Draft for Comment Purposes (Not for Implementation)

Draft Requirements for the Unique Device Identification System

Application Date: To be announced

Chapter One

General Rules

A. 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.

B. This document is requirements adopted by the Saudi Food and Drug Authority (SFDA) on the basis of the Medical Devices Interim Regulation and, in particular, Article 45 thereof, 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.

C. These *draft* requirements, in accordance with the Medical Devices Interim Regulation, specifies and refines the provisions of its Chapter Nine in relation to the unique identification and traceability of medical devices that have been placed on the market of the KSA. Moreover, SFDA supports and promotes the IMDRF UDI initiatives, which are focused on a globally harmonized and consistent approach to UDI.

This is expected to support SFDA's goal of increasing patient safety and optimizing patient care by facilitating the:

- 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, and
- documentation and longitudinal capture of data on medical devices.

Definitions

For the purpose of these requirements, the following definitions apply:

KSA: means the Kingdom of Saudi Arabia.

SFDA: means the Saudi Food and Drug Authority.

Medical device: means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:

- Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
  - Diagnosis, prevention, monitoring, treatment or alleviation of disease;
  - Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
  - Investigation, replacement, modification, or support of the anatomy or of a physiological process;
  - Supporting or sustaining life;
  - Control of conception;
  - Disinfection of medical devices;
  - Providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;

  And
- 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.

In-vitro medical devices: 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.

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.

Implantable device: means any device, including those that are partially or wholly absorbed, which is intended:

- to be totally introduced into the human body or,
- to replace an epithelial surface or the surface of the eye,

by surgical intervention which is intended to remain in place after the procedure.

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 considered an implantable device. [GHTF SG1/N77:2012]

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).

Authorized Representative: 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.

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.

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.

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.

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.

Own Brand/Private Labelers*:* means a company that relabels a device from a third party with his own name without making any further changes to the device thereby taking responsibility for it as the manufacturer.

Party: means any natural or legal person.

Person: a term that includes legal entities such as a corporation, partnership or an association.

User: means the health care institution, professional or patient using and or maintaining medical devices.

Marketing Authorization 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.

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.

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.

Making available on the market: means any supply of a device for distribution, consumption or use within the KSA, in the course of a commercial activity, whether in return for payment or free of charge.

Supplying to the market: the making available, in return for payment or free of charge, of a device, other than a device intended for clinical or performance evaluation, with a view to distribution and/or use in the KSA.

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.

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.

Device Identifier (hereinafter 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.

Production Identifier (hereinafter UDI-PI): means a numeric or alphanumeric code that identifies the unit of device production. The different types of Production Identifier(s) include serial number, lot/batch number, software version number, manufacturing date and expiration (use by) date.

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).

Direct Marked/Marking UDI (DM UDI): means a permanent marking providing the UDI on the device itself.

Reusable devices: means those devices that require cleaning, disinfection, sterilization or refurbishing between patient use.

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.

Automatic Identification and Data Capture (AIDC): means a technology used to automatically capture data. AIDC technologies include bar codes, smart cards, biometrics and RFID.

A 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.

Human Readable Interpretation (HRI): a legible interpretation of the data characters as encoded in the UDI.

Labeling: means written, printed or graphic matter,

- Affixed to a medical device or any of its containers or wrappers,
- Information accompanying a medical device related to its identification and/or technical description,
- Information accompanying a medical device related to its use, but excluding shipping documents.

Label: means written, printed, or graphic information that is:

- affixed to or appearing on the medical device itself (including electronic display), or if there is none,
- on the packaging of each unit (wrapper) or multiple devices (containers), and if none of that exists,
- on a package insert (is used where it is impractical or inappropriate to affix a label directly on the medical device itself or its packaging. Impractical means where physical constrains prevent this happening).

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.

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.

Device Packaging: means the various levels of homogenous device 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.

Kit: means any combination of 2 or more different devices (UDI-DIs), that are packaged together to achieve a common intended use and are being distributed as medical devices. These could also be called procedure packs or convenience kits.

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.

