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The *proposed* SFDA UDI System Requirements

G29 – *proposed Guidance* on the Unique Device Identification System

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Goals of SFDA's UDI System

- Promotes and leverages IMDRF UDI initiatives (+US and EU)
- Increase patient safety and optimize patient care by:
  - Improving traceability, especially field safety corrective actions
  - Control at ports, especially for counterfeits and recalls
  - Identification and documentation at the point of patient use,
  - Documenting and aggregating data in adverse event reports and other postmarket surveillance activities,
  - Improving safe use (thereby reducing medical errors),
  - Allowing longitudinal capture and analysis (long-term safety and effectiveness)

SFDA's UDI System – Overview

- Not IR – Guidance mandatory through National Provisions
- There are currently multiple, regulator-specific global UDI System requirements (origin for devices entering KSA)
- Leverage and improve upon IMDRF and current regulatory schemes to meet the needs of SFDA and KSA.
- Incorporate and leverage current regulatory systems, including:
  - Medical Device National Registry (MDNR) establishment registration and listing
  - Medical Device Marketing Authorization (MDMA)
  - Drug Track and Trace System (DTTS)

Definitions

- Most definitions are the same as EU, US, and/or GHTF/IMDRF.

- Home use medical device: means a medical device labeled for use in any environment outside of healthcare facility. This includes but not limited to home, 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.
- Reusable devices: means those devices that require cleaning, disinfection, sterilization or refurbishing between uses on different patients.

General Rules

Similar to US/EU/IMDRF – with a few minor differences

- A labeled PI shall not be removed because it is also in the UDI
- The *provisional* Issuing Agencies are GS1, HIBCC and ICCBBA
- Linear barcodes must be concatenated into a single barcode
- Barcodes shall be verified
- Full HRI

For Direct Marking:

- If the primary label is on the device – no need for separate DM
- The DM UDI may be the same or different than label DI
- Plain-text/HRI and/or AIDC

New UDI-DI

A new UDI-DI is required whenever there is a change made to a device that is subject to UDI, and the change either:

- 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 a change to any of these SUDID data elements:

Primary UDI-DI	Quantity	Requires Sterilization
Brand/Trade Name	Clinical Size	Single Use
Contains latex	MRI safety	Packaged as Sterile
Version/Model	Critical warnings/contraindications	

Implantable Devices

- Manufacturers of implantable devices shall provide an “implant card” with information allowing the identification of the device, including its UDI-DI.
- The UDI of an implantable device shall be readily available and readable (scannable) at the point of implantation.
- 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.

Configurable Devices

- A “configurable device UDI” (CD-UDI) must be assigned to the entire configurable device
- The CD-UDI must be placed on the assembly that is most unlikely to be exchanged during its lifetime
- Alternatively, the CD-UDI can be presented electronically (e.g., through a computer interface)
- If electronic, how to access is entered into SUDID
- Each component, sub-system or part must have its own, separate UDI if:
  - It can be removed or separated from the configuration, or
  - Is commercially available and distributed on its own

Components and Parts

- Component and replacement parts must have their own, separate UDI and meet all of the other UDI requirements, if:
  - commercially available, and
  - distributed on its own

- Component and replacement parts that significantly changes the intended purpose, safety or performance of the device are considered remanufacturing – and as such subject the device to a new UDI-DI.

SUD Packaging Exception

- Individual single-use devices (SUDs), *labeled (and packaged) individually*, are NOT required to have the UDI on the individual device label/package, if the SUDs are:
  - All of a single version or model,
  - Distributed together in a single device package,
  - Intended to be stored in that package until removed for use,
  - Not intended for individual distribution, and
  - Not implantable devices.
- In SAUDI-D, the Unit of Use (UofU) DI must be assigned and entered into the database.

Kits (generic)

- A kit shall have its own, unique UDI (DI and PI) – referencing this specific collection of devices
- The UDI-DIs (as applicable) of all devices within the kits, whether marked or not, shall be entered into the SUDID
- A kit is any combination of 2 or more different devices 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 or marked with UDI.

