MEDICAL DEVICE REGULATIONS

Reference has been made to WHO Medical Device Technical Series 2011, Development of Medical Device Policies; GOI, MOHFW, Central Drugs Standard Control Organisation (CDSCO) the Medical Devices Rules, 2017; CDSCO the Medical Devices Rules, 2020; FDA: Device Advice: Comprehensive Regulatory Assistance; Regulation (EU) 2017/745 and Regulation (EU) 2017/746 of the European Parliament.

WHAT IS A MEDICAL DEVICE

Deployment of Healthcare Technologies is essential for a Robust Healthcare Delivery System in any country. Standardised Healthcare Technologies, as deployed, in prevention, diagnosis, and treatment of illness and disease, as well as patient rehabilitation, are the Medical Devices.

World Health Organisation (WHO) defines “Medical Device” as any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, 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 medical purpose(s) of:

- Diagnosis, Prevention, Monitoring, Treatment, or Alleviation of Disease
- Diagnosis, Monitoring, Treatment, Alleviation of, or Compensation for an Injury
- 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 by means of in vitro examination of specimens derived from the Human Body

and does not achieve its primary intended action by Pharmacological, Immunological or Metabolic means, in or on the Human Body, but which may be assisted in its intended function by such means.

An **Accessory** is generally not considered to be a Medical Device, unless, the accessory is intended specifically by its manufacturer to be used together with the ‘parent’ medical device to enable the medical device to achieve its intended purpose. In such cases, it is subjected to the same procedures, as will apply to the Medical Device itself.

Note: Products which may be considered to be Medical Devices in some Countries but may not be so considered in other Countries, include:

- Disinfection Substances
- Aids for persons with disabilities
- Devices incorporating animal and/or human tissues
- Devices for.in-vitro fertilization or assisted reproduction technologies

WHO STANDARDISED DEFINITIONS

In order to obviate multiple interpretations for the following terms, WHO has defined them as under.

HEALTH TECHNOLOGY:

The application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a Health problem and improve quality of life.

It is used interchangeably with **Healthcare Technology**.

MEDICAL DEVICE:

An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some Health purpose.

Typically, the purpose of a Medical Device is not achieved by pharmacological, immunological or metabolic means.

MEDICAL EQUIPMENT:

Medical Equipment are Medical Devices, requiring calibration, maintenance, repair, user training, and decommissioning − activities usually managed by clinical engineers.

Medical Equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable, or other piece of medical equipment.

Medical Equipment excludes implantable, disposable or single-use medical devices.

OTHER DEFINITIONS

CONFIGURABLE MEDICAL DEVICE SYSTEM

A configurable Medical Device System consists of several components which can be assembled in multiple configurations. Those individual components may be medical devices itself and/or non-medical devices.

Examples are Computed Tomography (CT) systems, Ultrasound systems, Anaesthesia systems, Physiological Monitoring systems, Radiology Information System (RIS).

UNIQUE DEVICE IDENTIFICATION (UDI)

The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted Medical Device identification and coding standard.

It allows the unambiguous identification of a specific Medical Device on the market.

It is linked to a UDI Database (UDID) which contains identifying information and other elements associated with the specific Medical Device.

In case of a Software as a Medical Device, the UDI is assigned at the system level of the Software.

MEDICAL DEVICE REGULATIONS

Medical Devices range from simple tongue depressors to complex Radiotherapy Systems. These may be used in Hospitals or in the Patients, internally or externally. There are more than 10,000 types and 1.5 million individualised pieces of Medical Devices that are available in market for deployment as per choice of the Healthcare Provider. This huge market is growing at 3 – 5% per year as more technology innovations are being added to Healthcare Technology, especially the Digitisation of Diagnostic Tools, Robotics Technology as being deployed in therapeutics, Miniaturisation of system components of Medical tools and the nano Technology used in drug delivery.

