Saudi Unique Device Identification (UDI)

SAUDI-D

SFDA, Medical Devices Sector

Nov - 2019

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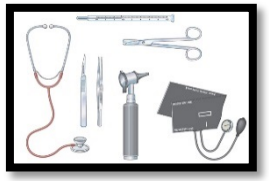
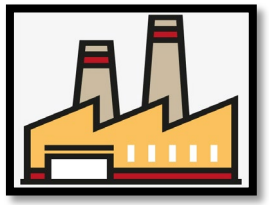
Medical Devices in Saudi Market



Certified Medical devices + Accessories = +180,000



Manufacturers = +25,000

Authorized Representatives = +2100

Importers & Distributors = +1200

MD Recalls from 2016 until now = +1700

What is UDI?

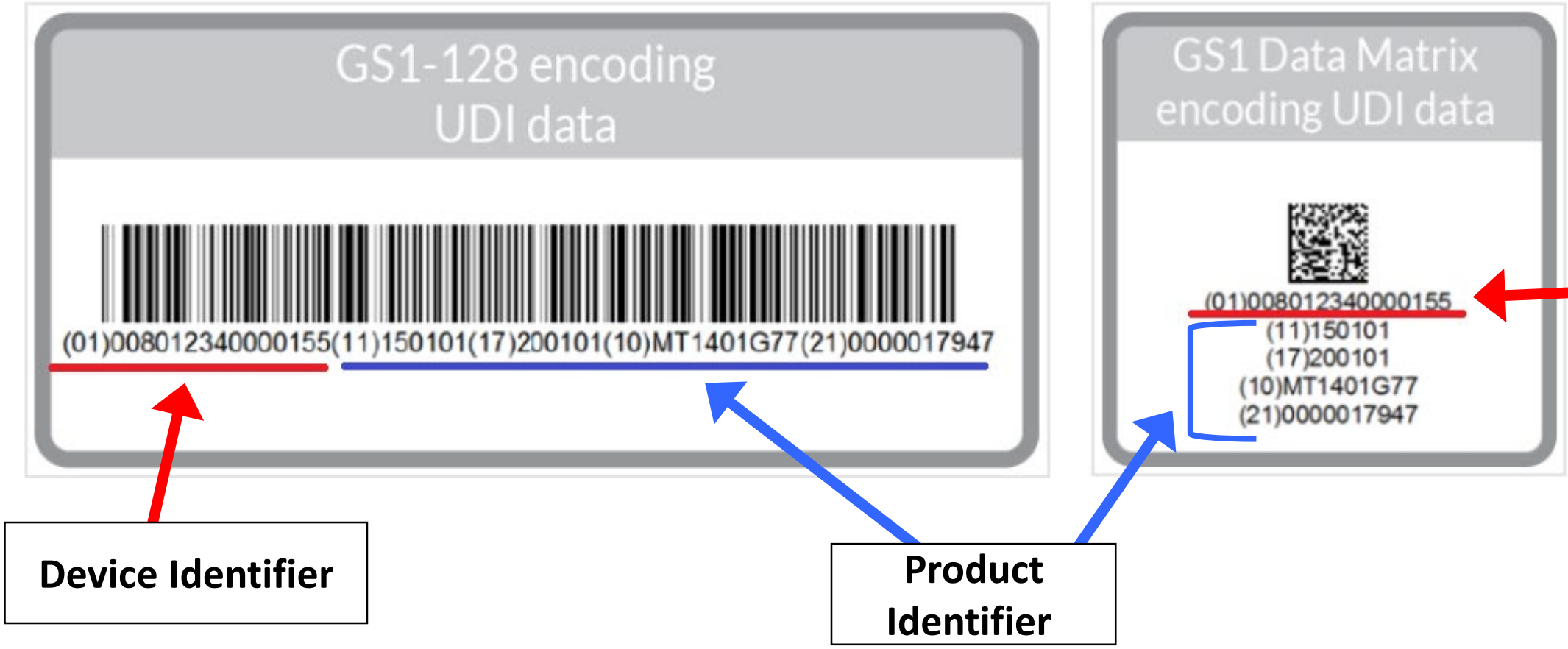
Series of numeric or alphanumeric characters that is created through a globally accepted coding standard. It allows the unambiguous identification of a specific device on the market.

UDI Parts

1. **Device Identifier (UDI-DI)**: 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.

2. **Production Identifier (UDI-PI):** 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.

UDI in Label


GS1-128 encoding
UDI data
(01)008012340000155(11)150101(17)200101(10)MT1401G77(21)0000017947
GS1 Data Matrix
encoding UDI data
(01)008012340000155
(11)150101
(17)200101
(10)MT1401G77
(21)0000017947
DI
Device Identifier
Product
Identifier

WHY UDI ?