Abbreviations

AIDC – Automatic Identification and Data Capture

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

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

UDI Requirements

A. General UDI Requirements:

1. All medical devices, IVDs, kits, configurable devices, and accessories placed onto the market or put into service in the KSA shall meet all of the requirements of this UDI System by the applicable compliance date.

2. The manufacturer, or its Authorized Representative, shall assign, manage, and place on the label of the device and, if applicable, on all device packages, a UDI, developed in accordance with these requirements.

3. Own brand/private labelers assume all of the manufacturers' obligations related to the UDI System, including the obligations to place the UDI on the label and to submit UDI information to the SAUDI-D.

4. The marking of the UDI is an additional requirement – it does not replace any other marking or labeling requirements. However, a device's UDI can and should replace any national or local existing medical device identifier with the same purpose of the UDI System.

5. 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.

6. Contact lenses and laser surgical equipment that are intended to be used only for cosmetic rather than medical purposes are also subject to these requirements.

7. The UDI Issuing Agencies shall be GS1, HIBCC and ICCBBA.

8. The manufacturer, or its Authorized Representative, shall assign and manage the UDI following the chosen issuing agency's specifications, standards and guidelines.

9. 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 must be included in the UDI.

10. The UDI must be presented in two forms:
    - Easily readable plain-text/human readable interpretation (HRI), and
    - Automatic identification and data capture (AIDC) technology.

11. The UDI may also include other data, such as quantity or internal reference number.

12. 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.

13. If the AIDC technology is not evident upon visual examination of the label or device package, the label or device package must disclose the presence of AIDC technology.

14. When AIDC carriers other than the UDI are part of the product labelling, the UDI shall be easily and readily identifiable.

15. If linear barcodes are used, the entire UDI must be concatenated into a single barcode.

16. Barcodes shall be verified according to the appropriate ISO/IEC standard and they shall meet the issuing agency's grading standards.

17. If the manufacturer is using RFID technology, a linear or 2D barcode shall also be provided on the label.

18. The UDI shall be readable during normal use and throughout the intended life of the device.

19. The UDI shall be placed so that the AIDC can be accessed during normal operation or storage.

20. 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 must also bear a Direct Marked 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 direct marking UDI (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 must bear a UDI as a direct marking, the UDI may be provided through either or both of the following:
   - Easily readable plain-text/human-readable interpretation (HRI);
   - Automatic identification and data capture (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 direct marking 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 device package, or
   - Is to any of these SAUDI-D data elements:
     - Issuing Agency
     - Primary UDI-DI Number
     - Quantity
     - Brand/Trade Name
     - Version or Model
     - Clinically Relevant Size
     - Labeled as Single Use
     - Device required to be labeled as containing natural rubber latex
     - MRI safety information
     - Device Packaged as Sterile
     - Requires Sterilization Prior to Use
     - Critical warnings or contraindications

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 these requirements.

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 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

   7.1 All of the following device attribute information must be provided (all fields are required unless otherwise noted):

   7.1.1 The GTIN-14 (GS1), HIBC-LIC (HIBCC), or ISBT 128-PPIC (ICCBBA)

   7.1.2 The authorized representative or local manufacturer's Medical Device National Registry (MDNR) establishment registration number

   7.1.3 The device's Medical Device National Registry (MDNR) listing number

7.1.4 The device's Medical Device Marketing Authorization (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 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 7.1.36 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 device has multiple (equivalent) DIs – the 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 Article 5, section "C" above) – 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 device 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

7.1.23 Device packaged/labeled as sterile (y/n)

7.1.24 Requires sterilization prior to use (y/n)

7.1.25 If yes, sterilization method (from a specified list of values)

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 labeled) (if none, state “none”)

Customer Contact – phone and email

7.1.35 GMDN Preferred Term code (auto-populates name and definition) – note that only one term Preferred Term can be 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)

7.2 For devices subject to Direct Marking:

7.2.1 The device is subject to the Direct Marking requirement (y/n)

7.2.2 If yes, the device is subject to the Direct Marking 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]
- What PIs are 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)

7.2.4 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 Device Package UDI-DI number

7.3.2 Package type [per defined vocabulary]

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 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 within the kits, whether marked or not.

