

MDS-G34

Guidance on Requirements for  
Unique Device Identification (UDI) for Medical Devices



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## Introduction

### Purpose

The purpose of this guidance is to specify the SFDA requirements for UDI for medical devices.

### Scope

This guidance applies to the following:

- A. All medical devices and their accessories that will be supplied to the KSA market, except custom-made medical devices, investigational medical devices and investigational IVD medical device.
- B. Manufacturers, authorized representative, importers, distributors, and healthcare providers.

### Background

SFDA/MDS has issued this guidance document in order to support SFDA's activities specified in Chapter Nine of the "Medical Devices Interim Regulation" issued by Saudi Food and Drug Authority Board of Directors decree No. (1-8-1429) dated 29/12/1429 H and amended by Saudi Food and Drug Authority Board of Directors decree No. (4-16-1439) dated 27/12/2017 that is in relation to safeguard activities.

The UDI system aims to increasing patient safety and optimizing patient care by facilitating the following:

- Traceability of medical devices, especially for field safety corrective actions.
- Control of devices at the ports, especially for identification of counterfeits and recalled devices.
- Identification of medical devices at the point of use.
- Identification of medical devices in adverse events.
- Reduction of medical errors.
- Safe and effective use of devices.
- Documentation and longitudinal capture of data on medical devices.

The purpose of SFDA's UDI System is to provide standardized granular identification of medical devices (and their accessories) and associated device-specific meta-data to support numerous and varied public-health and safety initiatives. These include device traceability, timely identification of counterfeits, recalls, adverse event reporting (both the specific identification of devices in individual reports – as well as the ability to aggregate reports), the inclusion of specific devices in various types of clinical information systems (such as patient records), as well as the inclusion of device information in population-based data sets, such as insurance data. This System will also allow integration of information across various government and non-government systems and processes to improve workflow and communication.

## Chapter One: UDI Requirements

### A. General UDI Requirements:

1. The marking of the UDI is an additional requirement – it does not replace any other marking or labeling requirements.
2. A label or package that currently contains, or should contain, a Production Identifier (e.g., expiration (use by) date, lot number) as a discrete information element shall not remove that information from the label or package because it is also being conveyed in the UDI.
3. The provisional accredited UDI Issuing Agencies shall be GS1, HIBCC and ICCBBA. Maintenance of their accreditation is covered in Chapter One, Section (G).
4. The manufacturer shall assign and manage the UDI following the chosen issuing agency's specifications, standards and guidelines.
5. The UDI shall contain two parts: the UDI-DI and the UDI-PI(s).
  - The UDI-DI is unique to a specific manufacturer's device and provides access to the information in the SAUDI-D.
  - The UDI-DI shall be globally unique at all levels.
  - If a lot number, serial number, software identification, or expiration (use by) date is on the label or package, it shall be included in the UDI-PI.
  - If there is also a manufacturing date on the label or package, it does NOT need to be included in the UDI-PI if there are other PIs in the UDI and the manufacturing date is not used to control the product.
  - If the manufacturing date is the only PI, then it shall be included in the UDI.
6. The UDI shall be presented in two forms:
  - Easily readable plain-text (also known as HRI), and
  - AIDC technology.
7. The information encoded in the UDI (both AIDC and plain-text/HRI) may also include other data, such as quantity or internal reference number, which is not considered part of the UDI.
8. The HRI format shall follow the rules of the UDI issuing agency; it shall be the full, proper HRI, including AIs, and NOT a mix of HRI and non-HRI text.
9. If the AIDC technology is not evident upon visual examination of the label or package, the label or package shall disclose the presence of AIDC technology.
10. When AIDC carriers other than the UDI are part of the product labelling, the UDI shall be easily and readily identifiable.
11. If linear barcodes are used, the entire UDI shall be concatenated into a single barcode.

12. Barcodes shall be verified according to the appropriate ISO/IEC standard and they shall meet the issuing agency's grading standards.
13. If the manufacturer is using RFID technology, a linear or 2D barcode shall also be provided on the label.
14. The UDI shall be readable during normal use and throughout the intended life of the device.
15. The UDI shall be placed so that the AIDC can be accessed during normal operation or storage.
16. If the UDI is readily readable and in the case of AIDC scannable through the device's package, then the placing of the UDI on the "outer" package shall not be required.

