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Unique Device Identification (UDI)& Medical Device Rules,2017-



Drugs and Cosmetics Act 1940 :



The quality, safety and efficacy of notified medical devices manufactured, imported and sold in the country are regulated under the Drugs and Cosmetics Act, 1940. Under this Central Act, medical devices are regulated as drugs as defined in Section 3 (b) (iv) that:

“Such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification after consultation with the Board”

The Govt of India has notified...



S No.	Name of the device	Notification Number	Date of notification
1	Disposable Hypodermic Syringes	GSR 365 (E)	17-03-1989
2	Disposable Hypodermic Needles	GSR 365 (E)	17-03-1989
3	Disposable Perfusion Sets	GSR 365 (E)	17-03-1989
4	In vitro Diagnostic Devices for HIV, HbsAg and HCV including substances used for In Vitro Diagnostics	GSR 601(E)	27-08-2002
5	Cardiac Stents	S.O. 1468 (E)	06-10-2005
6	Drug Eluting Stents	S.O. 1468 (E)	06-10-2005
7	Catheters	S.O. 1468 (E)	06-10-2005
8	Intra Ocular Lenses	S.O. 1468 (E)	06-10-2005
9	I.V. Cannulae	S.O. 1468 (E)	06-10-2005
10	Bone Cements	S.O. 1468 (E)	06-10-2005
11	Heart Valves	S.O. 1468 (E)	06-10-2005
12	Scalp Vein Set	S.O. 1468 (E)	06-10-2005
13	Orthopedic Implants	S.O. 1468 (E)	06-10-2005
14	Internal Prosthetic Replacements	S.O. 1468 (E)	06-10-2005
15	Ablation Devices	S.O.237(E)	25.01.2016

The Products which were already regulated as 'drugs' but now fall under the scope of Medical Devices Rules, 2017

16. Blood Grouping Sera
17. Ligatures, Sutures and Staplers
18. Intra Uterine Devices (Cu-T)
19. Condoms
20. Tubal Rings
21. Surgical Dressings
22. Umbilical tapes
23. Blood/Blood Component Bags

Govt. of India has already notified the following medical devices vide S.O. 5980 dated 03.12.2018, which are to be regulated with effect from 01.01.2020.

24. Nebulizer
25. Blood Pressure Monitoring Device
26. Digital Thermometer
27. Glucometer

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Ministry of Health and Family Welfare vide S.O. 775 (E) dated 08.02.2019 has notified eight categories of medical devices namely,

28. All implantable medical devices
29. MRI equipment
30. CT Scan equipment
31. Dialysis machine
32. PET equipment
33. X-ray machine
34. Defibrillator
35. Bone marrow cell separator
36. Ultrasound equipment (w.e.f. 1.11.2020)

Also, Ministry of Health and Family Welfare vide S.O. 1500 (E) dated 02.04.2019 has notified **Organ preservative solution** as drugs with immediate effect.

Medical Device Rules, 2017



- Medical Device Rules, 2017 have been published vide GSR 78 (E), dated 31.01.2017.
- New rules already effective from 01.01.2018.

Scope of the regulation

Medical Device Rules, 2017 shall be applicable to:

- (i) substances used for in vitro diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant covered under sub-clause (i) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940);
- (ii) substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified under sub-clause (ii) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940); and
- (iii) devices notified from time to time under sub-clause (iv), of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940);

Medical Device Rules, 2017 Content



Chapter- I	Title, Application, Commencement, Definition
Chapter - II	Classification of MD, Grouping of MD, Essentials Principles
Chapter - III	Authorities, delegation of powers, Notified bodies, Medical Devices Testing Centres,
Chapter - IV	Manufacture of MD-Application, Inspection, grant of lic, conditions of lic, Suspension, Cancellation, Appeal, Test License
Chapter - V	Import of MD-Application, Overseas Inspection, grant of lic, Test lic, Hospital use, Personal use
Chapter - VI	Labelling requirement
Chapter - VII	Clinical Investigation- Permission, Medical management, Compensation, Inspection
Chapter - VIII	Permission to import or manufacture medical device which does not have predicate medical device
Chapter -IX	Duties and Powers of Medical Device Officer, Medical Device Testing Officer and Notified Body
Chapter -X	Regulation of Laboratories for carrying test or evaluation
Chapter - XI	Sale of Medical Devices
Chapter - XII	Miscellaneous – Rejection of application, Debarment of applicant, Exemptions

Medical Device Rules, 2017-Schedules



Schedule	Title
First	Classification of MD and IVD
Second	Fee
Third	Registration and functions of Notified Bodies
Fourth	Documents required for grant of mfg and Import licence
Fifth	Quality Management System
Sixth	Post Approval - Major and Minor Changes
Seventh	Requirements to conduct Clinical Investigation
Eight	Exemptions

Salient Points....Regulatory Authorities



Device	Class A	Class B	Class C	Class D
Class Activity				
Import	CLA	CLA	CLA	CLA
Manufacture	SLA	SLA	CLA	CLA
Permission to conduct CI	Permission from CLA			
Sale	SLA			
QMS Verification by	*Notified Body	*Notified Body	CLA	CLA

***Note: Notified Bodies shall be registered with Central Licencing Authority. Prior inspection shall not be required before the grant of manufacturing of Class A devices.**

Class A and B

- Manufacturer shall apply through an identified online portal of Ministry with requisite documents as per Fourth schedule and fees specified in Second schedule.
- No audit for class A device prior to grant of license.
- The audit may be carried out within 120 days from the date of issue of license.
- The audit for Class B device is necessary prior to the grant of manufacturing license and the audit shall be carried out within 90 days from the date of application.
- The notified body shall furnish its report to SLA within 30 days.