7.5 For import control:

7.5.1 The applicable lot or serial numbers

7.5.2 Quantity of a lot-controlled devices

7.5.3 Shipment date (when expected to arrive at the designated port)

7.5.4 Destination (e.g., specific distributor, hospital)

7.5.5 Manufacturer confirmation date (date)

7.6 For end of commercial distribution

7.6.1 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 (based on the IMDRF[1] GHTF mapping of the risk class of the premarket registration path):
   - For Class D devices – 1 year after the publication of the requirements.
   - For Class B/C devices – 2 years after the publication of the requirements.
   - For Class A devices – 3 years after the publication of the requirements.
   - For the Direct Mark requirements – 2 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 rule.

2. A written request for an exception or alternative must:
   - Identify the device or devices that would be subject to the exception or alternative;
   - Identify the specific parts of the rule 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

[1] http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n15-2006-guidance-classification-060627.pdf

Chapter Two

Specific Additional Requirements

A. Stand-alone Software (Software as a Medical Device)

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.

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.

3. A UDI must be applied to the physical media containing SaS/SaMD.

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).

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).

6. Only the plain-text/Human Readable Interpretation (HRI) portion of the UDI shall be required in the software display and shall include the relevant Application Identifiers (AIs).

7. In addition to the change rules outlined in Article 5, section "C" above, 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.

B. Implantable Devices

1. All active implantable devices shall be controlled by serial number.

2. Manufacturers of implantable devices shall provide an "implant card" to the patient with information allowing the identification of the device, including its UDI.

3. The full UDI (UDI-DI and UDI-PI) of an implantable device shall be readily available and readable (scannable) at the point of implantation.

C. Configurable Devices

1. A UDI shall be allocated to the configurable device in its entirety and shall be called the configurable device UDI.

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. 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 must be entered into SAUDI-D.

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.

D. Device constituent parts of "Combination Products"

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.

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.

E. Components and Replacement Parts

1. Each component or replacement part shall have its own, separate UDI and meet all of the other UDI requirements of this rule, 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).

2. For purposes of UDI, replacement parts are intended specifically to replace an identical or similar part of a device that is defective or worn, in order to maintain or re-establish the function of the device without changing its performance or safety characteristics.

3. A component or replacement part 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.

F. Single Use Device Packaging Exception

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 device package,
   - Stored in that device package until removed for use,
   - Not intended for individual distribution, and
   - Not implantable devices.

2. The primary UDI will be on the device package of these individual SUDs.

   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.

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

1. A kit is any combination of two or more different devices (UDI-DIs) in a single package, whether or not they are finished devices, labeled, intended to be used together, created for the convenience of the user, subject to UDI, or marked with UDI.

2. A kit shall have its own, unique UDI (DI and PI) – referencing this specific collection of devices.

3. The UDI-DIs of all devices within the kits, whether marked or not, shall be entered into the SAUDI-D.

H. Convenience kit/procedure pack exception

1. For the purposes of this exception, a convenience 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.

2. The contents of a convenience kit or procedure pack are intended to remain packaged 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.

3. The convenience kit or procedure pack shall have its own UDI.

4. The device contents of a convenience kit or procedure pack shall also have its own UDI, unless the device is:
   - An individual single-use disposable device, which cannot be used outside the context of the convenience kit or procedure pack, or
   - Otherwise, exempt from having a UDI on the label or package of the device that is in the convenience kit or procedure pack.

5. The UDI-DIs of all devices within the kits/packs, whether marked or not, shall be entered into the SAUDI-D.

I. Shipping Containers

1. A UDI is not required to be placed on any "shipping container."

J. Devices Sold at Retail

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 UPC/EAN data carrier).

2. Higher levels of packaging, not intended for retail Point of Sale, must contain the full UDI.

3. A device intended both for retail POS and use in clinical environments, e.g., hospitals, must ALSO contain the full UDI on the label and packaging, in addition to the retail POS data carrier.

