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Department of
Pharmaceuticals

MAKE IN INDIA

QCI | NABCB

Resource Document
On
"MDR 17 – Regulation of Medical Devices"

Building Capabilities,
Enriching Quality and Patient Safety

Resource Document

On

"MDR 17 – Regulation of Medical Devices"

Building Capabilities,
Enriching Quality and Patient Safety

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सत्यमेव जयते

Dr. V. G. Somani
Drugs Controller General (India)
Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
Government of India
FDA Bhawan, Kotla Road,
New Delhi-110002 (India)

FOREWORD

I am delighted to write this foreword for the "Industry Awareness Programme on MDR 17 – Regulation of Medical Devices" being organized by Association of Indian Medical Devices Industry (AiMeD) and Biotech Consortium India Limited (BCIL), New Delhi. To provide impetus to this sector, ensure quality and robustness of the Indian Medical Devices, the Ministry of Health and Family Welfare, Government of India rolled out Medical Device Rules 2017 (MDR17), which became effective in the country since January 2018. The MDR17 were applicable to 24 categories of Medical Devices. Since then, there have been notifications by the GoI from time-to-time to bring in various other categories of medical devices under regulation.

As per the recent notification by the Government dated 11th February, 2020, all medical devices will fall under the preview of regulations from 1st Day of April, 2020 in phase wise manner to begin with voluntary registration followed by mandatory registration followed by licensing as given in notification over the period of 42 months to achieve smooth transition. At this important juncture, when all the Medical Devices will be regulated, capacity building of the medical device industry for smooth implementation and adoption of MDR17 becomes essential.

I am pleased to note that AiMeD and BCIL have joined hands to organise this workshop for awareness creation and capacity building of medical device industry in the Country. The Medical Device market in India, recognised as "Sunrise Sector" by the Government of India is estimated to be over USD 15 billion $ (105000 Crore Rs). The sector is highly import dependent with about 75% of the requirements being met through imports. The adoption of the MDR17 will bring in a lot of credibility to the Indian Medical Device industry and is expected to address the challenge of import dependency by promoting export and Make in India.

It is envisaged that this workshop will serve as a tool for capacity building of the Indian Medical Device Industry. It will help in creating awareness, building capabilities, enriching quality and patient safety by deliberation on key issues and pathway for smooth implementation of MDR17 for ensuring patient safety and consumer protection.

I wish this Workshop a huge success!!

V.G.S.

Dr. V G Somani,
Drugs Controller General (India)

Tel.: +91-11-23236965 Fax : +91-11-23236973 E-mail : dci@nic.in Website : www.cdsco.nic.in

ABBREVIATIONS

ACCCP	ASEAN Coordinating Committee on Consumer Protection
ACCSQ	ASEAN Consultative Committee on Standards and Quality
AECC	ASEAN Economic Community Council
AERB	Atomic Energy Regulatory Board
AIMED	Association of Indian Medical Device Industry
AMDD	ASEAN Medical Device Directive
AMTZ	Andhra Pradesh Medtech Zone
BCIL	Biotech Consortium India Limited
BIRAC	Biotechnology Industry Research Assistance Council
BIS	Bureau of Indian Standards
CAB	Conformity Assessment Body
CAGR	Compounded Annual Growth Rate
CDSCO	Central Drugs Standard Control Organization
CIC	Common Incubation Centers
CSSD	Central Sterilized Services Department
DBT	Department of Biotechnology
DIPP	Department of Industrial Policy and Promotion
DOP	Department of Pharmaceuticals
DOT	Department of Telecommunications
EEG	Electroencephalography
ENT	Ears Nose and Teeth
EODB	Ease Of Doing Business
FDA	Food and Drug Administration
FDI	Foreign Direct Investment
FSSAI	FoodSafetyand Standards Authority ofIndia
GMP	Good Manufacturing Practices

GOI	Government of India
GST	Goods & Services Tax
HTA	Health Technology Assessment
IAPO	InternationalAllianceof Patients' Organizations
IBSC	Indian Biomedical Skill Consortium
ICMED	Indian Certification of Medical Devices Scheme
IHPRA	Indian Healthcare Products Regulatory Authority
ISO	International Organization of Standardization
IVD	*In-vitro* Diagnostic Devices
MAAH	Market Access Authorization Holder
MDI	Medical Device Industry
MEITY	Ministry of Electronics and Information Technology
MHRA	Medicines and Healthcare products Regulatory Agency
MOEF	Ministry of Environment, Forest and Climate Change
MOHFW	Ministry of Health and Family Welfare
MSME	Ministry of Micro, Small and Medium Enterprises
NABCB	National Accreditation Board for Certification Bodies
NABH	National Accreditation Board for Hospitals and Healthcare Providers
NABL	National Accreditation Board for Testing and Calibration Laboratories
NITI	National Institution for Transforming India
NMDA	National Medical Device Authority
NMDPC	National Medical Devices Promotion Council
NPPA	National Pharmaceutical Pricing Authority
PPP	Public Private Partnership
QCI	Quality Council of India
USD	United Stated Dollars
WHO	World Health Organization