#### B. Direct Marking (DM)

1. Reusable devices subject to the UDI requirements shall also bear a DM UDI on the device itself if the device is intended to be used more than once and intended to be reprocessed between uses.
2. The DM UDI shall be permanent and readable during normal use and throughout the intended life of the device.
3. If the device's primary label is on the device itself and is permanent – a separate DM UDI is not required. However, the UDI label requirements will take precedent.
4. The UDI provided through the DM UDI may be:
  - Identical to the UDI that appears on the label of the device, or
  - A different UDI used to distinguish the unlabeled/unpackaged device.
5. When a device shall bear a UDI as a DM, the UDI may be provided through either or both of the following:
  - Easily readable plain-text/HRI;
  - AIDC technology, or any alternative technology, that will provide the UDI of the device on demand.
6. A device is exempt from the DM requirement if the manufacturer can adequately demonstrate and document that:
  - Any type of DM would interfere with the safety, performance or effectiveness of the device;
  - The device cannot be directly marked because it is not technologically feasible; or
  - The device has been previously directly marked.

### C. The UDI-DI Lifecycle

1. A new, unique UDI-DI is required whenever there is a change made to a device or its attributes, and the change:
  - Results in a new DI record,
  - Results in a new version or model,
  - Could lead to ambiguity in the identification of the device,
  - Could affect the traceability of the device,
  - Creates a new package, or
  - Is to any of these SAUDI-D data elements:
    - o Issuing Agency
    - o Primary UDI-DI Number
    - o Quantity
    - o Brand/Trade Name
    - o Version or Model
    - o Clinically Relevant Size
    - o Labeled as Single Use
    - o Device required to be labeled as containing natural rubber latex
    - o MRI safety information (if not already labeled as Safe, Unsafe, or Conditional)
    - o Device Packaged as Sterile
    - o Requires Sterilization Prior to Use
    - o Critical warnings or contraindications that appear on the device's label
2. If the new UDI-DI is an update to a previously entered UDI-DI, then this relationship shall be entered in SAUDI-D.

#### D. Saudi Arabia UDI Database (SAUDI-D)

1. The manufacturer, or its authorized representative, shall submit and maintain the appropriate data to the SAUDI-D for all devices subject to this guidance.
2. The manufacturer, or its authorized representative, shall implement and use standard industry practices, methods, and procedures for data validation prior to submission.
3. The data shall be reconfirmed in SAUDI-D annually (data review, update and attestation and is enforced by the SAUDI-D).
4. SFDA may request additional information, updates, or data confirmations at any time.
5. The data for new UDI-DI shall be available in SAUDI-D at the time the device is placed on the market. For changes not requiring a new UDI-DI, the manufacturer shall update the relevant record within 10 working (working) days of making the change.
6. All specified (non-private) data in the SAUDI-D will be made publicly available. Data relating to devices no longer on the market shall be retained in the SAUDI-D.
7. The manufacturer, or its authorized representative, shall provide to the Saudi UDI database (SAUDI-D) the following information for each Primary UDI-DI (defined as the UDI-DI on the device's primary label), or for those situations where there is no device label or package containing the label, the DM UDI-DI, or the Unit of Use UDI-DI (as applicable).

7.1 All of the following device attribute information shall be provided in English, unless stated otherwise (all fields are required unless otherwise noted):

- 7.1.1 The GTIN-14 (GS1) [and for those devices intended exclusively for retail Point of Sale (POS), the GTIN-12/13 provided in a 14-digit format], HIBC-LIC (HIBCC), or ISBT 128-PPIC (ICCBBA)
- 7.1.2 The establishment national registry number of the authorized representative or local manufacturer
- 7.1.3 The medical device national listing number
- 7.1.4 The MDMA number
- 7.1.5 Name and address of the manufacturer (as labeled)
- 7.1.6 Name and address of the authorized representative (as labeled)
- 7.1.7 Brand/Trade/Generic name (as labeled; if no formal brand or trade name is used or registered, enter generic device name that users are accustomed to using)
- 7.1.8 Arabic version of Brand/Trade/Generic name – for OTC or home-use devices
- 7.1.9 If exists, the version/model name/number or other high-level identifier (e.g., Basic UDI-DI) that links a group of devices with the same intended purpose, risk class and essential design and manufacturing characteristics. Note that this is a manufacturer

specified identifier – and is in addition to, and different from, the GMDN Preferred Term identified in 7.1.35 below.