Aims to increasing patient safety:

- Improving traceability: Control at ports, Identification and documentation at the point of patient use.
- Increase patient safety : Documenting and aggregating data in adverse event reports and other post market surveillance activities, field safety corrective actions

Utilized in other aspects

- Medical Insurance activities
- Cost control and monitor
- Purchasing and Inventory management

SFDA - UDI Project History

- Benchmark of UDI global framework and initiatives (IMDRF , FDA, EU,..)
- Review SFDA regulation (process guidance and procedures)
- Draft UDI framework (alignment with global guidance)
- Communicate with stakeholders
- Assess IT systems and infrastructures
- Define IT requirements
- Develop UDI Database

Guidance on Requirements for Unique Device Identification (UDI)

- First version April 2018.
- New updated version on Dec.2019

Guidance Scope

- All medical devices and their accessories that will be supplied to the KSA market, except custom-made & investigational as well as research use devices.
- Manufacturers, authorized representative, importers.

General UDI Requirements:

- Recognized issuing Agencies (GS1), (HIBCC) and (ICCBBA)
- The UDI shall contain two parts: the UDI-DI and the UDI-PI(s).
- The UDI-DI shall be globally unique at all levels.
- UDI-PI shall include labeled : lot number, serial number, software identification, or expiration (use by) date
- The UDI shall be presented in two forms:
  - Easily readable plain-text (also known as HRI), and
  - AIDC technology.
- The UDI shall be readable during normal use and throughout the intended life of the device.

Additional Requirements

- Software as a Medical Device
- Implantable Devices
- Configurable Devices
- Components & accessories
- Single Use Device Packaging Exception
- Kits (which includes other non-homogenous package configurations)
- Convenience Kit/IVD Kit/Procedure Pack exception
- Devices Sold at Retail
- Own Brand/Private Labelers
- Relabeled, Repackaged, Remanufactured

Direct Marking (DM)

- All reusable devices subject to DM UDI on the device itself
- DM-UDI may be provided through **either or both :** Readable plain-text - AIDC technology
- Exempt from the DM requirement
  - Interfere with the safety, performance
  - It is not technologically feasible

The UDI-DI Lifecycle

- A new, UDI-DI is required whenever there is a change made to a device or its attributes, **(Based on issuing agency criteria)**

  - New version or model
  - Primary UDI-DI Number
  - New package
  - Issuing Agency
  - Brand/Trade Name
  - Quantity

- The new **updated** DI shall be linked to previous DI in SAUDI-D

UDI Database

- The manufacturer, or its authorized representative, shall submit and maintain the appropriate data to UDI database
- The data for new UDI-DI shall be available in UDI database at the time the device is placed on the market.
- All specified (non-private) data in the UDI database will be made publicly available.

Saudi UDI Database

- **Harmonized Data such as:**
- Devices code DI by the issuing agency
- Manufacturer information
- Brand/Trade name & Device description
- Production identifier(s)
- Configurable device UDI-DI
- Single-use device
- Sterile
- The UDI-DIs of all devices within the kit

Local Data such as:

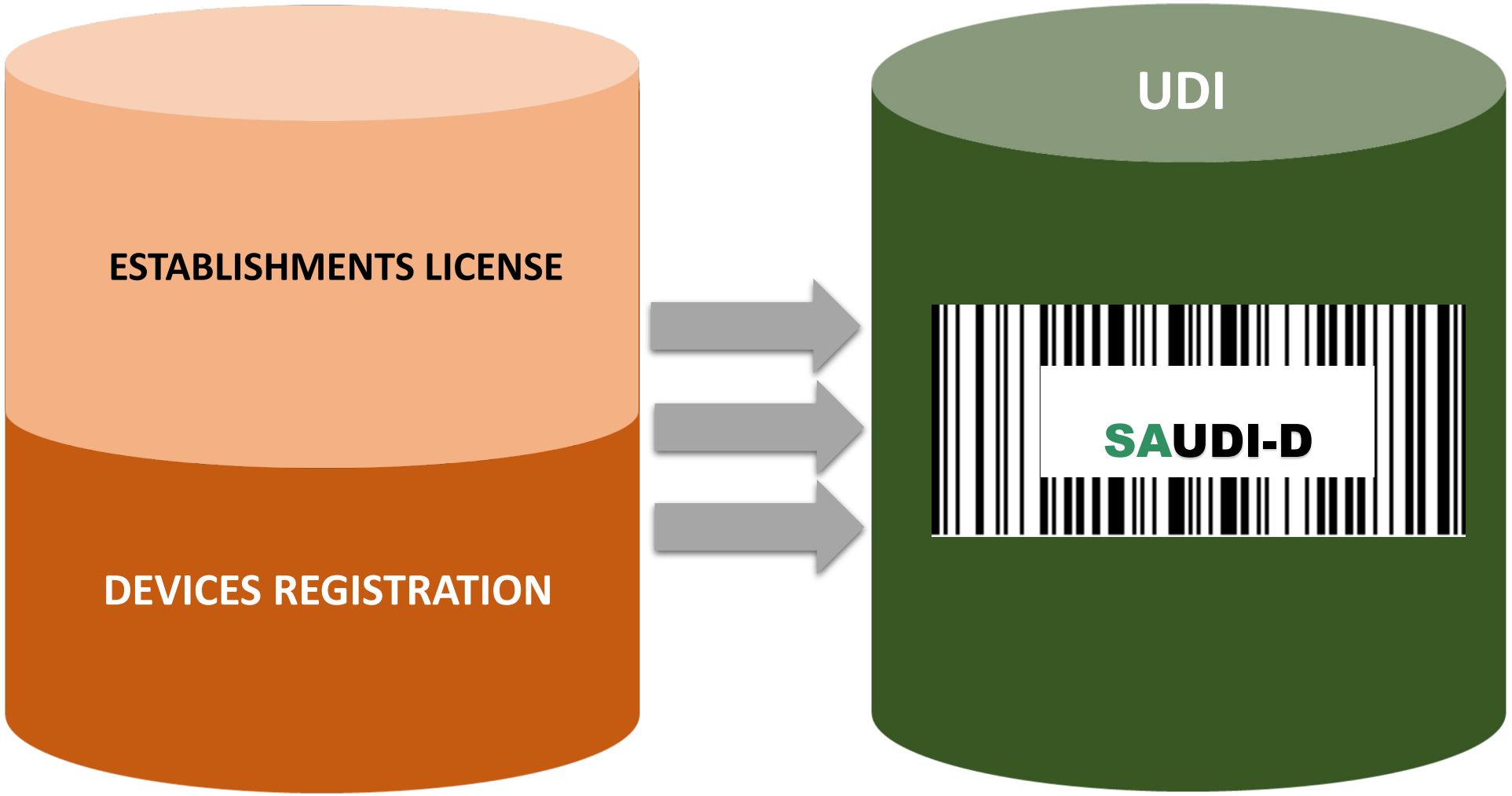
- Registration of Authorized representative
- MD listing number
- Arabic language of Brand name & description when product for lay person

UDI Data Elements

SFDA Data Elements	Description	Data Entry Notes	Source (MDMA or SAUDI-D)	Required in Database?	Publicly Released?
requires sterilizataion prior to e-)use is yes, provide terilization method (from a pecified list of values)	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	Select from LOV	Entered in MDMA; Linked via MDMA and Listing Number entered	Conditional, if requires sterilization prior to use	Yes
he maximum number of reuses	The max the max	Enter whole number	Entered in SAUDI-D	Yes	Yes
evice labeled as containing atural rubber latex or dry atural rubber (y/n)	Device natural			Yes	Yes
evice labeled as "Not made ith natural rubber latex" (y/n)	Device			Yes	Yes
IRI safety status (safe, unsafe, r conditional – or label does ot contain)	Known MRI Safety status	Select from LOV		Yes	Yes
ritical warnings or contra-ndications (as labeled)	Warnings, contraindications, precautions that need to be brought to the immediate attention of the user of the device, and to any other person, as they are indicated on the label.	Enter as indicated on the device label (if none, state "none")	Entered in SAUDI-D	No	Yes
rescription use (Rx) and/or ver the Counter (OTC)	Indicate if the medical device requires a prescription, is sold over the counter or both	Select one or more option - i.e., allow user to select both options	Entered in SAUDI-D	Yes	Yes

Some data elements will be retrieved from SFDA registration systems

SFDA Systems



Import & Distribute Control

A separate section after DIs records, to identify shipment's information

Manufacturer or ARs or Importers shall submit per each shipment the following :

- The applicable Production Identifiers (UDI-PIs),
- Quantity of lot-controlled devices,
- Destination (e.g., specific distributor, hospital).

Compliance Dates

Once launching the UDI database :

- **All MD DIs can be submitted**
- **Enforcement plan will be based on product's risk class**
- **High Risk Devices – (6) months from launching SAUDI-D database.**
- **Direct Marking – (1) years after applicable class compliance date.**

UDI in Healthcare facilities

- Patient's electronic health records,
- Inventory management and billing systems
- Communication of device safety concerns
- Replace in-house coding by UDI

Next steps

- Update UDI guidance
- Launch UDI database

For more information please contact

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