaining disconnected, regional processes)

### Document Structure

For each challenge identified, the following information is provided:

- a. Identification of global requirements governing the UDI topic (including references to applicable regulations and/or standards) and the challenges / barriers industry has in meeting those requirements
- b. Suggestions for global UDI requirement harmonization opportunities



## CONTENTS

Introduction.....	5
Document Scope.....	5
References.....	5
IMDRF Documents.....	5
Global UDI Regulations and/or Standards.....	5
GS1 Standards.....	6
Acronymns.....	6
Challenge #1: Inconsistent requirements between global regulations and Issuing Entities.....	7
IMDRF Intent.....	7
Problem Statement.....	7
Inconsistencies in Governing Regulations.....	7
Inconsistent Issuing Entity Data Formats.....	7
UDI Exemptions and Exceptions.....	9
Device Identifier Allocation Rules.....	9
Challenge #2: Non-standard definitions for UDI elements.....	10
Challenge #3: Emerging nomenclature systems and identification symbology.....	12
Challenge #4: Lack of harmonization between global UDI databases.....	12
Challenge #5: Expansion of Regional UDI Requirements.....	15
Challenge #6: Lack of focused education for healthcare delivery organizations.....	16
Recommendations.....	17
Conclusion / Summary.....	17

## Introduction

Unique Device Identifiers (UDIs) serve important regulatory and supply chain functions for medical devices:

- They allow for tracking of devices throughout the global supply chain to the patient.
- They provide global visibility to device adverse event reporting.
- They provide a better means to perform post-market surveillance, thereby enhancing patient safety.
- Provide access to additional product information that supports the above activities which usually is not contained within the traditional label information

The International Medical Device Regulators Forum (IMDRF) established a harmonized global proposed infrastructure for a UDI system of requirements (N7:2013 and N48:2019) with the intent to improve patient safety, traceability, post-market surveillance, and support supply chain efficiency. However, as regulators globally start building and deploying regionally the UDI systems and infrastructure, we are seeing an increasing trajectory of non-harmonized requirements challenge manufacturers' compliance, 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. The challenges described in this document focus impact on processes and implementation.

## Document Scope

This document describes the emerging trend of global de-harmonization from IMDRF and the challenges industry is facing with complying with this trend. It further delves into specific examples, concerns and recommendations to resolve these emerging challenges. It is important to note that this document, while it includes both implemented and emerging regulation regulations, it is not meant to be all-inclusive as it will not reflect all the emerging challenges around non-harmonized requirements. It represents the various categories of challenges that medical device manufacturers are experiencing.

## References

### IMDRF Documents

- N7:2013 Unique Device Identification guidance document
- N19:2016 Common Data Elements for Medical Devices
- N48:2019 Harmonized Unique Device Identification (UDI) Application Guide
- N53:2019 Use of UDI Data Elements across different IMDRF Jurisdictions

### Global UDI Regulations and/or Standards

- Brazil ANVISA | RDC/ANVISA No. 591 Unique Medical Device Identification System (2021)
- China NMPA | Rules for the Unique Device Identification System for Medical Devices (2019)
- Columbia MHSP | Resolution No. 1405 Semantic standard and coding for medical devices (2022)
- Ecuador ARCSA | Resolution ARCSA-DE-013-2020-MAFG Sanitary Control and Surveillance (2020)
- European Union Commission | MDR Regulation 2017/745
- India CDSCO | India Medical Device Rules (IMDR) (2017)
- Japan | Resolution 913-2 Codes on Containers to Identify Medical Devices and In-Vitro Devices (2022)
- Saudi Arabia SFDA | MDSG-G34 Guidance on Requirements for Unique Device Identification (UDI) for Medical Devices (2020)
- Singapore HSA | Guidance on Medical Device Unique Device Identification (UDI) System (2021)
- South Korea MFDS | Medical Device Law
- Taiwan | Labeling Requirements for Unique Device Identification (2021)

- US FDA | 21CFR 801 Labeling
- US FDA | 21CFR821 Medical Device Tracking
- US FDA | 21CFR830 Unique Device Identification
- US FDA | Federal Register 78: Final Rule on UDI