Convenience Kit/IVD Kit/Procedure Pack Exception

- It shall bear its own UDI.
- Devices within must also have a UDI unless it is:
  - An SUD, which cannot be used outside the convenience kit, or
  - Otherwise exempt from UDI on this label/package
- The UDI-DIs (if the exist) of all devices within the kits/packs, whether marked or not, shall be entered into the SAUDI-D
- Convenience kit is a combination of devices packaged for the purpose of being used for a single, specific medical purpose
- A convenience kit is intended to remain packaged until used, and not replaced or repackaged, and all devices are consumed or discarded after opened.

Own Brand/Private Labelers

- 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.

Existing Inventory Exception

- 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.

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

- Reprocessors of single use medical devices, relabelers, refurbishers, and remanufacturers, shall create their own, new UDI, which will replace the OEM's UDI, if it exists
- 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.
- 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.

Verification and Traceability

- The manufacturer, ARs, 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
- ARs, importers, and distributors must verify, in SAUDI-D, that a UDI has been properly assigned and appropriately appears on the device's label and device packages
- Where a retail pharmacy and other point of sale shop distributes medical devices, they shall store and maintain the UDI of the devices which they have received and distributed

Saudi UDI Database (SAUDI-D) – General

- The manufacturer or its AR is responsible for the data
- Appropriate methods/procedures for data validation shall be implemented
- All data must be reconfirmed annually (enforced by SAUDI-D)
- The data for a new UDI-DI must be available by the time the device is placed on the market
- For changes not requiring a new UDI-DI, the relevant UDI database record within 10 days of making the change

SAUDI-D – Data Elements (1/4)

For each primary UDI-DI (on the primary label), or, where there is no primary label/package, the DM UDI-DI, or Unit of Use UDI-DI:

1. The ARs or local manufacturer's MDNR number
2. Device's MDNR listing number and MDMA number
3. Name and address of the manufacturer (as labeled)
4. Name and address of the AR (as labeled)
5. Brand/Trade(/Generic) name (as labeled) [also in Arabic if OTC or home-use]
6. Version/model name/number or high-level identifier
7. Catalog number
8. Device description [also in Arabic if OTC or home-use]

SAUDI-D – Data Elements (2/4)

9. Quantity (for primary UDI-DI)
10. Unit of use DI number (when quantity >1)
11. Clinical size (as indicated on the label)
12. Production identifier(s) included in the UDI
13. Equivalent UDI-DIs
14. Previous UDI-DIs
15. Is this a configurable device UDI-DI (y/n)
    [If UDI only presented electronically, where it can be found]
16. Labeled as a single-use device (y/n)
17. Reprocessed single-use device (y/n)
18. Device packaged/labeled as sterile (y/n)

SAUDI-D – Data Elements (3/4)

17. Requires sterilization prior to use (y/n)
    If yes, sterilization method (specified list of values)
18. The maximum number of reuses (where the label indicates the maximum number of reprocessing cycles)
19. Device labeled as containing latex (y/n)
20. Device labeled as "Not made with natural rubber latex" (y/n)
21. Prescription use (Rx) and/or Over the Counter (OTC)
22. Home-use (y/n)
23. MRI safety status (safe, unsafe, or conditional – or none)
24. Special storage conditions (if labeled)

SAUDI-D – Data Elements (4/4)

25. Disposal/Scraping method (free text)
26. Storage and handling conditions (as indicated on the label or in the instructions for use)
27. Critical warnings or contra-indications (as labeled)
28. Customer Contact – phone and email
29. GMDN PT code (auto-populates name and definition)
30. Risk class of the device linked to MDMA
31. URL for additional information, such as electronic instructions for use (optional)
32. Date device is no longer available on the market

SAUDI-D – Data Elements (Direct Marking)

1. The device is subject to the Direct Marking requirement (y/n)
2. If exempt, claiming the following exemption (a. interfere with safety; b. not technologically feasible; or c. previously marked)
3. The DM UDI is different than the label UDI:
   - The UDI-DI (y/n): [if yes, list the DM DI]
   - The PIs: lot number (y/n), serial number (y/n), use by (expiration) date (y/n), manufacturing date (y/n)
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)