ACKNOWLEDGEMENTS

Association of Indian Medical Device Industry (AiMed) and Biotech Consortium India Limited (BCIL) would like to thank the following stakeholders for their support and contribution to the Industry Technical Workshop on MDR-17 – Regulation of Medical Devices focused on Building Capabilities, Enriching Quality and Patient Safety:

- Ministry of Health and Family Welfare (MoHFW)
- Department of Pharmaceuticals (DoP)
- National Institution for Transforming India (NITI Aayog)
- Central Drug Standard Control Organization (CDSCO)

The following contributors are acknowledged:

Association of Indian Medical Device Industry (AiMed):

Mr. Rajiv Nath, Founder and Forum Coordinator

Mr. Manoj Tiwari, Secretary to the Forum Coordinator

Mr. Rajiv Chibber, Vice President, Sahajanand Medical Technologies

Mr. Gurmit Chugh, Managing Director, Translumina & Jt. Coordinator, Implants, AiMeD

Biotech Consortium India Limited (BCIL):

Dr. Suchita Markan, Asst. General Manager

Dr. Yogmaya Verma, Deputy Manager

Dr. Vasundhara Shukla, Senior Project Executive

Overall Guidance:

Dr. Purnima Sharma, Managing Director, BCIL

Industry Awareness Workshop on

"MDR 17 – Regulation of Medical Devices"

Building Capabilities, Ensuring Quality and Patient Safety

Workshop Agenda

Date: 29.02.2020

Venue: India Habitat Centre, New Delhi

Start Time	Session Topic	Speakers
0900 to 0930	**Registration**	
0930 hrs	Welcome address	**Dr.Purnima Sharma, MD, BCIL**
0935 hrs	Opening address	**Dr. V G Somani, DCGI. CDSCO** (TBC)
0945 hrs	Inaugural address	**Dr. V. K. Paul**, Member, NITI Aayog (TBC)
09:55 hrs	Vote of Thanks	**Mr. Rajiv Nath**, Forum Coordinator, AiMeD
	Tea / Coffee Break	
10:30 hrs	MDR'17 – An Overview including Risk Based Classification of Medical devices and use of Online Portal for MDR.	**Dr. Ravi Kant Sharma,** DDC, CDSCO
11:15hrs	Medical Device Bill and Way Forward	**Dr. Sonali Rawal, NITI Aayog** (TBC)
11:45hrs	QMS Requirements as per Vth Schedule of Medical Device Rules	**Mr. Mrutunjay Jena**, Director, NABCB
12:30hrs	Standards Requirements for Medical Devices- Where we are and Way Forward	**Mr. Prakash Bachani** Scientist E & Head, Medical Equipment & Hospital Planning Department, Bureau of Indian Standards
1300 hrs-1400hrs	**Lunch Break**	
1400hrs	Panel Discussion – Comprehensive Regulation of Medical Devices in India: Challenges / Opportunities and Way Forward	**Moderator: Mr. Anil Jauhri**, Ex-CEO, NABCB

		Panellists: 1. **Dr. Ravi Kant Sharma,** DDC, CDSCO or **Dr. V G Somani, DCGI, CDSCO** 2. **AiMeD Representative** – **Dr. Siva Kumar**. Consultant, ESI MedTek 3. **MNC representative**: **Mr. Shishir Agarwal**, MD,Terumo India Pvt. Ltd. 4. **Start-up representative**: Mr. Tarun Kumar, Infinity Mediquip 5. **Mr. Rajesh Maheshvari**, CEO, QCI 6. **Ms. Malini Aisola**, AIDAN
14:45hrs	Processing of the Application and Clinical Performance Evaluation of IVDs	**Shri. Sella Senthil**, ADC, CDSCO
15:30hrs	**Coffee Break**	
15:45hrs	Clinical Investigation of Medical Devices	**Shri. Arvind Hiwale**, ADC, CDSCO
16:30 hrs	UDI – Unique Device Identification (Technology Presentation)	**Mr. Amrit Garg**, GS1 Representative
16: 45hrs	Registry of Orthopedic Implants	**Bodhisatya OM**, Northgate Public Services
17:00hrs	**Concluding Remarks**	**Dr. Suchita Markan, Asst. General Manager, BCIL**

Introduction

Introduction

Medical devices are an important part of health care, yet they are an extraordinarily heterogeneous class of products. The term —medical device includes such technologically simple items as ice bags and tongue depressors on one end of the continuum and very sophisticated items such as cardiac pacemakers and proton therapy devices on the other end. Broadly based on the function of medical device, they may be classified as preventive care device, assistive care device, diagnostic device and therapeutic device.

Indian medical device sector, Asia‘s fourth largest market of approximate US $ 10.00 billion (Rs. 61,800 Crore) in 2013-14 as per retail sales, growing steadily at a rate of over 15-17% CAGR, currently about US $ 15 billion. The sector presents an exciting business landscape and opportunities for both domestic as well as international manufacturers/entrepreneurs and expanding at a steady pace. Till the early 1990s, the medical device sector was significantly dominated by domestic players but after India opened up its market post-New Economic Policy-1991, tables have turned in favour of Indian market. The technological advancement and expertise in the field of medical devices that the global market leaders offered has proved as an advantage. India’s medical device sector is highly import dependent with about 75% of the sales and supply to its healthcare system being met through imports. Over the years, many multi-nationals have set up operations in India. However, the nature of majority of the operations is to only distribute imported devices and provide support function.