K. Own Brand/Private Labelers

1. For the purposes of UDI, an Own Brand or Private Labeler, who labels or relabels a device from a 3rd 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.

L. Custom-made and Investigational Devices

1. For the purposes of UDI, a "custom-made device" means any device specifically made in accordance with a written prescription of any person authorized by national law by virtue of this person's professional qualifications which gives, under his responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs. However, mass-produced devices which need to be adapted to meet the specific requirements of any professional user and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of any authorized person shall not be considered to be custom-made devices

2. For the purposes of UDI, an "investigational device" means any device being assessed for safety and/or performance in a clinical investigation

3. Both Custom-made and Investigational Devices are exempt from UDI.

M. Existing Inventory Exception

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 Direct Marking requirement.

N. Reprocessed , Relabeled, Repackaged, Refurbished, Remanufactured, and Serviced Devices

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.

2. The new UDI must meet all of the requirements of this rule.

3. The re-processor, re-labeler, re-packager, re-furbisher, or re-manufacturer shall keep, where available, the UDI of the original device.

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.

O. Verification and Traceability

1. The manufacturer, authorized representative, importer, and distributor shall store and maintain, in an easily searchable electronic format, the UDI of the devices which they have both received and distributed.

2. Authorized representatives, importers and distributors must verify, in SAUDI-D, that a UDI has been properly assigned by the manufacturer and appropriately appears on the device's label and device packages.

3. Health institutions shall store and maintain, in an easily searchable electronic format the UDI of the devices which they have received.

4. Where a retail pharmacy 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. In keeping with the requirements of MDS-IR3 Implementing Rule on Medical Devices Listing, Article Eight, the importer (registrant) shall submit to the SAUDI-D, for each UDI-DI being imported into the KSA market:
   - The applicable lot or serial numbers,
   - Quantity of lot-controlled devices,
   - Shipment date (when expected to arrive at the designated port), and
   - Destination (e.g., specific distributor, hospital).

2. The manufacturer shall confirm that this information is accurate.

B. Track & Trace

1. For all serialized devices, the Import Control activity ("A." above) will also initiate the SFDA Track & Trace process.

2. 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, pharmacies, medical supply companies, etc.).

3. All distributors, hospitals, and other end-users (including patients), shall submit, upon receipt and distribution (as applicable), the GTIN-14 and Serial Numbers to the Track & Trace System.

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 must 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.

Chapter Five

SAUDI-D Features and Functions

The following list of features and functions are meant to provide a general overview of the SAUDI-Database high-level requirements.

A. Submission Options

1. There are 2 ways in which data can be uploaded – and both can be used by a manufacturer or authorized representative:
   - A user may enter data in a web-based user interface, and/or
   - A user may upload data submissions (in XML format) via a web-based import functionality

B. Web-based Role-based Access Control

1. The SFDA Unified system will manage the user accounts and access functionality. The SAUDI-D will use the SFDA Unified system access credentials to enable access to the UDI module.

2. The SAUDI-D will have various user roles and access permissions for the following user types:
   - SFDA
   - Authorized Representative
   - Manufacturers
   - Importers
   - Trusted Partners (e.g. Insurance, Procurement, Hospital)

3. Users will have full database access, role-specific functionality and/or be restricted in their access to data attributes based on their assigned access control credentials.

C. System Initiated Actions

1. Versioning and History
   - The system will track all versions of the UDI-DI record based on user data entry and/or upload activities.
   - The system will track all history of changes by user.
   - The system will display all versions, history and change logs.
   - The system will record all user and system actions that result in a change to the UDI-DI record.

2. Confirmation of data
   - Annual Confirmation
     - An Annual confirmation action will be triggered two weeks prior to the due date to inform the UDI-DI Record email contacts that a confirmation is required.
     - The system will track Annual confirmation request through to completion.
     - The user must complete the request prior to the due date to avoid suspension of the UDI-DI Record (and subsequent SFDA processes – e.g., Import and Track and Trace).
   - Ad-hoc Confirmation
     - The SFDA reserves the authority to request data confirmation for an UDI-DI record at any point in time.
     - The system will enable notifications for any ad-hoc confirmation requests.