This deployment must be optimised according to the local or national priorities and to meet the needs of their National Healthcare Systems. In order to provide this regulated management, safe use, appropriate use policy, and standardised training to Healthcare Providers, Countries have framed **Medical Device Regulations.** The Medical Device Regulations must be able to accelerate patient access to safe, effective, and innovative Medical Devices.

The Medical Devices Regulations must regulate all organisations that are involved in manufacturing, assembling, re-packaging, re-labelling and importing the Medical Devices for deployment in a Country as well as it must regulate all processes that are required for manufacturing, assembling, calibrating, commissioning, maintenance and repairing and re-commissioning the Medical Devices in a Country. The Medical Devices Regulations must encourage collaboration between Device Manufacturers and Healthcare Providers.

The Medical Device Regulations must ensure that these devices are safe at all times, for consumers in the markets, where these Regulations are applicable.

NOUS recommends that these Regulations should be harmonised across various countries and should provide for testing protocols, pre-market approval, registration, post-market surveillance, and adverse event reporting. When harmonised, the use of Medical Technologies across countries can become truly universal and borderless.

The Medical Device Regulations are framed to provide safe and quality Medical Devices, including radiation-emitting devices. The Medical Device Regulatory Authorities must provide to the patients with verified information about the Medical Device. At the same time, this regulatory process must provide adequate freedom for innovation. Well defined regulations must be able to establish a confidence between the patient and the Healthcare Providers that the intended Medical Device is fit for their intended purpose.

To achieve this, first provide detailed technical specifications for Systems Engineering, Installation, Commissioning, Verification and Validation for each Medical Device. The selection of material and manufacturing process must also be properly regulated and verifiable. The design must minimize use-related hazards and risks. All Medical devices must be assigned a Unique Device Number and this database must be available publicly. Once the Medical Device is in use, clear regulated mechanisms

should be instituted for post-market surveillance which can quickly identify poorly performing devices (Medical Device Recall Provision).

In addition, an empowered authority should be established which must evaluate constantly, deployment of all Class III (High Risk) Medical Devices, the specifying organisation's SOPs which specifies its use, the executing organisation's SOPs which provides the Medical Device and undertakes to use it or deploy it. This authority shall never carry out post-market surveillance. The SOPs shall always be based on Evidence Based Practice of delivering Healthcare. This is to ensure that Medical Devices must remain safe, effective, and of high-quality for the duration of their use as a device and with the patient.

This is why, the Medical Device Regulations become country specific. When they are imported or exported, these Medical Device follow the regulations of country of origin as well as the regulations of country where these Medical Devices will be used.

That is how, the Medical Devices Industry gas become one of the highly regulated sectors in the world.

The Medical Device Regulations of a Country must take into account differing internal and external perspectives and focus on collective protection and promotion of Public Health. This protection and promotion of Public Health cannot be realised by individuals or by small consumer groups. The Medical Device Regulations must be transparent, accountable and provide publicly all the information and the regulatory authority decisions. It has to adhere to the highest ethical standards and the law.

The Medical Device Regulations must be able to accelerate patient access to safe, effective, and innovative Medical Devices at their respective point of Healthcare Delivery and must be able to promote Health and Longevity of the populace.

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MEDICAL DEVICE REGULATION IN INDIA

In India, Medical Devices are regulated by the Indian Drugs and Cosmetics Act 1940, (IDCA) and the Rules framed therein. The scope of IDCA is restricted to only those medical devices which are notified by the Government of India from time to time as “drugs” (commonly referred to as “Notified Medical Devices”).

Then came the Medical Devices Rules, 2017 by the Central Drugs Standard Control Organisation (CDSCO). These rules provided risk-based classification system and product standards for the Medical Devices. This also facilitated import of Medical Devices.

Salient features of the Medical Devices Rules, 2017

1. Risk Classification

1.1. All registered Medical Devices and In-vitro Diagnostic Devices (IVDs), based on the perceived risk parameters as scheduled in these rules and on the intended use of the device, will be classified as under.