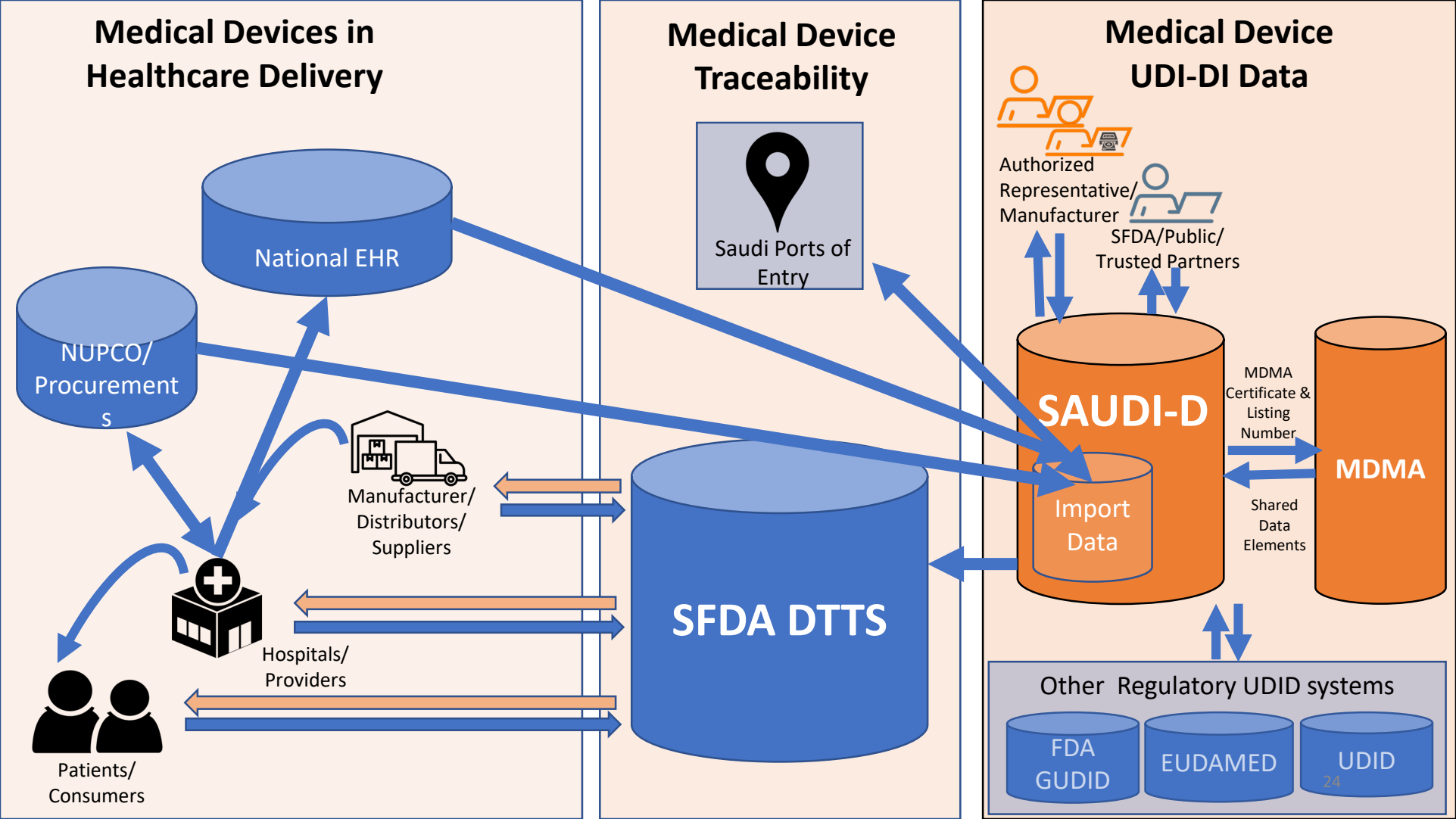
SAUDI-D – Data Elements (Packages and Kits)

For each device package:

1. Device Package UDI-DI number
2. Package type [defined vocabulary]
3. Quantity per package
4. Contains UDI-DI package
5. The PIs of the packages
6. Package discontinuation date (for packages no longer offered)