## GS1 Standards

- Application Identifiers
- Basic UDI
- General Specifications
- GTIN Management Standard

## Acronyms

Acronym	Definition
AIDC Symbology	Automatic Identification and Data Collection- used to collect information without manual data entry
Basic UDI	The access key for device-related information entered in the EUDAMED database
Device Identifier	A mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device
EMDN	European Medical Device Nomenclature
GMDN	Global Medical Device Nomenclature
GTIN	Global Trade Item Number
<b>Issuing Entity</b>	
UDI	Unique Device Identifier
UDI-DI	Device Identifier
UDI-PI	Production Identifier
Master UDI	

Table 1

## Challenge #1: Inconsistent requirements between global regulations and Issuing Entities

### IMDRF Intent

IMDRF identified the critical need for the harmonization of UDI data across the various jurisdictions in order to achieve the intent of the UDI directive.

### Problem Statement

When medical device manufacturers commercialize products globally, they must comply with all applicable regulations and standards. When those requirements are harmonized, a single product solution can meet the expectations. However, when those requirements are not harmonized, manufacturers must complicate their commercial offerings to ensure all requirements are met. Below are a few examples in non-standard requirements.

### Inconsistencies in Governing Regulations

Product Marking and /or labelling:

There are two types of UDI product Marking / Labelling that is not applied consistently across jurisdictions:

- Direct Marking
- Product Labeling

Direct Marking - In regard to the definition of Direct Marking – this is defined inconsistent across the various 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.

Product Labelling – The requirements for what content is required on Product Labeling are not harmonized, as shown by examples in Table 1 below. Non-harmonized labeling requirements prevent manufacturers from establishing global labeling procedures and require localized processes/execution. In addition, they also create a challenge around clarity of labelling for the healthcare providers and consumers, as more information on label results in smaller font and potentially confusing labelling.

TABLE 1: PRODUCT LABELING REQUIREMENTS

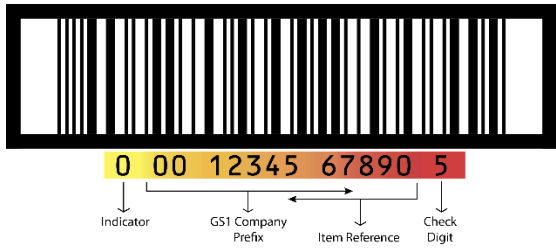

Component	IMDRF	US FDA	EU MDR	Korea	China
Device Identifier	Required	Required for all classes			
Product Identifier(S)	Required	Required for Class 2 and 3 only (not required for Class 1)	Required for all classes		

### Inconsistent Issuing Entity Data Formats

There are currently three globally recognized issuing agencies: [GS1](#), [HIBC](#), and [ICCBBA](#). Each Issuing Agency uses a different format for a device identifier. Table 2 below describes the difference in formats between these issuing agencies.

These differences and non-standardized formats complicate automated scanning/analysis of barcodes and capture of device information in digitized systems. It also makes comparison of device information for “like” devices challenging.

TABLE :2 ISSUING AGENCY DEVICE IDENTIFIERS

Issuing Agency	Format	Description	Example
<p>GS1 =</p>	<p>Global Trade Item Number (GTIN)</p>	<p>Length: 8, 12, 13, or 14 digits long</p> <p>Components:</p> <ul style="list-style-type: none"> <li>• Company Prefix</li> <li>• Item Reference</li> <li>• Calculated Check Digit (GTIN-14 adds another component- the Indicator Digit, which can be 1-8).</li> </ul> <p>Format: 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.</p> <p>Note: China requires an additional filing authorization declaration.</p>	 <p>The example shows a barcode with the number 0 00 12345 67890 5 below it. Arrows indicate the components: 'Indicator' points to '0', 'GS1 Company Prefix' points to '00', 'Item Reference' points to '12345' and '67890', and 'Check Digit' points to '5'.</p>
<p>HIBCC</p>	<p>LIC Primary Data Structure</p>	<p>Length: 8 – 25</p> <p>Components:</p> <ul style="list-style-type: none"> <li>• HIBC Supplier Data Structure</li> <li>• Labeler Identification Code (LIC)</li> <li>• Product or Catalog Number (PCN)</li> <li>• Unit of Measure Identifier (U/M)</li> <li>• Check Character (C)</li> </ul> <p>Format: Supplier Data structure identified as "+". LIC shown as 4-character, alphanumeric string. PCN consists of contains 1–8-character, alphanumeric</p>	 <p>The example shows a barcode with the alphanumeric string '+A123ABCDEF GHI1234567891E' below it.</p>