Regulations of Medical Devices in India

Medical Devices in India are regulated as drugs by the Central Drugs Standards Control Organization (CDSCO) as per the provisions of Medical device rules 2017 issued by the Government under the Drugs and Cosmetics Act, 1940 (“D&C Act”). Only the devices notified by the Government are regulated and falls under the provisions of regulations as per MDR17. In tune with the global practice, the 2017 Rules has introduced a risked based classification system for regulation of medical devices including Low risk (Class A),

Low Moderate (Class B) Moderate High (Class C) and High Risk devices classified as (Class D).

Salient Features of MDR 2017:

- Risk based classification
- Provisions of Notified Bodies
- Quality Management System in line with ISO 13485;
- Provisions related to the 'Essentials Principles of Safety and Performance' for manufacturers have been specified in the Rules;
- Separate provisions for regulation of Clinical Investigation of investigational medical devices (i.e. new devices) have been made at par with international practice.
- Provision is made to designate or establish Central Government medical device testing laboratories to verify conformance with the quality standards.

Under the 2017 Rules, medical devices mean:

a. Specific devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals which are notified by the government from the time to time under the Drugs and Cosmetics Act, 1940 ("D&C Act"). Some categories of devices have already been notified by the government. A list of classes of currently notified medical devices is annexed as Annexure D.

b. Specific substances intended to affect the structure or any function of the human body which
are notified by the government. At present, the substances notified are mechanical contraceptives (eg. condoms, intra-uterine devices, tubal rings) and disinfectants.

c. Surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant;

d. Substances used for in vitro diagnosis (referred to in the 2017 Rules as “In Vitro Diagnostic Medical Device”)

e. All substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals. This is a catch-all category for substances;

As per recent notifications issued by theMinistry of Health and Family Welfare on 11thFebruary, 2020, all medical devices intended for use in human beings or animals as drugs will come under the purview of regulations with effect from the 1stday of April, 2020.

The definition of Medical Devices, as notified by the Ministry of Health and Family Welfare, Government of India for which medical device regulations will be applicable is given below:

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 specially 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:

(i) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
(ii) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;
(iii) investigation, replacement or modification or support of the anatomy or of a physiological process;
(iv) supporting or sustaining life;
(v) disinfection of medical devices; and
(vi) control of conception.

Purpose and Scope of the Guidance Document

Considering that all medical devices will be regulated as per the provisions of Medical Device Rules 2017, the present workshop and this guidance document becomes essential for reference by the Indian medical device industry helping them in its smooth adoption.

This document provides guidance to assist manufacturers, traders/distributors, importers, clinical establishments, healthcare professionals and general public on nationally recognized medical devices standards and other regulatory requirements concerning medical device in India.

It is a consolidated reference document made available for manufacturers, traders/distributors, importers, clinical establishments, healthcare professionals and general public about the standards, regulatory and other requirements for medical devices in India as per MDR17 and notifications, guidance documents issued by the Government for smooth implementation of the MDR17 from time-to-time.

The guidelines describe the information to be included with applications for medical devices and in vitro diagnostics to enable:

- Import, manufacture for sale or for distribution; and
- Stock, exhibit or offer for sale of medical devices in India
- Healthcare Professionals
- Policy makers/Government organizations
- Medical devices Procurement persons or agencies/organizations
- Private and public hospitals or its representatives
- Medical devices testing, Quality monitoring organizations
- Associations of Industry, professionals, Hospital etc.
- General Public/Citizen of India

The guideline also describes post-market, labelling requirements and traceability issues for the medical devices. Since, all the application for manufacturing, sale, import of medical devices is to be undertaken through the online Sugal Portal of the CDSCO, a reference document for online submission of applications has also been included for reference by the medical device industry.

Medical Devices Rules – 2017

MEDICAL DEVICES RULES-2017

Regulation of Medical devices in India

The Central Drugs Standard Control Organization (CDSCO) under Directorate General of Health Services in Ministry of Health and Family Welfare (MoHFW), Government of India (GoI) is the National Regulatory Authority (NRA) responsible for approval of manufacturing, import, conduct of clinical trials, laying down standards, sale and distribution of medical devices through enforcement and implementation of the Medical Devices Rules, 2017 released through Gazette of India notification G.S.R. 78(E), dated 31st January 2017 by the MoHFW, GoI, effective from 01.01.2018, under the Drugs and Cosmetics Act 1940. The main moto of these rules is to regulate the Clinical Investigation, Manufacture, Import, Sale and Distribution of the medical devices in the country.The Medical Devices Rules, 2017 are harmonised with the international regulatory practices and provide comprehensive legislation for the regulation of Medical Devices, which will foster Make in India.