1.1.1.	Class A	Low Risk
1.1.2.	Class B	Low-Moderate Risk
1.1.3.	Class C	Moderate -High Risk
1.1.4.	Class D	High Risk

2. Medical Device Grouping

2.1. All Medical Devices and IVDs may be grouped for grant of Licence, in accordance with the guidelines, as under;

2.1.1. For Import

2.1.2. For Manufacture, sale or for distribution

2.1.3. For Sale, Stocking, Exhibitions or for offering for sale

3. The Medical Devices shall conform to the standards laid down by Bureau of Indian Standards (BIS) under section 3 of the Bureau of Indian Standards Act, 1985 (63 of 1985) or may be notified by Central Government from time to time. If, such standards are not available then these should conform to the International Organisation for Standardisation (ISO), the International Electro Technical Commission (IEC) or any other Pharmacopoeial standard. If all these are not available then the Medical Device shall conform to the Validated Manufacturer’s Standard.

4. 16 Technical Committees of BIS, have been established specifically for Medical Devices and In-Vitro Diagnostics (IVDs)

5. Create an online Dynamic Listing of the Medical Devices with their General Intended Use

6. All suspected, unexpected, serious adverse event and action taken thereon including any recall within fifteen days of such event coming to the notice of licence holder, will be brought to the notice of the Licensing Authority.

7. Import of all Medical devices will require an import License under these rules. Import of Medical devices for personal use will be declared as per personal baggage custom rules.

8. The Medical Devices Rules, 2017 will provide for

   8.1. Online processing of Registration (Online Portal is functional)

   8.2. Establishment of Medical Device Testing and Confirmatory Assessment Infrastructure

   8.3. Guidance to the Indian Manufacturers for the WHO Pre-qualification of IVDs Programme in India

   8.4. Training of the Regulatory and Industry Professionals.

   8.5. Harmonising Medical Device Tax Structure

   8.6. Simplifications and convergence of rules and practices as per International and National expectations so as to ensure Patient Safety.

9. Labelling of Medical Devices

   9.1. The following particulars shall be printed in indelible ink on the label, on the shelf pack of the medical device or on the outer cover of the medical device and on every outer covering in which the medical device is packed.

      9.1.1. Name of the Medical Device

      9.1.2. The details necessary for the user to identify the device and its use

      9.1.3. The name of Manufacturer and address of manufacturing premises where the device has been manufactured

      9.1.4. The correct statement about the net quantity in terms of weight, measure, volume, number of units, as the case may be, and the number of the devices contained in the package expressed in metric system

      9.1.5. The month and year of manufacture and expiry or the shelf life of the product

      9.1.6. In case of sterile devices, the date of sterilization will be given

      9.1.7. In case the device is made up of stable materials such as stainless steel or titanium and supplied non-sterile or in case of medical equipment or instruments or apparatus, the date of expiry is not necessary.

10. With effect from 1st day of January, 2022, a Medical Device, approved for manufacture for sale or distribution or import, must bear Unique Device Identification Number.

In February 2020, a new definition of Medical Devices was provided by CDSCO which is similar to the WHO definition.

> "All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specifically for Human Beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of;

- Diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder
- Diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability
- Investigation, replacement or modification or support of the anatomy or of a physiological process
- Supporting or sustaining life
- Disinfection of medical devices, and
- Control of conception"

In February 2020, the Medical Devices (Amendment) Rules, 2020 (MDR) were also notified.

These amended rules ensure quality and safety of notified Medical Devices at all levels of the supply chain by enforcing a mandatory license requirement by their respective Manufacturers and Importers.