		string. U/M and check character each shown as 1 numeric character.	
ICCBBA	ISBT-128	<p>Length: 18</p> <p>Components:</p> <ul style="list-style-type: none"> <li>• Data identifier</li> <li>• Device Identifier</li> </ul> <p>Format: Data identifier (not printable) represented by 2-3 characters that identifies the data structure. Device Identifier is alphanumeric string containing Facility Identification Number, Product Code, and Product Description Code.</p>	<p style="text-align: center;">A 9 9 9 7 A B 3 4 5 6 T 0 1 2 3</p> <div style="display: flex; justify-content: space-around; text-align: center;"> <div style="width: 30%;"> <p>Facility Identification Number of the Facility Assigning the Product Codes</p> </div> <div style="width: 30%;"> <p>Facility-Defined Product Code or FPC</p> </div> <div style="width: 30%;"> <p>Standardized Product Description Code or PDC</p> </div> </div>

### UDI Exemptions and Exceptions

The expectation for medical device manufacturers is to develop products whose labels and markings meet all UDI requirements for a particular region in which their products are commercialized, except where explicitly stated within the applicable regulation.

When certain requirements are exempted in some regions but not others, it makes development and distribution of products challenging.

Example: With regard to traceability solutions for multidevice surgical sets, there is an exemption in the US. However, there is no exemption in the EU.

### Device Identifier Allocation Rules

Device identification numbers are allocated based on the medical device status within a particular region. All current UDI regulations require all medical devices to be identified. However, when the medical device status of a product is different between regions (e.g., product identified as a medical device in Europe but not in the United States), there is ambiguity in how to manage these differing UDI requirements.

## Challenge #2: Non-standard definitions for UDI elements

When defining the data elements associated with a medical device, global UDI regulations include definitions of those elements to ensure understanding of what is expected. However, a comparison of these definitions (as shown in Table 3 below) shows that different terms are used to represent the same intended information.

TABLE 3: TERMS AND DEFINITIONS

Definition / Intended Information	IMDRF	US FDA	EU MDR	Korea	China
Term to identify a medical device	Brand Name	Brand Name	Name/device Model	Product Model Name	Trade name
Medical devices that are reusable should have a UDI Carrier on the device itself in way that the AIDC method can be accessed during normal operation and storage	Reusable devices that require reprocessing between patient uses.	Reusable products requiring cleaning and disinfection/sterilization between patients must have UDI directly marked on device.	All reusable devices	Devices that are either – intended to be reused in medical institutions (e.g. hospitals, clinics, etc.) or must be sterilized before use – and are on a list of product categories to be published by MFDS must include a UDI carrier directly marked on the device itself. The list has not been published yet.	
Information related to “latex”	Critical warnings or contraindications (included in dropdown list of values)	Device required to be labeled as containing natural rubber latex or dry natural rubber (Yes/No)	Containing Latex (Yes/No)		

Information related to a product license, authorization, and/or registration number	License and/or marketing authorization or registration number	FDA Listing Number -or- FDA Premarket Submission Number -or- Supplement Number	Single Registration Number		
---	---	--	----------------------------	--	--

The result of the above difference in terminologies / definitions is that in order to meet the regulatory expectations, medical device manufacturers create new UDI device identifiers and/or new regional-specific data elements to accommodate different rules.

## Challenge #3: Emerging nomenclature systems and identification symbology

It is important to be able to identify medical devices throughout their product lifecycle. Identification should be unique and detailed. However, competing identification strategies introduce ambiguity in identification.

### **Nomenclature Systems**

One mechanism to categorize products is with a medical device nomenclature code. However, there are several, competing nomenclature codes in existence:

- GMDN- Global Medical Device Nomenclature
- SAM (US only)-Unique Entity Identity
- EMDN (EU only)- European Medical Device Nomenclature
- CMD (Italy only)- The Italian Code of Medical Deontology
- WHO (nomenclature under development)- World Health Organization

When these nomenclature systems do not align in definition and detail, the effectiveness of the system decreases.