- 7.1.10 Catalog number
- 7.1.11 Device description – as labeled, in the labeling, or presented in marketing material, including a website.
- 7.1.12 Arabic version of device description – for OTC or home-use devices
- 7.1.13 Quantity (for primary UDI-DI) – number of units in this device or package
- 7.1.14 Unit of use DI number (when the number of units (quantity) >1) [can be used in multiple DI records]
- 7.1.15 Clinically relevant size (as indicated on the label) – if the device is available in more than one size and this information is necessary for the hospital, clinician, or patient to know or use.
- 7.1.16 Production identifier(s) included in the UDI [lot/batch number (y/n), serial number (y/n), expiration (use by) date (y/n), manufacturing date (y/n), and/or software version number (y/n)]
- 7.1.17 If the same device can be provided to the KSA market with different DIs – the other equivalent DIs that are about the same or equivalent device and how the equivalent DIs are different [controlled vocabulary – e.g., regional difference, language, voltage] than the primary DI (separate DI records for the other DIs may, or may not, be in SAUDI-D).
- 7.1.18 Previous DI (see Chapter One, section (C)) – the UDI-DI that was changed because there was a change made to a device or its attributes that resulted in a new DI record, a new version or model, or a new package.
- 7.1.19 Is this a configurable device UDI-DI (y/n)
  - If yes, and the configurable device UDI is not physically on the label/device, but rather presented electronically, where/how it can be found (free text)
- 7.1.20 Labeled as a single-use device (y/n)
- 7.1.21 Reprocessed single-use device (y/n)
- 7.1.22 Disposal/Scraping method – if the label or labeling specifies a disposal or scraping methods (free text)
- 7.1.23 Device packaged/labeled as sterile (y/n)
- 7.1.24 Requires sterilization prior to (re-)use (y/n)

- 7.1.25 If #24 is yes (not #23 above), sterilization method (from a specified list of values) to inform the end user of the sterilization methods that may be used to sterilize the device, if in fact the manufacturer of said device intends the end user to sterilize device prior to use, or as applicable, reuse
- 7.1.26 The maximum number of reuses (where the label indicates the maximum number of reprocessing cycles)
- 7.1.27 Device labeled as containing natural rubber latex or dry natural rubber (y/n)
- 7.1.28 Device labeled as "Not made with natural rubber latex" (y/n)
- 7.1.29 Prescription use (Rx) and/or Over the Counter (OTC) (one or both, never neither)
- 7.1.30 Home-use (y/n)
- 7.1.31 MRI safety status (safe, unsafe, or conditional – or label does not contain)
- 7.1.32 Special storage conditions (if labeled) (if none, state “none”)
- 7.1.33 Storage and handling conditions (as indicated on the label or in the instructions for use) (if none, state “none”)
- 7.1.34 Critical warnings or contra-indications (as indicated on the device label) (if none, state “none”)
- 7.1.35 GMDN Preferred Term code (auto-populates name and definition) – note that ideally only one term Preferred Term is used/entered.
- 7.1.36 Risk class of the device linked to MDMA (premarket registration path)
- 7.1.37 URL for additional information, such as electronic instructions for use (optional)
- 7.1.38 Customer Contact – phone and email

7.2 For devices subject to DM:

- 7.2.1 The device is subject to the DM requirement (y/n)
- 7.2.2 If yes, the device is subject to the DM requirement, but the manufacturer is claiming the following exemption (a. interfere with safety, performance or effectiveness; b. not technologically feasible; or c. previously marked)
- 7.2.3 If the DM UDI is different than the label UDI:

- Is the UDI-DI different (y/n): if yes, list the DM DI [can be used in multiple DI records]
- If the DM UDI contains PIs that are different than those used in the label UDI, the different PIs used in the DM UDI [defaults to primary DI PIs]: lot number (y/n), serial number (y/n), expiration (use by) date (y/n), manufacturing date (y/n)
- The DM UDI is presented as:
  - Plain-text/human-readable interpretation (HRI) (y/n)
  - AIDC (y/n)
  - An alternative technology (y/n) – if yes, describe (free text)

7.3 For devices packages (repeatable for multiple packages):

7.3.1 The Package UDI-DI number

7.3.2 Package type (free text, e.g., case, carton, box)

7.3.3 Quantity per package

7.3.4 The UDI-DI of the next lower device/package contained within this package

7.3.5 If the package contains PIs that are different than those used in the label, the PIs used in this package UDI [defaults to primary DI PIs]: lot number (y/n), serial number (y/n), expiration (use by) date (y/n), manufacturing date (y/n)

7.3.6 Package discontinuation date (for package configurations no longer offered)

7.4 For kits

7.4.1 The UDI-DIs of all devices assigned or labeled with a UDI-DI within the kit, whether marked or not.

7.5 For end of commercial distribution

7.5.1 Date no longer available on the market (that is, commercial distribution end date, date device is no longer offered for sale)