It requires;

1. From 01 April 2020, all Medical Devices, that meet the Medical Device definition under notification S.O. 648(E) dated 11.02.2020, will be regulated as drugs within India.
2. As per the MDR 2020 amendment, a new chapter has been introduced for registration of "Newly Notified Medical Devices" in which the manufacturers or importers of the will be required to register their medical devices with the Central Licensing Authority through a dedicated online portal established by the CDSCO.
3. The registration shall be on voluntary basis for a period of eighteen months (1st April 2020 to 30 Sep 2021), from the commencement of this rule, after which (from 01 October 2021), it shall be compulsory.
4. **All Importers / Manufacturers / Sellers of notified medical devices, in India, must obtain a license from the appropriate licensing authority (Centre or State) before undertaking any commerce in notified Medical Devices.**

5. **The registration shall be on voluntary basis for a period of eighteen months (1st April 2020 to 30 Sep 2021), from the commencement of this rule, after which (from 01 October 2021), it shall be compulsory.**

6. After end of the voluntary registration period, it shall be mandatory to obtain the registration number. The timelines for obtaining the registration number will be 30 months for Class A (Low Risk) and Class B (Low Moderate Risk) Medical Devices; and 42 months for Class C (Moderate Risk) and Class D (High Risk) Medical Devices.

7. After all the required information is uploaded to the **"Online System for Medical Devices"**, a registration number will be generated, and the manufacturer/importer will be required to mention this registration number on the label of the Medical Device.

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MEDICAL DEVICE REGULATION IN OTHER COUNTRIES

Medical Device Regulation is an integral part of any country's effort at protecting the Human and Veterinary Health. This effort includes implementation of appropriate regulations for drugs, biological products, medical devices and radiation-emitting products, human and animal food, and cosmetics.

The Pure Food and Drugs Act, 1906 of USA is the First and oldest comprehensive consumer protection regulation. In 1960s and 1970s, several amendments were specifically made to improve the safety of use of Medical Devices in USA. Gradually many other countries including Canada, European Union, Japan, etc. also implemented similar acts, creating a plethora of definitions and safety parameters.

To harmonise these globally, International Medical Device Regulators Forum (IMDRF), a voluntary group of Medical Device Regulators from around the world, was established in 2011. They setup the Global Harmonization Task Force on Medical Devices (GHTF). It included representatives from the Medical Device regulatory authorities of Australia, Brazil, Canada, China, European Union, Japan and the United States, as well as the World Health Organization. Now more countries have either joined GHTF or are represented via WHO.

Medical Devices are created with principles of Safe Design Engineering, yet these carry a potential for an adverse event. Evaluation of this potential is called Risk Assessment. Risk analysis evaluates;

- The possible Hazard(s) of use of the Medical Devices
- The likelihood of occurrence of the adverse event during the use of the Medical Devices
- The severity or overall impact of the adverse event

In addition, the Risk Assessment of Medical Devices is based on the experience of Healthcare Professionals, individually as well as a group.

Most of this early work has been done in USA by Food and Drugs Administration (FDA), in Europe by Medical Device Directives Authority, now redesignated as Medical Device Regulations Authority and in Canada by the Medical Devices Bureau of the Therapeutic Products Directorate (TPD).

Currently, ISO 13485:2016, Medical Devices — Quality Management Systems — Requirements for Regulatory Purposes; has become the Universal Code and it has embodied most of the Regulatory Requirements from these countries. It has a greater emphasis on risk management and risk-based decision making, as well as changes related to the increased regulatory requirements for organizations in the supply chain.

World over, Medical Devices are classified on their intended use and their inherent risks, as per risk assessment, into Class I, II (IIa, IIb,) and III. A description of device classification and a link to the Product Classification Database is usually available for reference in every country that is regulating the use of the Medical Devices.

The classification determines the regulatory controls necessary to provide a reasonable assurance of safety and effectiveness when these Medical Devices are used. Regulatory control increases from Class I to Class III. Most Class I devices are exempt from Premarket evaluation. Most Class II devices require Premarket Notification. Most Class III devices require Premarket Approval.

All Medical Devices of all classes are subject to General Controls.

General Controls include Medical Device Registration, Listing in Countries UDI Database, Labelling, and Good Manufacturing Practices.

USA

Medical Devices are regulated by FDA's Centre for Medical Devices and Radiological Health (CDRH). All radiation-emitting electronic Medical Devices have specific regulations which also must be met. The FDA's Medical Device Product Classification database lists over 6,000 types of Medical Devices. These Medical Devices are also subject to the Orphan Drug Act (ODA) of 1984; the Safe Medical Devices Act of 1990, part of the Humanitarian Device Exemption (HDE) Program, a marketing application for an HUD (Section 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)) and section 520(m)(6)(A)(i) of the FD&C Act, Prohibition on Profit.