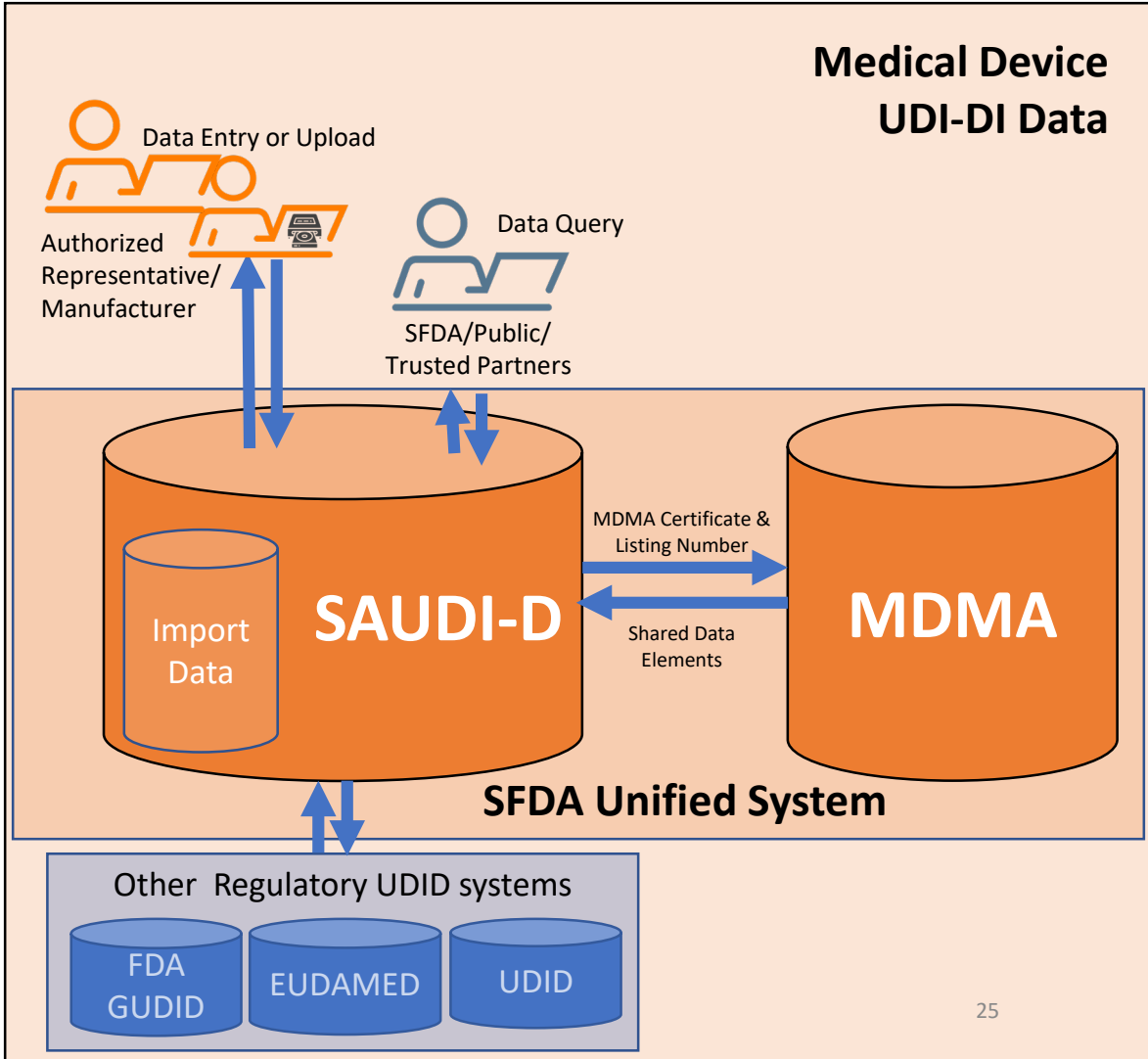
For each kit:

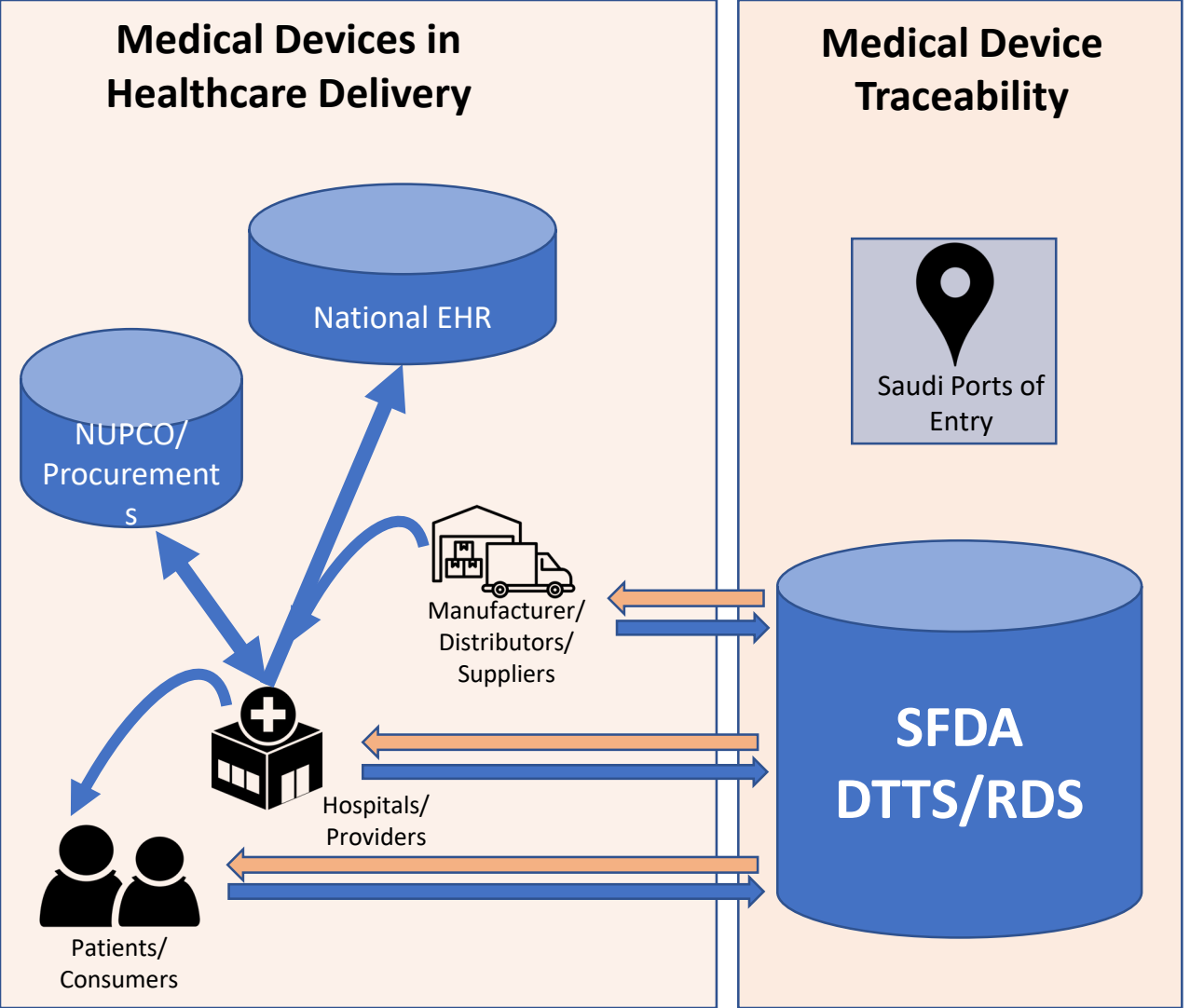
1. The UDI-DIs of all devices within the kit


Medical Devices in Healthcare Delivery
Medical Device Traceability
Medical Device UDI-DI Data
National EHR
NUPCO/ Procurements
Saudi Ports of Entry
Authorized Representative/ Manufacturer
SFDA/Public/ Trusted Partners
SAUDI-D
Import Data
MDMA Certificate & Listing Number
MDMA
Shared Data Elements
Manufacturer/ Distributors/ Suppliers
SFDA DTTS
Hospitals/ Providers
Patients/ Consumers
Other Regulatory UDID systems
FDA GUDID
EUDAMED
UDID

SFDA UDI-DI Data Exchange

- Need to address overlap in data collected during premarket regulatory activities
- Data from the premarket authorization (e.g., TFA and low-risk medical device) process will be linked (reused) during the UDI-DI submission
- Data will be available for reuse – but specificity must be selected during data entry or validated during import





Track and Trace of Medical Devices

- Import data can be sent to the SFDA DTTS/RDS
- Traceability using available UDI data (specifically production identifiers) from the SAUDI-D

Issue: Shipping containers are not labeled with UDI-DI

Exceptions and Alternatives

A manufacturer or its authorized representative may submit a request for an exception from or alternative to any of the requirements of this Guidance – written request must:

- Identify the device subject to the exception or alternative
- Identify the specific parts of the Guidance
- If requesting an exception, explain why you believe the requirements are not feasible;
- If an alternative, describe the alternative and explain why it would provide for more accurate, precise, or rapid device identification

Import Control

The importer 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).