The Medical Devices Rules 2017 consists of 12 Chapters, 8 Schedules and 40 Medical Devices forms to assist the medical device manufacturers, innovators in adopting MDR17. Please refer to the link below for details about the MDR17 notified by the Government of India for adoption by the medical device industry.

https://mohfw.gov.in/sites/default/files/Medical%20Device%20Rules%2C%202017.pdf

Summary of the Chapters, Schedules and Forms included in the MDR17 are summarised below:

Medical Device Rules, 2017 Chapters:

Chapters	Description
Chapter- I	Title, Application, Commencement, Definition
Chapter - II	Classification of MD, Grouping of MD, Essential 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 Number	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

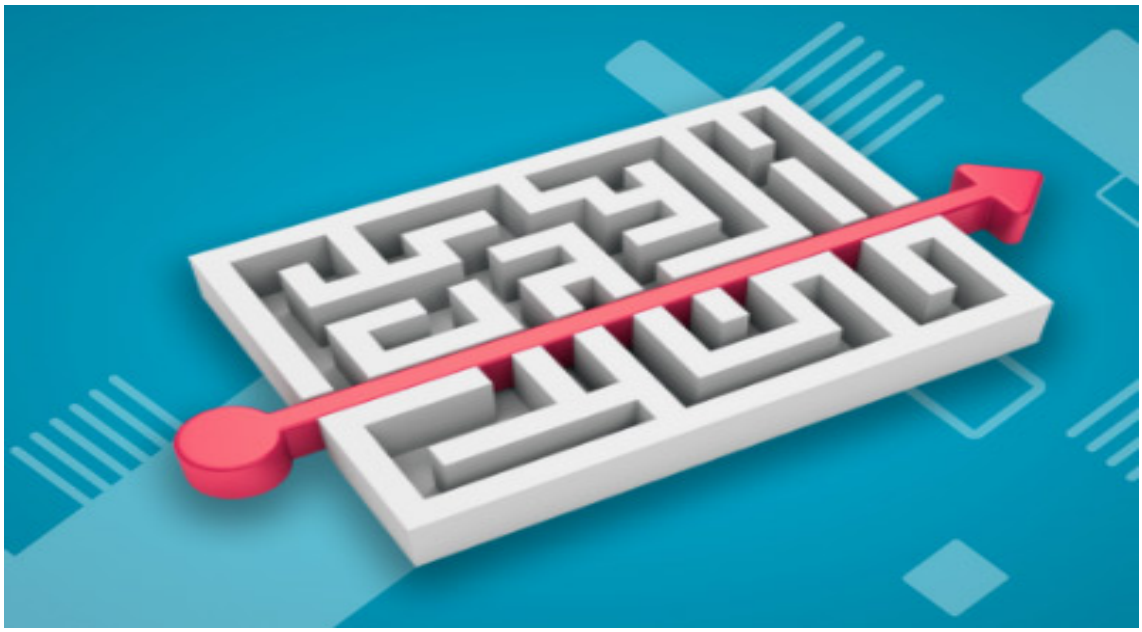
List of forms under Medical Devices Rules, 2017:

Description	Form No
Application for grant of certificate of registration of a notified body	Form MD1
Certificate of Registration for a notified body under the Medical Devices Rules, 2017	Form MD2
Application for grant of license to manufacture for sale or for distribution for Class A or Class B medical device	Form MD3
Application for grant of loan license to manufacture for sale or for distribution of Class A or Class B medical device	Form MD4
Licence to manufacture for sale or for distribution of Class A or Class B Medical Device	Form MD5
Loan Licence to manufacture for sale or for distribution of Class A or Class B Medical Device	Form MD6
Application for grant of license to manufacture for sale or for distribution of Class C or Class D medical devices	Form MD7
Application for grant of loan license to manufacture for sale or for distribution of Class C or Class D medical device	Form MD8
Licence to manufacture for sale or for distribution of Class C or Class D Medical Device	Form MD9
Loan Licence to manufacture for sale or for distribution of Class C or Class D Medical Device	Form MD10
Form in which the audit or inspection book shall be maintained	Form MD11
Application for license to manufacture medical device for purpose of clinical investigations, test, evaluation, examination, demonstration, or training	Form MD12
Licence to manufacture Medical Device for	FormMD13

Application for issue of import license to import medicaldevice	FormMD14
Licence to import MedicalDevice	FormMD15
Application for license to import medical devices for the purposes of clinical investigations or test or evaluation or demonstration ortraining	FormMD16
Licence to import medical devices for the purposes of clinical investigations or test or evaluation or demonstration ortraining	FormMD17
Application for license to import investigational medical devices for the purposes by a government hospital or statutory medical institution for the treatment ofpatients	FormMD18
Licence to import investigational medical devices for the purposes by a government hospital or statutory medical institution for the treatment of patients	FormMD19
Application for permission to import small quantity of medical devices for personaluse	FormMD20
Permission to import small quantity of medical devices for personaluse	FormMD21
Application for grant of permission to conduct clinical investigation of an Investigational MedicalDevice	FormMD22
Permission to conduct clinical investigation of an Investigational Medical Device	FormMD23
Application for grant of permission to conduct clinical performance evaluation of New In-Vitro Diagnostic MedicalDevice	FormMD24
Permission to conduct clinical performance evaluation of New In-Vitro Diagnostic MedicalDevice	FormMD25
Application for grant of permission to import/manufacture for sale or for distribution of medical device which does not have a predicate medicaldevice	FormMD26
Permission to import/manufacture for sale or for distribution of medical device which does not have a predicate medicaldevice	FormMD27