In addition, FDA implements Medical Device Single Audit Program (MDSAP) to meet the Quality Management System of ISO 13485. MDSAP comply with the standard and regulatory requirements of up to five different medical device markets: Australia, Brazil, Canada, Japan and the United States.

In USA, all imported Medical Devices must have been manufactured conforming to FDA's Current Good Manufacturing Practices (CGMP's). At times, FDA also undertakes Verification of this compliance. It also evaluates the Supply Chain Security.

Essentially, Manufacturers and Distributors must comply with following regulations for Medical Devices in USA, as per Device Class.

1. Registration & Listing of all Medical Devices
2. Meet the Labelling Requirements
3. Premarket Notification
4. Premarket Approval
5. Quality System Regulations
6. Medical Device Reporting

EUROPEAN UNION (EU)

1. The EU is one of the largest global producers of Medical Devices, and the biggest exporter of finished devices in the world. It has proposed a plurilateral Global Agreement on Medical Equipment and Supplies (GAMES) in April 2020.

2. Medical Devices are regulated vide “Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017”.
3. In-vitro Diagnostic Medical Devices are regulated vide “Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017”.
4. Additionally, all Medical Devices shall successfully pass ISO 13485 audit.
5. These regulations apply to anybody who is a manufacturer, authorised representative, importer or distributor of medical devices in the European Single Market, or a regulatory affairs or quality management professional involved with Medical Devices.
6. Under Article 103 of these Regulations, a Medical Device Coordination Group (MDCG) will be established for consultation and administration.
7. These regulations require that before putting the device in market, it must be ensured that the device has been CE marked and that the EU declaration of conformity of the device has been drawn up.
8. These regulations require creation and maintenance of a Harmonised European Database on Medical Devices (Eudamed) that will list Medical Devices in EU market and their conformity assessment.
9. For Class I, Medical Devices, the conformity assessment does not involve a notified body. But for all other classes (I*, IIa, IIb, III) a notified body must be involved. The number of the notified body shall appear on the CE-mark.
10. It is required that the Medical Device shall be assigned an UDI number.
11. Right to claim compensation for damage caused by a defective device in accordance with applicable Union and national law is provided in these regulations.
12. For export, a Certificate of Free Sale must be provided. Additionally, the manufacturing process must comply with good manufacturing practice and good distribution practices.

13. CE Marking for Medical Devices in EU

13.1. There is no CE Certification.

13.2. Originally CE stood for Communauté Européenne (European Community) and later for Conformité Européenne. This was required to market products in EU markets.

13.3. With the CE mark, a manufacturer expresses conformity with the European legislation, specifically with European directives and European regulations. For Medical Devices, these regulations are the Medical Device Regulation MDR and the In-vitro Device Regulation IVDR.

13.4. The four-digit number that is displayed next to the CE mark on Medical Devices is the identification Number of the Notified Body (NB). If there is no four-digit number, this means that the Medical Device is a Class I Medical Device that does not require NB involvement and CE mark is based on self-declaration. All Class I Medical Devices with a NB number next to the CE mark, denote that it is either a Sterile Device or has a Measuring Function. This identification of NB is listed in EU NANDO

Information System for Public Information. NB is also responsible for post marketing surveillance and investigations.

13.5. Additionally, for Medical Devices of class IIa or higher, compliance to a certified Quality Management System like ISO 13485 or other notified bodies is required. Only those Medical Devices that successfully pass the conformity assessment procedure are legally labelled with a CE mark.

13.6. When the Medical Device has a CE mark, the seller of the product shall provide copies of Technical Assessment Reports, Quality System Reports and Clinical Evaluation Reports, when asked or when required.