Class C and D

- The application shall be made with requisite documents and fees through online portal of the Central Government to CLA.
- CLA may use the services of any expert and of a notified body and may carry out an inspection within a period of 60 days from the date of application.
- No inspection of a medical device manufacturing site for grant of loan license to be carried out if the site is already licensed to manufacture such devices.
- After completion of inspection , the inspection team shall forward the report to CLA through online portal.

Unique Device Identification (UDI)

- The Unique Device Identification (UDI) is a system used to mark and identify medical devices within the healthcare supply chain.

Chapter VII - labelling of medical devices:

As per Rule 46 of Medical Devices Rules, 2017, Unique Device Identification (UDI) of the medical device will be effective from **1st January, 2022**.

A medical device, approved for manufacture for sale or distribution or import, shall bear Unique Device Identification which shall contain device identifier and production identifier.

For the purposes of this rule:

- (i) “**device identifier**” means a global trade item number.
- (ii) “**production identifier**” means a serial number, lot or batch number, software as a medical device version, manufacturing and or expiration date.

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IMDRF (International Medical Device Regulator Forum), the United States Food and Drug Administration (FDA) and the European Commission are aiming for a globally harmonised and consistent approach to increase patient safety and help optimise patient care by proposing a harmonised legislation for Unique Device Identification (UDI), using global standards.

As per application guide of IMDRF for Unique Device Identifier system:

➤ **Unique Device Identifier (UDI):**

The UDI is 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 medical device on the market. The UDI is comprised of the UDI-DI and UDI-PI.

➤ **Unique Device Identification System (UDI system)**

A system that is intended to provide single, globally harmonized positive identification of medical devices through distribution and use, requiring the label of devices to bear a globally unique device identifier based upon standard, with the UDI-DI of that unique identifier being also linked to a jurisdiction-specific public UDI database.

➤ **The UDI is composed of two parts:**

Device Identifier (UDI-DI) + Production Identifier (UDI-PI) = Unique Device Identifier (UDI).

➤ **Unique Device Identifier - Device Identifier (UDI-DI):**

The Device Identifier of the UDI is a unique numeric or alphanumeric code specific to a model of medical device and that is also used as the "access key" to information stored in a UDID. This mandatory, fixed portion of a UDI identifies a manufacturer's specific product and package configuration. Examples of the UDI-DI include GTIN (Global Trade Item Number), UPN (Universal Product Number), PPIC (Processor Product Identification Code).

➤ **Unique Device Identifier - Production Identifier (UDI-PI):**

The Production Identifier of the UDI is a numeric or alphanumeric code that identifies the unit of device production when one or more of the following is included on the package label of the device. The different types of Production Identifier(s) include:

- a) The Lot or Batch within which a device was manufactured;
- b) The Serial Number of a specific device;
- c) The Expiration Date of a specific device;
- d) The date of manufacture (may not be required if other Production Identifiers are on the label);
- e) The Version, for Software as a Medical Device (SaMD),
- f) The Distinct Identification Code (DIC), when applicable. This number is an essential identifier for medical products of human origin.

Advantages of UDI system

The Unique Device Identification (UDI) System will benefit healthcare providers, manufacturers, and individual consumers by enabling:

- Faster discovery of faulty medical devices
- Faster recalls
- Reduction in medical errors
- Reduction in counterfeiting
- Better assessment of device performance
- Improved inventory management
- Mergers and acquisitions (M&A)

➤ **Faster discovery of faulty medical devices**

The regulatory authority receives adverse events or SAE to constitute a pattern of defects that necessitate a recall. The manufacturers/clinicians submitting these reports are often unsure of when they received the faulty medical device and from which supplier, let alone the manufacture date or batch number. This greatly hampers the FDA's ability to determine if a reported medical device fault is a single occurrence or a concerning pattern. This Unique Device Identification system greatly reduces the timeline between the first faulty device identification and the determination that a recall is necessary.

➤ **Faster recalls**

With the Unique Device Identification System, medical providers can quickly and easily check if medical devices in their facilities are included in a recall, and remove those devices from use. UDI eliminates all guesswork, so hospitals no longer need to guess which medical devices came from the affected manufacturer during the recall dates. They simply scan a barcode and know for certain if the device has been recalled.

➤ **Reduction in medical errors**

By providing specific information regarding device characteristics, the Unique Device Identification barcode makes it easy for healthcare professionals to accurately identify medical devices. This cuts down on time and prevents confusion regarding different medical device models.