**E. Compliance Dates**

1. All UDI Requirements shall apply:

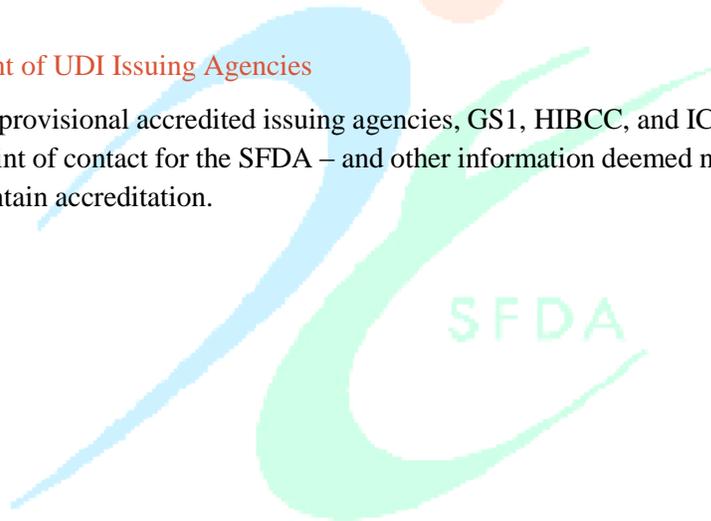
- For Class D devices – (6) months after the SAUDI-D is available.
- For Class B and C devices – (1) years after the SAUDI-D is available.
- For Class A devices – (2) years after the SAUDI-D is available.
- For the DM requirements – (1) years after applicable class compliance date.

#### F. Request for an Exception from or Alternative to a UDI Requirement

1. A manufacturer or its authorized representative may submit a request for an exception from or alternative to any of the requirements of this guidance.
2. A written request for an exception or alternative shall:
  - Identify the device or devices that would be subject to the exception or alternative;
  - Identify the specific parts of this guidance for an exception or alternative;
  - If requesting an exception, explain why you believe the requirements are not feasible;
  - If requesting an alternative, describe the alternative and explain why it would provide for more accurate, precise, or rapid device identification than the requirements or how the alternative would better ensure the safety or effectiveness of the device that would be subject to the alternative.

#### G. Management of UDI Issuing Agencies

1. The provisional accredited issuing agencies, GS1, HIBCC, and ICCBBA, shall provide a point of contact for the SFDA – and other information deemed necessary by SFDA to maintain accreditation.



## Chapter Two: Additional Requirements

### 1. Stand-alone Software (Software as a Medical Device)

- 1.1. The term Stand-alone Software (SaS) or Software as a Medical Device (SaMD) means software intended to be used for one or more medical purposes that performs this purpose without being part of a hardware medical device.
- 1.2. SaS/SaMD that is distributed in both a physical, packaged form and in a form that is not packaged (e.g., when downloaded) may use the same or a different UDI.
- 1.3. A UDI shall be applied to the physical media containing SaS/SaMD.
- 1.4. A UDI shall be provided on a readily accessible screen for the user in an easily-readable plain-text format (e.g., in an about, help or start-up screen).
- 1.5. Software lacking a user interface (e.g. middleware for image conversion) shall be capable of transmitting the UDI through an Application Programming Interface (API).
- 1.6. Only the plain-text/HRI portion of the UDI shall be required in the software display and shall include the relevant AIs.
- 1.7. In addition to the change rules outlined in Chapter One, section (C), a new UDI-DI shall be required whenever there is a modification that changes:
  - a. the original performance and effectiveness,
  - b. the safety or the intended use of the Software, or
  - c. the interpretation of data.

### 2. Implantable Devices

- 2.1. All active implantable devices shall be controlled by serial number.
- 2.2. Manufacturers of implantable devices shall provide an “implant card” to the patient with information allowing the identification of the device, including its UDI.
- 2.3. The following implants are exempted from the need to provide an implant card: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors.
- 2.4. The full UDI (UDI-DI and UDI-PI) of an implantable device shall be readily available, either electronically or readable (scannable), at the point of implantation.

### 3. Configurable Devices

- 3.1. A UDI shall be allocated to the configurable device in its entirety and shall be called the configurable device UDI.
- 3.2. The configurable device UDI shall be placed on the assembly that will not be exchanged during the lifetime of the system and shall be identified as the Configurable device UDI.
- 3.3. Alternatively, the configurable device UDI can be presented electronically (e.g., through a computer interface) – and not physically located on the label. If so, then the location and how to access it shall be entered into SAUDI-D.
- 3.4. Each component, sub-system or part that can be removed or separated from the configuration or is available and distributed on its own (placed on the market) shall have its own, separate UDI and meet all of the other UDI requirements.