CANADA

1. The Medical Devices Bureau of the Therapeutic Products Directorate (TPD) is the national authority that monitors and evaluates the safety, effectiveness and quality of diagnostic and therapeutic medical devices in Canada.
2. In Canada, all medical devices are grouped into four classes with Class I devices presenting the lowest potential risk (e.g. a thermometer) and Class IV devices presenting the greatest potential risk (e.g. pacemakers).
3. A Medical Device Licence is required for Class II, III and IV devices.
4. An Establishment Licence is required for Class I devices.
5. Health Canada requires manufacturers of Class II - IV Medical Devices to meet the Quality Management System of ISO 13485 or have undergone MDSAP audit.
6. TPD monitors Medical Devices to ensure their continued safety and effectiveness. If a Medical Device is considered to be no longer safe and effective, the manufacturer may be requested to recall or refit the Medical Device.
7. All associated advertising and information provided to public in relation to all Medical Devices is also regulated in Canada.

TO CONCLUDE

1. Medical Devices are used to maintain and improve Health and well-being of Humans. All Medical Devices have expected or unexpected risks of adverse events when these are used on patients. Therefore, their use has to be regulated.
2. Medical Devices should achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the stated functions within the scope of the definition of a Medical Device applicable in each Country.
3. Using Medical Devices across countries need common QMS System. Gradually, ISO 13485 is becoming this system.

4. Use of Medical Devices must provide a device recall system to minimize the adverse incidents. The Device Recall System must provide a clear description of compliance and enforcement actions. This is where country specific regulations are required.
5. In general, Harmonised International Standards are declarative. It means, Individual Countries needs to adopt and implement these with the national context to further ensure the safety, effectiveness and quality of these Medical Devices. It also requires that information related to medical device's adverse events be shared. Non-compliance with regulations attracts penal action within respective National Context.
6. Therefore, in context of Medical Devices, Regulations in country of origin and country of use must be reviewed and these impact the country specific License provided.

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SAMPLE DATABASE SHEET FROM FDA DATABASE

Device	Vacuum Powered Body Fluid Collection Kit
Regulation Description	Powered Suction Pump.
Definition	This product code has been established in accordance with the May 20, 1997, Guidance entitled, Convenience Kits Interim Regulatory Guidance, found at www.fda.gov/cdrh/ode/convkit.html. This type of convenience kit, as listed in the guidance above, is under enforcement discretion, and does not require a premarket notification (510(k)) to market if it meets all criteria in the guidance.
Physical State	This product code has been established in accordance with the May 20, 1997, Guidance entitled, Convenience Kits Interim Regulatory Guidance, found at www.fda.gov/cdrh/ode/convkit.html. This type of convenience kit, as listed in the guidance above, is under enforcement discretion, and does not require a premarket notification (510(k)) to market if it meets all criteria in the guidance.
Technical Method	This product code has been established in accordance with the May 20, 1997, Guidance entitled, Convenience Kits Interim Regulatory Guidance, found at www.fda.gov/cdrh/ode/convkit.html. This type of convenience kit, as listed in the guidance above, is under enforcement discretion, and does not require a premarket notification (510(k)) to market if it meets all criteria in the guidance.
Target Area	This product code has been established in accordance with the May 20, 1997, Guidance entitled, Convenience Kits Interim Regulatory Guidance, found at www.fda.gov/cdrh/ode/convkit.html. This type of convenience kit, as listed in the guidance above, is under enforcement discretion, and does not require a premarket notification (510(k)) to market if it meets all criteria in the guidance.
Regulation Medical Specialty	General & Plastic Surgery
Review Panel	General & Plastic Surgery
Product Code	OJR
Premarket Review	Infection Control and Plastic Surgery Devices (DHT4B) Infection Control and Plastic Surgery Devices (DHT4B)
Submission Type	Enforcement Discretion
Regulation Number	878.4780
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible
Recognized Consensus Standard	• 1-133 ISO 10079-3 Third Edition 2014-05-01 Medical suction equipment - Part 3: Suction equipment powered from a vacuum or positive pressure gas source
Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

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