Application for grant of permission to import or manufacture for sale or for distribution of a New In-Vitro Diagnostic MedicalDevice	FormMD28
Permission to import or manufacture New In-Vitro Diagnostic MedicalDevice	FormMD29
Memorandum to Central Medical Device TestingLaboratory	FormMD30
Certificate of Test or Evaluation by the Central Medical Device Testing Laboratory	FormMD31
Report of Test or Evaluation of Medical Devices by Medical Device Testing Officer	FormMD32
Application from a purchaser for test or evaluation of a medical device under section 26 of the Drugs and Cosmetics Act, 1940 (23 of1940)	FormMD33
Order under clause (c) of subsection (1) of section of the Drugs &Cosmetics Act, 1940, (23 of 1940) requiring a person not to dispose of stock in hispossession	FormMD34
Receipt of stock of medical devices for record, register, document or material object seized under clause (c) or clause (cc) of sub-section (1) of Section 22 of the Drugs and Cosmetics Act (23 of1940)	FormMD35
Intimation of person from whom sample istaken	FormMD36
Receipt for Sample of medical device(s) taken where fair price tendered thereof under sub-section (1) of Section 23 of the Drugs and Cosmetics Act, 1940 is refused	FormMD37
Memorandum to Medical Device TestingOfficer	FormMD38
Application for grant of registration to Medical Device Testing Laboratory for carry out Test or Evaluation of a medical device on behalf ofmanufacturer	FormMD39
Certificate of registration to Medical Device Testing Laboratory for carry out Test or Evaluation of a medical device on behalf ofmanufacturer	FormMD40

Process Flowchart for Obtaining Manufacturing License



Process for obtaining Manufacturing License for Sale or for Distribution of Medical Devices or *In-vitro* Diagnostic Kits

Filing Application for Manufacturing **Class A or Class B** Medical Devices or *In-vitro* Diagnostic Kit

Form MD-3
(Manufacturing License)
Fee*: Rs. 5,000 each manufacturing site + Rs. 500 per Medical Device
*(as per Schedule II)

Form MD-4
(Loan License)
Fees is decided as per Schedule II

1. Technical documents as per Part-II of Fourth Schedule and
2. Undertaking as per requirements of QMS as per Schedule V

Submit application through online portal of MOH & FA

Scrutiny of documents by SLA

Within 45 days

Application accepted

For Class A Device

Manufacturing License issued

Audit of site by Notified Body within 120 days from the issuance of license

For Class B Device

Audit of site by Notified Body within 90 days from the date of application

Notified Body furnish its report to SLA within 30 days from the audit

Scrutiny of report by SLA

SLA satisfied with report
1. Manufacturing license is granted on form MD-5
2. Loan License is granted on form MD-6

SLA not satisfied, rejects application

Filing Application for Manufacturing **Class C or Class D** Medical Devices or *In-vitro* Diagnostic Kit

Form MD-7
(Manufacturing License)
Fee*: Rs. 50,000 each manufacturing site + Rs. 1000 per Medical Device
*(as per Schedule II)

Form MD-8
(Loan License)
Fees is decided as per Schedule II

1. Technical documents as per Part-II of Fourth Schedule and
2. Undertaking as per requirements of QMS as per Schedule V

Submit application through online portal of MOH & FA

Scrutiny of documents by CLA

Within 45 days

If manufacturing site already licensed to manufacturer same medical devices, no inspection of a medical device manufacturing site will be carried out for grant of loan license for sale or distribution by SLA

If the documents are in order

Inspection of manufacturing site by medical device officer of CLA with in 60 days from the date of application (CLA Team with or without Expert)

Inspection report submission to CLA with recommendation through online Portal

CLA satisfied with report
1. Manufacturing license is granted on form MD-9
2. Loan license is granted on form MD-10

CLA not satisfied with the report rejects the application within 45 days from the date of receipt of inspection report , with reason for rejection

- **Perpetual License issued by CDSCO/ SLA**
- **License Retention fees payable before completion of 5 years from date of issuance**

Import License Procedure under MDR17-

Applicant on Sugam Portal

Within 9 Months

As per Chapter V of Medical Devices Import and Chapter XII of Export of Medical Devices
Rule – 34 (Import)
Rule – 91 (Export)

Foreign Medical Device Company via Authorized Agent in India files Application

Application for Import of Medical Devices or *In-vitro* Diagnostic Kits for all classes

MD – 14
Application for Import License

Fees:
Class A: USD 1000 each manufacturing site + USD 50 per Medical Device
Class B: USD 2000 each manufacturing site + USD 1000 per Medical Device
Class C&D: USD 3000 each manufacturing site + USD 1500 per Medical Device
Class A&B IVDs: USD 1000 each manufacturing site + USD 10 per Medical Device
Class C&D IVDs: USD 3000 each manufacturing site + USD 500 per Medical Device

Required documents:
1. PoA for Authorised Agent in India
2. Technical File
3. Details of Medical Device, Class, Intended Use
4. Clinical Evaluation Data supporting Safety and Performance in Country of origin
5. Data supporting Substantial equivalence to predicate device