➤ **Reduction in counterfeiting**

UDI prevents counterfeiting with its in-line scanning technology. UDI barcodes lock a medical device into a chain of custody process. With UDI, medical devices are controlled from the manufacturer, to the distributor, to the healthcare provider, all the way to patient use. This means medical devices are confirmed at multiple checkpoints, greatly reducing the possibility of sneaking a counterfeit device into the supply line.

➤ **Better assessment of device performance**

UDI is creating a massive amount of trackable data for medical devices. By creating a common vocabulary, medical device information can be used to construct real-time analytics regarding cost, recalls, and waste. Doctors will be able to assess medical implants by looking at the health outcomes by the model of device, the hospital where it was implanted, and in some cases the physician who performed the surgery.

➤ **Improved Inventory Management**

Once all medical devices have a scannable barcode, inventory will no longer be an arduous process that is vulnerable to human error. This empowers healthcare providers to reduce waste, audit inventory more regularly, and more effectively stock their facilities. Health care providers can even share their inventory information with their distributors and manufacturers and help manufacturers avoid overproduction. In this way, UDI would clarify the demand for certain medical devices and help manufacturers more accurately determine production.

➤ **Mergers and acquisitions (M&A)**

Before manufacturers embark on M&A deals, it is required that both companies perform the appropriate due diligence; UDI can help towards making this as seamless as possible. The identification of products, volume manufactured and in use, expired products and other equivalent or even identical products is a much easier process with UDI.

➤ **The Unique Device Identification Database (UDID)**

The UDID is a designated source for device identification information. To ensure that all stakeholders, in particular the healthcare sector, are able to obtain value from the UDI system and the UDID. UDID is designed in such a way that

1. Central Medical Device Master Database containing all essential information to identify devices in the jurisdiction.
2. Include the entire package level hierarchy of a medical device.
3. Freely and effectively accessible to all stakeholders.
4. UDI-DI related information can be integrated through Application Programming Interfaces (APIs) into device registries, healthcare supply chain systems, clinical systems, and clinical engineering device maintenance systems.
5. Ensure high availability and reliability (e.g. multi-access automatic uploads and downloads 24*7).
6. Ensure the integrity of data and data transmission processes using recognized data exchange standards.
7. Inform manufacturers about reported data quality issues and track correction, data quality improvements and responses regarding the information submitted.

UDI-DI Triggers

UDI-DI triggers are data elements within a device's UDID entry that, if changed, would require a device to obtain a new UDI-DI.

Any change of one of the following UDID data elements determines the need for a new UDIDI:

- a. Brand Name;
- b. Device version or model;
- c. Clinical Size (including Volume, Length, Gauge, Diameter);
- d. Labeled as single use;
- e. Packaged sterile;
- f. Need for sterilization before use;
- g. Quantity of devices provided in a package
- h. Critical warnings or contraindications

Global scenario

US FDA UDI Regulation

The US FDA released, in September 2013 a rule which establishes that a common, worldwide system for product identification should be applied to all medical devices placed on the US market. The rule establishes that:

- a unique device identifier number should be assigned by the device manufacturer to each version or model of a device
- the unique device identifier should be both in human readable format and in Auto ID format. By default, this information will be applied on the label of each device uniquely identified.

UDI should be applied to all medical devices made available on the US market. Issuing UDIs will help manufacturers comply with the requirements of the FDA UDI regulation, to support patient safety and supply chain security.

➤ **European Union UDI requirements**

The [EU Medical Device Regulation \(MDR\) and In-vitro Diagnostic Regulation \(IVDR\)](#) have been adopted on 5 April 2017 and define the requirements for the EU UDI system. This enables healthcare manufacturers from around the world, to create and maintain UDI numbers by following the EU Regulations. According to the Regulations, a UDI number must be applied to the medical device label, its packaging and, in some cases, the device itself. A new concept has been introduced by the EU Regulations: the Basic UDI-DI, that allows to group regulated medical devices within EUDAMED.

➤ **Other regions of the world**

Several other regulatory authorities are cooperating with IMDRF and converging towards the UDI system to achieve global harmonization. Japan's Federation of Medical Devices Associations (JFMDA) already implemented a system following the IMDRF guidance. Turkey has a similar traceability system in place and full compliance to the global guidance is expected. China's CFDA makes use of a national tracking system, but alignment to IMDRF is being considered. Other countries that have a similar UDI system or are expected to enforce the global guidelines include Canada, Argentina, Saudi Arabia, Brazil and Taiwan.

➤ **Establishing Responsibility for Creating and Maintaining a UDI System**

Establishing the fundamental elements of a UDI system requires that all relevant parties have a clear understanding of their role to achieve the UDI system goals.

- Regulatory authority is responsible for establishing the basic regulatory requirements and vision for the UDI as a global standard.
- Issuing agencies/entities accredited or recognized by regulatory authorities are responsible for defining the general UDI specifications based on relevant international standards.
- Manufacturers are responsible for creating and maintaining globally unique UDIs for their medical devices by following the issuing agency/ entity's specifications. Distributors, importers, retail pharmacies, healthcare providers and users significantly contribute to enhance the potential of the UDI as a key standard to facilitate adequate device identification through distribution and use with patients.

Thank you