### **AIDC Symbology**

UDI AIDC symbology requirements emerge without regard for UDI issuing entity standards or the ability to read these symbols in the global supply chain. Radio Frequency Identification (RFID) has become a standard of marking particularly when it comes to direct marking. RFID systems can be broken down by the frequency band within which they operate: low frequency, high frequency, and ultra-high frequency. There are also two broad categories of systems—passive and active RFID

Similarly, there are several barcode technologies which may be used depending on the item being identified. In addition to the endorsed issuing agencies, a medical device may bear a UPC code as a means for complying with UDI – yielding a total of 4 barcode formats available to identify a medical device through the 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

## Challenge #4: Lack of harmonization between global UDI databases

To harmonize the list of UDI data elements required to define a product, IMDRF released guidance document N53:2019 Use of Data Elements Across IMDRF Jurisdictions, with the expectation that jurisdictions align to this list. However, actual implementation of regional UDI lists of data elements shows several deviations from this approach.

### **Data Elements Required for Publication**

In 2016, the IMDRF established a list of data elements intended to harmonize nomenclature and structure for medical device identification (refer to N19:2016 Common Data Elements for Medical Devices). Each UDI regulation has since defined their own list of data elements, some harmonized and some region-specific. See examples in Table 2: Data Elements Required for Publication.

**TABLE 2: DATA ELEMENTS REQUIRED FOR PUBLICATION\***

	<b>Total # of Data Elements</b>	<b># of Data Elements Harmonized with IMDRF</b>	<b>% Harmonized</b>
<b>IMDRF (baseline)</b>	28	-	-
<b>US FDA</b>	56	14	25
<b>EU MDR</b>	88	19	22
<b>South Korea</b>	34	12	35
<b>China</b>	42	11	26
<b>Saudi Arabia</b>	63	18	29

\*These numbers are for reference only. Exact numbers may change as database development progresses. Consult released regulations for more information

An additional challenge is even when the data element is harmonized between jurisdictions, the application of said data element is not consistent. For example, an element may be required for publication in one region and may be conditional or optional for another region.

### **New Device Identifier Triggers**

A device identifier is intended to uniquely identify a medical device; therefore, when changes are made that would result in a new device, the expectation is that manufacturer's assign a new device identifier. The rules built into the regional databases that trigger new device identifiers are not consistent. See examples in Table Table 3: New Device Identifier Triggers by Regional Jurisdiction.

**TABLE 3: NEW DEVICE IDENTIFIER TRIGGERS BY REGIONAL JURISDICTION**

<b>Attribute Changes</b>	<b>IMDRF</b>	<b>GS1</b>	<b>US FDA</b>	<b>EU MDR</b>	<b>Korea</b>
Brand Name	X	X	X	X	X
Version or model number on the device label or accompanying packaging	X		X	X	
Clinical Size	X				
Single Use status of a device or accessory	X		X	X	
Device Packaged as Sterile Status	X		X	X	
Device/accessory requires sterilization prior to use	X		X	X	
Device Count (quantity)	X	X	X	X	
Critical Warnings or Contra-indications	X			X	X
Product form, fit or function or intended use		X		X	
Dimensional or gross weight		X			
Addition/Removal of a certification mark		X			

Time Critical or promotional product		X			
Price on Pack		X			
Packaging configuration		X			X
Issuing Agency (e.g., GS1 or HIBCC)			X		
Device classification of a kit (e.g., Class III to Class II)			X		
Latex Content (i.e., required to be labeled as containing Latex)			X		
MRI Safety Status			X		
Basic UDI-DI				X	
Manufacturing company					X
License owner					X

### ***Publication Strategies***

For medical device manufacturers that manage large numbers of medical devices, simplification of data publication for UDI information is essential to prevent a delay in providing products to customers. There are several mechanisms available for publication (some regions have made allowances for more than one mechanism):

- Fully automated, machine-to-machine connections
- Manual, bulk-load data entry
- Manual, single product data entry

When publication technologies are different between regions, manufacturers must develop, maintain, and implement region-specific strategies.