3. Interface with other SFDA Systems
   - The system shall interface with the other Unified System modules (e.g., MDNR, MDEL and MDMA) to retrieve and present data to the user for inclusion in the UDI-DI record.
   - The system shall provide an API to Custom and Border Controls.
   - The system shall interface with the Drug Track and Trace system.
   - The system shall provide an API to Healthcare Trusted Providers (e.g., Hospitals, Providers, and Procurement agencies).

4. Management of Value Sets and Externally managed terminologies
   - The system will version all value sets for user in the web-based interface.
   - The system will validate all UDI-DI Records (i.e., web-based entry or import) based on the most currently available value set or externally managed terminology (e.g., GMDN)

D. User Initiated Actions

1. Web-based Entry of UDI-DI Records

- The user will be able to manage a UDI-DI Record. The UDI-DI Records has the following potential states: draft and submitted.
  - Draft UDI-DI records may be saved, viewed, edited, and deleted or submitted.
  - Draft UDI-DI records may only be saved for 1 year without any activity – i.e., the system will purge any inactive Draft UDI-DI Records.
  - Submitted records may be viewed, edited and resubmitted.
  - Edited Submitted records require confirmation that the UDI-DI does not constitute a new device record, i.e., only an update to an existing record.
  - Submitted records may be copied to enable efficient data entry activities.

- The user will be able to review and validate the UDI-DI Records prior to submitting the record to the SAUDI-D.

- A UDI-DI Record may be updated at any time regardless of the state.

- The UDI-Record will require user confirmation of changes when a "UDI-DI trigger" is changed. Note: this will serve as an attestation that the UDI-DI record changes should not have resulted in a new UDI-DI record.

- The UDI-DI Record will store a change history record for all data element attributes.

2. Web-based Upload of UDI-DI Records

- The user will be able to upload an XML file for each UDI-DI Record.
- The system will enable the upload of one or more files at a time to the SAUDI-D.

- The system will process and validate all individual XML files.
  - The system will add all successful files to the SAUDI-D.
  - The system will log all failed XML files for the user to reconcile based on the error messages.
- The system will enable versioning of the UDI-DI record based on a unique SAUDI-D identifier for the UDI-DI record. Note: this identifier will be created during web-based entry or import for each successful UDI-DI record.

E. Transfer of UDI-DI Records

When the responsibility for a medical device is transferred to another company, the UDI-DI record will need to be transferred to a new manufacturer and all access to the record will be transferred.

1. Transfer Request
   - The system will enable the UDI-DI Record to be transferred from one company to another.
   - The system will enable the existing manufacturer to initiate a transfer of the UDI-DI record.

2. Transfer Confirmation
   - The system will enable confirmations of the transferred UDI-DI record by the new company.
   - The system will enable the new company to accept or reject the transfer of a UDI-DI record.
   - The system will version the UDI-DI Record at that transfer point to account for the change in the manufacturer.

F. Search Functionality

The system will enable the search functionality draft and submitted UDI-DI Records

1. SAUDI-D User Functionality
   - The system will enable the user access to search functionality based on role-based access controls.
   - The system will enable the user to search draft UDI-DI records assigned to the user.
   - The system will enable the user to search submitted UDI-DI records assigned to their account.
   - The system will enable the user to export the search results in a common format.

2. Public Availability
   - The system will enable a publicly available search module and include non-private submitted data.
   - The device identification information will be made available in the SFDA mobile search application.
   - The system will enable download capability and include non-private data.

G. Device Traceability

The system will enable the traceability activities for individual medical devices.

1. Import Control
   - The system will enable the data entry of device traceability information – i.e., production identification information for a UDI-DI record, shipment date, and destination.
   - The system will require confirmation from the manufacturer prior to approval of shipments through any of the SFDA ports.
   - The system will initiate track and trace activities for serialized medical devices listed in the import control module once the manufacturer approves the shipment record.

2. Track and Trace
   - 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.