### 4. Device constituent parts of “Combination Products”

- 4.1. When a device, when placed on the market or put into service, incorporates a substance which, if used separately, would be considered to be a medicinal product, the medical device(s), and/or its components, shall meet the UDI requirements.
- 4.2. However, if the device is intended to administer a medicinal product and the product forms a single integral product which is intended exclusively for use in the given combination and which is not reusable, the product shall be governed by appropriate regulatory pathway and identification.

### 5. Components

- 5.1. Each component shall have its own, separate UDI and meet all of the other UDI requirements of this guidance, if it:
  - is available and distributed on its own (placed on the market), or
  - can be installed or removed by the end-user (regardless of whether it is commercially available and distributed on its own).
- 5.2. A component that significantly changes the intended purpose, safety or performance of the device shall, for the purposes of UDI, be considered a remanufacturing operation – and as such subject the entire device to a new UDI-DI.

## 6. Single Use Device Packaging Exception

- 6.1. Individual single-use devices, which are labeled and packaged individually, are not required to have the UDI on the individual device label/package if all of the following conditions are thoroughly documented and met – the single-use devices are:
  - All of the same version or model,
  - Distributed together in a single package,
  - Stored in that package until removed for use,
  - Not intended for individual distribution, and
  - Not implantable devices.
- 6.2. The primary UDI will be on the package of these individual single-use devices.
- 6.3. When this exception is used, SAUDI-D will require that a Unit of Use DI be assigned to the unmarked individually labeled and packaged device and entered into the database.

## 7. Kits (which includes other non-homogenous package configurations)

- 7.1. A kit shall have its own, unique UDI (DI and PI) – referencing this specific collection of devices.
- 7.2. The UDI-DIs of all devices within the kits, whether marked or not, shall be entered into the SAUDI-D.

## 8. Convenience Kit/IVD Kit/Procedure Pack exception

- 8.1. For the purposes of this exception, a convenience kit, IVD kit or procedure pack, which is a specific kind of kit, means a combination of medical products packaged together and placed on the market with the purpose of being used for a single, specific medical procedure or purpose.
- 8.2. The contents of a convenience kit, IVD kit, or procedure pack are intended to remain in its original packaging until used by the end-user, and not replaced or repackaged, and all devices are consumed or discarded after opened and used for the single, intended medical procedure or purpose.
- 8.3. The convenience kit, IVD kit, or procedure pack shall have its own UDI.
- 8.4. The device contents of a convenience kit, IVD kit, or procedure pack shall also have its own UDI, unless the device is:
  - 8.4.1 An individual single-use disposable device, which cannot be used outside the context of the convenience kit or procedure pack, or
  - 8.4.2 Otherwise exempt from having a UDI on the label or package of the device that is in the convenience kit or procedure pack.
- 8.5. The UDI-DIs of all devices within the kits/packs, whether marked or not, shall be entered into the SAUDI-D.

## 9. Shipping Containers

- 9.1. A UDI is not required to be placed on any shipping container.

## 10. Devices Sold at Retail

- 10.1. For devices intended exclusively for retail point of sale (POS), the UDI-PI(s) of the UDI's AIDC do not need to appear on the point of sale package (that is, in the EAN/UPC/EAN data carrier).
- 10.2. Higher levels of packaging, not intended for retail Point of Sale, shall contain the full UDI.
- 10.3. A device intended both for retail POS and use in clinical environments, e.g., hospitals, shall also contain the full UDI on the label and packaging, in addition to the retail POS data carrier.

## 11. Own Brand/Private Labelers

- 11.1. For the purposes of UDI, an Own Brand or Private Labeler, who labels or relabels a device from a third party under his own name and/or Trade/Brand name, is considered the manufacturer of the devices – and is responsible for the UDI of the labeled or relabeled device.

## 12. Existing Inventory Exception

- 12.1. A finished device manufactured and labeled prior to the applicable compliance date may be distributed without being UDI compliant for an additional (1) year after the applicable compliance date. This exception does not apply to the DM requirement.

## 13. Reprocessed , Relabeled, Repackaged, Refurbished, Remanufactured, and Serviced Devices

- 13.1. Reprocessors of single use medical devices, re-labelers, re-packagers, re-furbishers, and re-manufacturers, shall create their own, new UDI for the reprocessed, relabeled, repackaged, refurbished, or remanufactured medical device, which shall replace the OEM's UDI where it exists.
- 13.2. The new UDI shall meet all of the requirements of this guidance.
- 13.3. The re-processor, re-labeler, re-packager, re-furbisher, or re-manufacturer shall keep, where available, a record of the UDI of the original device.
- 13.4. The act of servicing a device, if returned to the original user, does not in and of itself subject the device to UDI. However, if the serviced device is not necessarily returned to the original user, the serviced device is subject to UDI.