## Challenge #5: Expansion of Regional UDI Requirements

In addition to the proliferation of region-specific attributes as shown in Challenge #4, certain processes are diverging as well. Examples of region-specific expectations include but are not limited to:

- Basic UDI-DI
- UDI publication vs. transactional data submissions

The European Commission introduced the concepts of a Basic UDI-DI, intending to group medical devices with consistent properties, such as:

- Brand / Tradename
- Risk class
- Intended use
- Legal manufacturer

The intent of this grouping was to simplify post-market vigilance. However, implementation of this requirement has shown that other product elements should be considered, including:

- Patient risk
- Complaint history
- Risk-based approach to lifecycle management

Because of these considerations, manufacturers are not implementing Basic UDI-DI as originally intended and are instead choosing to segregate products, reducing the effectiveness of the Basic UDI-DI key.

The expanded publication requirement for transactional data submissions was introduced by South Korea in 2021. In addition to publishing a master data set representing a product, the expectation is to publish a data set specific to a unit (e.g., full UDI string including serial/lot number, country of origin). While this additional information does provide greater visibility to individual devices commercialized in a region (and makes post-market vigilance more efficient), the ability to comply with these requirements have often resulted in overhauling supply chain processes and developing fully automated data processing solutions. Sustaining said infrastructure is burdensome, especially with changing publication requirements and database configurations.

## Challenge #6: Lack of focused education for healthcare delivery organizations

As stated in the IMDRF document N54, the benefits of UDI strongly rely on effective integration of the UDI to support various regulatory activities during the lifecycle of medical devices and uptake of UDI across the whole healthcare sector.

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

Healthcare delivery organizations are slow to adopt UDI because their systems are not prepared to consume the UDI-DI proliferation according to the standards used to create UDI.



## Recommendations

In order to remedy the implementation challenges highlighted in this paper, there are certain actions that could be taken to better harmonize on UDI.

### ***IMDRF and/or GHWP Governance***

While the existing IMDRF body of work around UDI has provided a sound foundation for emerging regulations, there are several updates that should be considered:

- Update to N48, N53, and N7 to support a globally harmonized approach to the implementation of a UDI system
  - N53- Add in new data elements
- Support manufacturers and regulators through continued educational seminars and workshops

### ***Local Regulator Strategies***

Ensuring alignment with globally recognized standards while still meeting the regulatory needs of a particular jurisdiction can be challenging. The following guiding principles should be considered:

- Ensure regional regulations and standards align with the verbiage set forth in the IMDRF guiding documentation. Eliminate the introduction of region-specific requirements or processes, when possible.
- Consider adopting the IMDRF UDI guidance documents N7: 2016 Common Data Elements for Medical Device Identification & N48:2019 Unique Device Identifier (UDI) Application Guide
- Adhere to processes set forth by UDI Issuing Entities and other recognized standards such as IEC and ISO standards.

### ***Medical Device Manufacturer Best Practices***

While the expectations for global UDI compliance continues to grow, there are “best practices” that manufacturers should consider when implementing their UDI systems:

- Enable digitized, machine-to-machine publication (consider cost of implementing a digitized solution vs. cost of sustaining manual labor)
- Develop global product structures (consider implementing a global, cross-functional strategy for product management vs. sustaining disconnected, regional processes)

## Conclusion / Summary

Due to the issues raised in this paper, the benefit of a harmonized, global UDI system is not able to be effectively utilized by all health care institutions. These issues are contradictory to the spirit of UNIQUE Device Identification and potentially hamper the global interoperability of the UDI system. These issues affect traceability of medical devices, adverse event reporting, global data sharing and transparency, and ultimately result in inefficient processes, higher costs and a decrease of patient safety.

### Acknowledgments

The DITTA UDI Task Force:

Hirokazu Fukuda, FUJIFILM

Kelly Mallinger, GE HealthCare

Tania Pearson, Medtronic

Mia Spiegelman, Medtech Canada

Toshiko Suzuki, JIRA

Bodo Winkler, Siemens Healthineers

Zita Yurko, Philips

Contact:

Carolyn Hull, [chull@medicalimaging.org](mailto:chull@medicalimaging.org)

**-End-**