Clinical Investigation

Waived off, in case Free Sales Certificate (FSC) already issued by regulators at USA, Australia, Canada, Japan or Europe

If not waived off:

Overseas Site Inspection (Not mandatory)
Fees*: USD 6000
***paid by Applicant (importer)**

Evaluation of Safety and Performance data through Clinical Investigation
Within 45 days

Not-Satisfied

Application Rejected
Within 45 days
Appeal to MoHFW
Within 90 days
Order Issued by Ministry after Case Evaluation

Satisfied

MD – 15
Import License Granted

Import License Procedure for Investigational Medical Devices

Applicant on Sugam Portal

According to Chapter V of Medical Devices Import and Chapter XII Export of Medical Devices
Rule – 34 (Import)
Rule – 91 (Export)

Foreign Medical Device Company via Authorized Agent in India files Application

Application for Import of Medical Devices or *In-vitro* Diagnostic Kits for all classes (Investigational Medical Device)

↓

Application for Test License (MD – 16)

↓

Clinical Investigation

↓

Results – Safety & Performance submitted

↓

MD – 17
Test License Issued
(Valid for 3 years)

↓

Application for Import License
MD – 27 or MD – 29

↓

MD – 15
Perpetual License for Import Issued
Retention Fee is to be paid, five yearly basis

Import License Procedure of Medical Devices for Government use

Applicant on Sugam Portal

Application for Import of Medical Devices for Government use by Government Hospitals or Statutory Bodies

↓

MD – 18

↓

Small quantity of products Imported-
-Life threatening diseases
-Disease requiring therapies

↓

Conformation to Quality Management Systems (QMS)

Reviewed documents:
1. Technical Files
2. Safety and Performance data generated in country of origin

↓

Product – approved in Country of Origin, data reviewed by Regulators

↓

MD – 19
License issued (if satisfied)

Import License Procedure for Medical Devices for Personal Use

Applicant on Sugam Portal

Application for Import of Medical Devices or *In-vitro* Diagnostic Kits for personal use

↓

MD – 20
For Personal use in Small quantity

↓

CDSCO reviews the application

Within 7 days

↓ MD – 21
Permission granted

↓ Application Rejected

Export License Procedure for Medical Devices

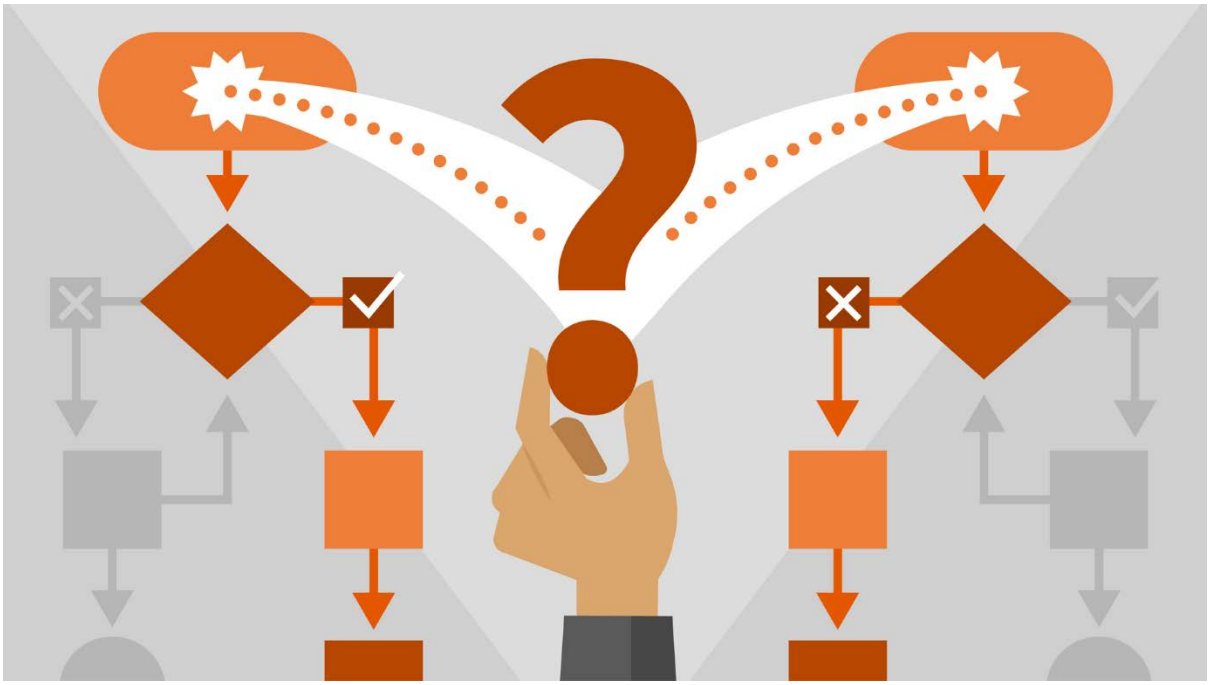
Applicant on Sugam Portal

Application for Export of Medical Devices or *In-vitro* Diagnostic Kits

↓

Free Sale Certification as mentioned in Rule – 91

Medical Device Classification



The Ministry of Health and Family Welfare, Government of India vide notification ref.no. 29/Misc/3/2017-DC (292), dated 15th May, 2019, classified medical devices based on risk based classification. The details of devices along with the Risk based classification issued by the Government is available in the public domain and can be accessed through the following link at the CDSCO website:

https://cpdm.iisc.ac.in/utsaah/wp-content/uploads/2019/09/CDSCO_notifiedmd15may19.pdf

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi.