#### 14. Verification and Traceability

- 14.1. The manufacturer, authorized representative, importer, distributor and health institution shall store and maintain, in an easily searchable electronic format, the UDI of the devices which they have both received and distributed.
- 14.2. Authorized representatives, importers and distributors shall verify, in the SAUDI-D, that a UDI-DI has been properly assigned by the manufacturer and appropriately appears on the device's label and packages.
- 14.3. Where a retail pharmacy and other point of sale shop distributes medical devices, they shall store and maintain, in an easily searchable electronic format, the UDI of the devices which they have received and distributed.



## Chapter Three: Device Traceability

### A. Import Control

1. Importers shall submit, for each UDI-DI being imported into the KSA market:
  - The applicable Production Identifiers (UDI-PI(s)),
  - Quantity of lot-controlled devices,
  - Shipment date (when expected to arrive at the designated port), and
  - Destination (e.g., specific distributor, hospital).

### B. Track & Trace

1. All serialized medical device will be entered into the SFDA Track and Trace system to track the device through its supply chain activities and usage in medical facilities (e.g., hospitals, healthcare providers, point of sales, medical supply companies, etc.).
2. Through Track and Trace process, importers and distributors shall submit and confirm their products information.
3. Database information:
  - The SAUDI-D will submit serialized medical device data into the SFDA Track and Trace system.
  - The SFDA Track and Trace system will track the serialized medical device.
  - The SAUDI-D will have access to query the status of any serialized medical device through the supply chain activities – i.e., ability to locate a medical device for postmarket patient safety activities.

## Chapter Four: UDI in Healthcare Delivery

The adoption, implementation and use of UDIs across and throughout the healthcare ecosystem by health systems, hospitals, healthcare providers, patients, insurance companies, and others will bring about significant cost, quality, safety, and efficiency improvements in the delivery and management of medical-device related healthcare.

The documentation and use of a device's UDI throughout healthcare will vastly improve the:

- Accurately and efficiency of the supply chain,
- Inventory management of devices,
- Traceability of medical devices, especially for field safety corrective actions,
- Identification of SFDA approved medical devices for procurement activities,
- Identification of counterfeit devices,
- Identification of medical devices at the point of use,
- Identification of medical devices in adverse events,
- Reporting, reviewing and analyzing of adverse event reports,
- Development of processes and systems to reduce medical errors,
- Enable effective consumer-focused information,
- Safe and effective use of devices,
- Safety surveillance of devices,
- Assessment of device performance, and
- Documentation and longitudinal capture of data on medical devices.

Health systems shall take the critical steps necessary to facilitate and leverage the implementation of UDI throughout KSA by putting systems and processes in place to capture and use UDI in real time. This includes the documentation of the use or implementation of a device's UDI in patient's electronic health records, the inclusion of UDI in inventory management and billing systems, the use of UDI in the communication of device safety concerns, and leveraging UDI for easily accessible clinician and patient information.



## Annex (1): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
MDS	Medical Devices Sector
AI(s)	Application Identifier(s)
API	Application Program Interface
DI	Device Identifier
DM	Direct Marking
GHTF/IMDRF	Global Harmonization Task Force/International Medical Device Regulators Forum
GMDN	Global Medical Device Nomenclature
GTIN-14	Global Trade Item Number-14
HIBC	Health Industry Bar Code
HRI	Human Readable Interpretation
IVD	InVitro Diagnostic
OEM	Original Equipment Manufacturer
OTC	Over The Counter
PI(s)	Production Identifier(s)
RFID	Radio-Frequency IDentification
SaS/SaMD	Stand-alone Software/Software as a Medical Device
SAUDI-D	Saudi Arabia UDI – Database
UDI	Unique Device Identifier
UPC/EAN	Universal Product Code/European Article Number
URL	Uniform Resource Locator (also known as a web address)
XML	Extensible Markup Language
Placing on the Market	means the first making available in return for payment or free of charge of a medical device, with a view to distribution and/or use within the KSA, regardless of whether it is new or fully refurbished.
Putting into Service	means the stage at which a device has been made available to the final user as being ready for use for the first time in the KSA for its intended purpose.