Track and Trace (DTTS)

- 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.
- Importers and distributors shall submit and confirm their products 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

SFDA's UDI System – IR2 Establishment Registration

- MDS - IR2 Implementing Rule on Establishment Registration
- Article Six: Parties subject to registration
- Any person who changes the intended use of, or modifies a finished medical device in a way that affects its safety or performance, without acting on behalf of the original manufacturer, and who makes it available for use is deemed to be the manufacturer of the modified device and is subject to establishment registration requirements **and is, for the purposes of UDI, the manufacturer of the device and must, on their own, meet all of the UDI requirements for that device.**

SFDA's UDI System – IR3 Device Listing

- MDS - IR3 Implementing Rule on Medical Devices Listing
- Article Six: Parties subject to listing requirements
  B. Any person who changes the intended use of, or modifies a finished medical device in a way that affects its safety or performance, without acting on behalf of the original manufacturer, and who makes it available for use is deemed to be the manufacturer of the modified device and is subject to medical device listing requirements **and is, for the purposes of UDI, the manufacturer of the device and must, on their own, meet all of the UDI requirements for that device.**

SFDA's UDI System – IR3 Device Listing

- MDS - IR3 Implementing Rule on Medical Devices Listing
- Article Eight: Information to be submitted for listing purposes
- For the purposes of medical device listing, the registrant shall access the electronic application form available in Section C of the MDNR by providing the Medical Device National Listing Number of the medical device it is supplying to the KSA market. It shall complete the electronic form submitting the following information:
  Indicate **the (full) UDI (DI and PIs)**, quantity, serial numbers or lot numbers, shipment date, and destination of the medical devices that are being supplied to the KSA market.

SFDA's UDI System – IR4 Establishment Licensing

- MDS - IR4 Implementing Rule on Establishment Licensing
- Article Five: General
  A. 3. The appropriate procedure to trace medical devices, **based on UDI**, through … the supply chain …it is …involved.
- Article Six: Parties subject for importation activities
  B. Healthcare facilities and professionals working within …. are not required to be licensed. **They are, however, required to manage the UDIs of those devices that they import.**
- Article Nine: Post-license responsibilities
  B. To ensure that each medical device is accompanied by…
  7. The UDIs of the devices being imported.

SFDA's UDI System – IR6 Marketing Authorization

- MDS - IR6 Implementing Rule on Marketing Authorization
- Article Eight: Documentary evidence
- The applicant shall provide the SFDA with:
  A. A copy, in electronic form, of the labeling associated with the medical device that will be placed on the market of the KSA, i.e. both the labels affixed to the device, **including its UDI**, and the instructions for use…

SFDA's UDI System – IR7 Post-Marketing Surveillance

- MDS - IR7 Implementing Rule on Post-Marketing Surveillance
- Article Six: Medical device reportable AEs within KSA
  A. SFDA will encourage users and persons involved in provision of healthcare to … inform the manufacturer… and the SFDA… **of a device's UDI associated with** any adverse event…
- Article Seven: Medical device reportable AEs outside the KSA
  A. When an adverse event … occurs outside the KSA and has potential consequences for a medical device … on the KSA market, the manufacturer… shall immediately inform the SFDA … and provide all available details on the medical device, **including its UDI**, concerned and…

SFDA's UDI System – IR8 Safeguard Procedures

- MDS - IR8 Implementing Rule on Safeguard Procedures
- Article Four: Actions to safeguard public health
  C. …the SFDA's safeguard measure may include the issuing of a field safety notice to medical device users and/or hospital authorities, warning them that there is a public health threat associated with the use of the medical device, **identifying the UDI of the affected device(s)**, describing the risks involved …

SFDA's UDI System – Compliance Dates

All UDI Requirements:

- Class D devices – 1 year after SAUDI-D is ready
- Class B/C devices – 2 years after SAUDI-D is ready
- Class A devices – 3 years after SAUDI-D is ready

- For the Direct Mark requirements – 2 years after the applicable class compliance date

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Questions?

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Thank You!

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