File No. 29/Misc/3/2017-DC (292) **Date: 15.05.2019**

Notice

Classification of newly notified Medical Devices

S. No.	Notified Category	Intended Use	Risk Class
1.	**CT scan Equipment**	Use of x-ray source and digitally scanned computer technology to create cross-sectional images of the body.	**Class C**
2.	**MRI Equipment**	It is a medical imaging procedure using radio waves, magnetic fields, and magnetic field gradients to generate images of organs in the body.	**Class C**
3.	**Defibrillators**	It is a device that automatically analyzes the rhythm of heart of cardiac arrest patients and delivers an electrical shock to the heart for restoring the normal rhythm of heart.	**Class C**
4.	**Dialysis Machine**	It is used for acute or chronic kidney failure that filters blood to remove excess water and waste products.	**Class C**
5.	**PET Equipment**	Intended to detect the gamma radiation and positron emitting radionuclides in the body and produce cross-sectional images which reflect the distribution in the body or individual organs.	**Class C**
6.	**X-Ray Machine**	Use of X-rays to diagnose or treat patients by imaging the internal structure of the body to assess the abnormalities in the body.	**Class C**
7.	**Bone marrow cell separator**	It is a general lab equipment to be used to isolate target cells and cells concentrate from bone and blood.	**Class B**

8.	**Nebulizer**	It is device used to administer medications in the form of mist to inhale for respiratory disorders.	**Class C**
9.	**Blood Pressure Monitoring Devices**	It is device used to measure the diastolic and systolic blood pressures.	**Class B**
10.	**Digital Thermometer**	It is device used to record the body temperature.	**Class B**
11.	***Glucometer**	It is a device used to measure the concentration of glucose in blood.	**Class C**
12.	**Organ Preservative Solution**	Solution for hypothermic flushing, storage and transport of organs and to maintain the organ vitality during transplant into human recipients.	**Class C**

*** Glucometer will be regulated under IVD category**

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

NOTICE

File No: 29/Misc./3/2017-DC(292) **Date:** 01 NOV 2017

Subject: Classification of medical devices and in vitro diagnostic medical devices under the provisions of the Medical Devices Rules, 2017 - Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices for their with respect to the import, manufacture, clinical investigation, sale and distribution, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which are to be commence from 01.01.2018.

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned is hereby classify the medical devices and *in vitro* diagnostic medical devices, Appendix -1, based on the intended use of the device, risk associated with the device and other parameters specified in the First Schedule.

List of medical devices and in vitro diagnostic medical devices placed at Annexure-1 is subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. The component and accessories to a medical device or companion *in vitro* diagnostic medical devices has been classified separately.
3. It is also recognised that some of the medical devices or *in vitro* diagnostic medical devices may have dual use and they may be classified accordingly.
4. This list is dynamic and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

(Dr. G. N. Singh)
Drugs Controller General (India)

To,

1. All Stake holders.
2. CDSCO Website.
3. Guard File.

Status of Implementation of MDR-17

Implementation Updates

- New Medical Device Online portal is functional for uploading the applications for Import License and Manufacturing License of Medical devices and IVDs, for post approval changes, registration of medical devices testing laboratories, clinical investigation etc.
- Classification of Medical Devices and IVDs has been finalized in consultation with the stakeholders and uploaded in the CDSCO website.
- Medical device online portal is functional for the registration of Notified Bodies. Four notified bodies have been registered and information is available on the CDSCO website.
- Grouping of Medical Devices and IVDs along with essential principle checklist has been finalized in consultation with the stakeholders and uploaded in the CDSCO website.
- Notification of Medical Device Officer and Medical Device Testing Laboratories have been published.
- CDSCO organised workshops to impart trainings to State Licensing Authorities i.e. Delhi, Rajasthan and stakeholders for the effective implementation of Medical Devices Rules, 2017.
- For addressing various questions on regulatory practices in medical devices, Frequently Asked Questions (FAQ) on medical devices and in vitro diagnostics is uploaded on CDSCO website. Also, regular interactions are taking place with all the stakeholders to resolve their regulatory practices issues.
- Guidance on Performance Evaluation of In-vitro Diagnostic Medical Devices have been published on the website.
- Public relation office is established by CDSCO to guide the start-ups and innovators.

- 16 Technical Committees of BIS are framing the standards of Medical devices and IVDs.
- As part of skill development initiatives, various officials from the central and state regulators in India are being sent for training on Medical Device Regulation at PMDA academy.

Way Forward- Comprehensive Regulation of Medical Devices under MDR17

Ministry of Health and Family Welfare, Government of India has recently issued notifications to bring all medical devices under the provisions of regulations in India as per the MDR17 with effect from April 1, 2020 in a phased manner. The notifications are being placed below for reference by the Indian medical Device industry.