Manufacturer	means any natural or legal person with responsibility for design and manufacture of a medical device with the intention of making it 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.
Establishment	means any place of business within the KSA that is involved in the manufacture and/or placing on the market and/or distribution of medical devices or acting on behalf of the manufacturer.
Authorized Representative (AR)	means any natural or legal person established within the KSA who has received a written mandate from the manufacturer to act on his behalf for specified tasks including the obligation to represent the manufacturer in its dealings with the SFDA.
Importer	means any natural or legal person in the supply chain who is the first to make a medical device, manufactured in another jurisdiction, available in the KSA.
Distributor	means any natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user.
User	means the health care institution, professional or patient using and /or maintaining medical devices.
Supply Chain	means different elements of the distribution activities of a medical device occurring between it being available for importation into the KSA and it being put into service.
Medical Device Marketing Authorization (MDMA) Number	means the code assigned by the SFDA to one or more medical devices, that have been included in a single marketing authorization application, to indicate these devices are authorized to be placed on the KSA market.
National Registry Number	means the number issued to a person by the SFDA under the establishment registration provisions of the Medical Devices Interim Regulation.
Medical Device National Listing Number	means the code assigned by the SFDA to a single medical device to indicate the device is authorized to be placed on the KSA market and facilitate traceability.
Medical Device	means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:  A. Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of: <ul style="list-style-type: none"> <li>- Diagnosis, prevention, monitoring, treatment or alleviation of disease;</li> </ul>

	<ul style="list-style-type: none"> <li>- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;</li> <li>- Investigation, replacement, modification, or support of the anatomy or of a physiological process;</li> <li>- Supporting or sustaining life;</li> <li>- Control of conception;</li> <li>- Disinfection of medical devices;</li> <li>- Providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;</li> </ul> <p>and</p> <p>B. Which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.</p>
In-Vitro Medical Device	means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software and related instruments or apparatus or other articles.
Accessory	means a product specifically intended by its manufacturer to be used together with one or several particular medical device(s) or in vitro diagnostic medical device(s) to enable the device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in view of its/their intended purpose(s).
Implantable Device	means any device, including those that are partially or wholly absorbed, which is intended: <ul style="list-style-type: none"> <li>- To be totally introduced into the human body or,</li> <li>- To replace an epithelial surface or the surface of the eye,</li> </ul> <p>by surgical intervention which is intended to remain in place after the procedure.</p> <p>Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also</p>
Active Implantable Medical Device	means any implantable device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy,

	substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices. Software shall also be deemed to be an active device.
Configurable Device	means a device that consists of several components which can be assembled by the manufacturer in multiple configurations. The individual components may be medical devices themselves.
Fully Refurbished Medical Device	means a used device that has been returned to a state which would allow it to be subject to the same conformity assessment procedures as applied to the original device.
Reusable Devices	means those devices that require cleaning, disinfection, sterilization or refurbishing between uses on different patients.
Single Use Medical Device	means a medical device intended for use once, on an individual patient for a single procedure, and then should be discarded.
Kit	means any combination of two or more different devices (UDI-DIs), regardless of whether they are finished devices, labeled, intended to be used together, created for the convenience of the user, subject to UDI, or marked with UDI, that are packaged together to achieve a common intended use and are being distributed as a medical device. Specific kinds of kits include procedure packs/convenience kits.
Generic Device Group	means a set of devices having the same or similar intended uses or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics.
Custom-Made Medical Device	<p>a medical device that, at a minimum, meets the following requirements:</p> <ul style="list-style-type: none"> <li>- It is intended for the sole use of a particular individual; and</li> <li>- It is specifically made in accordance with a written request of an authorized healthcare professional, which gives, under their responsibility, specific design characteristics; and</li> <li>- It is intended to address the specific anatomic-physiological features or pathological condition of the individual for whom it is intended.</li> </ul> <p>Note 1: patient-specific medical devices, adaptable medical devices and mass-produced medical devices made by means of industrial manufacturing processes in accordance with the written request of an authorized healthcare provider, shall not be considered to be custom-made.</p> <p>Note 2: ‘Specific design characteristics’ means unique design specifications that are based on an individual’s specific anatomic-physiological features or pathological condition, and that cannot be</p>

	proposed by a manufacturer without the involvement of a healthcare professional during the conception phase. (For example, transmitting only dimensions/geometric parameters (such as DICOM files from CT scans) to a manufacturer prior to the production of a medical device is not sufficient to be considered as giving specific design characteristics.)
Patient-Specific or Patient-Matched Medical Device	a medical device produced by a manufacturer based on a standard device template model, or specified design envelope (e.g., minimum and maximum dimensions, mechanical performance limits, and other clinically relevant factors), that is matched to a patient's anatomy using techniques such as scaling of the device based on anatomic references, or by using the full anatomic features from patient imaging, and which is produced through a process that is capable of being validated.
Adaptable Medical Device	a mass-produced medical device that must be adapted or assembled at the point of care, in accordance with the manufacturer's validated instructions, to suit an individual patient's specific anatomic-physiologic features prior to use.
Mass-Produced Medical Devices	identical medical devices that are produced in continuous production runs or homogenous batches.  Note: A batch is considered homogeneous when equivalent parts or materials are manufactured and/or tested in the same manner, without interruption, typically on the same day or in the same time period, and produced by the same person, or with the same machine/equipment set-up and fulfill the same specifications
Investigational Medical Device	medical device being assessed for safety or performance in a clinical investigation.
Investigational IVD Medical Device	in vitro diagnostic medical device that are being assessed for safety or performance in a performance evaluation study.
Home Use Medical Device	is a medical device labelled for use by users in any environment outside of healthcare facility. This includes but not limited to office environments, schools, and vehicles. If the medical device is intended to be used in healthcare facilities and outside those facilities, it meets this definition
Unit of Use DI	means a way to associate the use of a device to/on a patient to data related to that patient in instances when a UDI is not labelled at the level of the device unit of use (e.g. several device units contained in a plastic bag).
Unique Device Identification (UDI)	means 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 the UDI-DI and the UDI-PI. Note: The word "Unique" does not imply serialization of individual production units.
Basic UDI-DI	is the main key in SAUDI-D and relevant documentation (e.g. certificates, declaration of conformity, technical documentation and summary of safety and clinical performance) to connect devices with same intended purpose, risk class and essential design and manufacturing characteristics.
Device Identifier (UDI-DI)	means a unique numeric or alphanumeric code specific to a device and that is also used as the "access key" to information stored in a UDI database.
Direct Marked/Marking UDI (DM UDI)	means a permanent marking providing the UDI on the device itself.
Production Identifier (UDI-PI)	means a numeric or alphanumeric code that identifies the unit of device production. The different types of Production Identifier(s) include, but are not limited to, serial number, lot/batch number, software version number, manufacturing date and expiration (use by) date.
Human Readable Interpretation (HRI)	a legible interpretation of the data characters as encoded in the UDI.
Automatic Identification and Data Capture (AIDC)	means a technology used to automatically capture data. AIDC technologies include, but are not limited to, bar codes, smart cards, biometrics and RFID.
Labeling	means written, printed or graphic matter, <ul style="list-style-type: none"> <li>- Affixed to a medical device or any of its containers or wrappers,</li> <li>- Information accompanying a medical device related to its identification and/or technical description,</li> <li>- Information accompanying a medical device related to its use, but excluding shipping documents.</li> </ul>
Label	means written, printed, or graphic information that is: <ul style="list-style-type: none"> <li>- affixed to or appearing on the medical device itself (including electronic display), or if there is none,</li> <li>- on the packaging of each unit (wrapper) or multiple devices (containers), and if none of that exists,</li> <li>- on a package insert (is used where it is impractical or inappropriate to affix a label directly on the medical device</li> </ul>

	<p>itself or its packaging. Impractical means where physical constraints prevent this happening).</p> <p>Among other information, the label contains that name of the device, the name and address of the manufacturer, the control information (e.g., lot number, serial number, manufacturing date, expiration (use by) date), if the device is intended for single use, and whether the device is an IVD medical device.</p>
Primary Label	means the label on the device itself, or, if there is no label on the device itself, on the package containing the device.
Package	means the various levels of homogenous packages that contain a defined quantity of a single type (a single UDI-DI) of devices, e.g. each carton or case.
Shipping Container	means a container used during the shipment or transportation of devices, such as a pallet or tote, and whose contents vary both within the container and from one shipment to another. Shipping container's traceability is controlled by a process specific to the applicable logistics systems.
Radio Frequency Identification (RFID)	means an AIDC technology that uses communication through the use of radio waves to exchange data between a reader and an electronic tag attached to an object, for the purpose of identification.
Field Safety Corrective Action	means an action taken by a manufacturer to reduce or remove a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market.
Field Safety Notice	means a notification from the SFDA to relevant medical device users in relation to a Field Safety Corrective Action.
Reportable Adverse Event	means any adverse event or any technical or medical reason leading to a Field Safety Corrective Action, which, directly or indirectly, might lead to or may have led to (a) the death of a patient, a user or another person or (b) a serious deterioration in their state of health.