रजिस्ट्री सं. डी.एल.- 33004/99 REGD. NO. D. L.-33004/99

भारत का राजपत्र
The Gazette of India

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असाधारण
EXTRAORDINARY
भाग II—खण्ड 3—उप-खण्ड (i)
PART II—Section 3—Sub-section (i)
प्राधिकार से प्रकाशित
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MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 11th February, 2020

G.S.R. 102 (E).— Whereas a draft of certain rules further to amend the Medical Devices Rules, 2017, was published as required by under subsection (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), *vide* notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 797 (E), dated the 18th October, 2019, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the Official Gazette were made available to the public on 18th October, 2019;

And whereas objections and suggestions received from the public on the said rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Medical Devices Rules, 2017, namely:—

1. (i) These rules may be called the Medical Devices (Amendment) Rules, 2020.

(ii) These rules shall come into force on the 1st day of April, 2020.

2. In the Medical Devices Rules, 2017 (hereinafter to be referred as said rules), after CHAPER III, the following CHAPTER IIIA shall be inserted, namely:—

"CHAPTER IIIA
REGISTRATION OF CERTAIN MEDICAL DEVICES

19A. (1) This Chapter shall be applicable to all devices notified under clause (b) of section 3 of the Act except the medical devices and devices specified in the Annexure of Eighth Schedule of these rules.

(2) The Medical devices referred in sub-rule (1) shall be registered with the Central Licensing Authority through an identified online portal established by the Central Drugs Standard Control Organisation for this purpose:

Provided that registration under this Chapter shall be on voluntary basis for a period of eighteen months from the commencement of this Chapter there after it shall be mandatory.

19B. (1) The manufacturer of a medical device shall upload the information specified in sub rule (2) relating to that medical device for registration on the "Online System for Medical Devices" established by the Central Drugs Standard Control Organisation for this purpose

(2) The manufacturer shall upload, -

(i) name & address of the company or firm or any other entity manufacturing the medical device along with name and address of manufacturing site of medical device,

(ii) Details of medical device

Generic Name	Model No.	Intended Use	Class of Medical device	Material of Construction	Dimension (if any)	Shelf Life	Sterile or Non Sterile	Brand Name (if registered under the Trade Marks Act, 1999)

(iii) certificate of compliance with respect to ISO 13485 standard accredited by National Accreditation Board for Certification Bodies or International Accreditation Forum in respect of such medical device.

(iv) undertaking duly signed by the manufacturer stating that the information furnished by the applicant is true and authentic.

19C. After furnishing of the above information on the "Online System for Medical Devices" established by Central Drugs Standard Control Organisation for this purpose by the applicant's, registration number will be generated. Manufacturer shall mention the registration number on the label of the medical device.

19D. (1) Any person who imports any medical device referred in rule 19A shall upload the following information relating to that medical device for registration on the "Online System for Medical Devices" established by the Central Drugs Standard Control Organisation for this purpose.

(2) The importer shall upload, -

(i) name of the company or firm or any other entity importing the medical device and specification and standards of that medical device,

(ii) Details of medical device

Generic Name	Model No.	Intended Use	Class of Medical device	Material of Construction	Dimension (if any)	Shelf Life	Sterile or Non Sterile	Brand Name (if registered under the Trade Marks Act, 1999)

(iii) certificate of compliance with respect to ISO 13485 standard accredited by National Accreditation Board for Certification Bodies or International Accreditation Forum in respect of such medical device.

(iv) Free sale certificate from country of origin.

(v) undertaking duly signed by the importer stating that the information furnished by the applicant is true and authentic.

19E. After furnishing of the above information on the "Online System for Medical Devices" established by the Central Drugs Standard Control Organisation for this purpose by the applicant's, registration number will be generated. Importer shall mention the registration number on the label of the medical device.

19F. Central Licensing Authority may verify the documents at any point of time and investigate quality or safety related failure or complaints. The Central Licensing Authority may, after giving the registrant an opportunity to show cause as to why such an order should not be passed, by an order in writing stating the reasons therefor, cancel the registration number or suspend it for such period as the Central Licensing Authority thinks fit either wholly or in respect of any of the medical devices to which it relates, if in its opinion, the registrant has failed to comply with any provision of these rules.

3. In the said rules, in the Eighth Schedule, in the table relating to exemptions, after S.N. 6, the following entry and Annexure shall be inserted, namely:—

"

7	All medical devices except those specified in the Annexure of Eighth Schedule.	All the provisions of these rules subject to the condition that such medical devices shall be registered under CHAPTER IIIA of these rules: Provided that such exemption shall cease after a period of *thirty months* for low risk - Class A and low moderate risk - Class B and after a period of *forty-two months* for moderate high risk – Class C and high risk – Class D devices, respectively from the date of this notification.

Annexure

(See rule 19A)

S. No.	Name of the device
1.	Disposable Hypodermic Syringes
2.	Disposable Hypodermic Needles
3.	Disposable Perfusion Sets
4.	Substances used for in vitro diagnosis including Blood Grouping Sera
5.	Cardiac Stents
6.	Drug Eluting Stents
7.	Catheters
8.	Intra Ocular Lenses
9.	I.V. Cannulae
10.	Bone Cements
11.	Heart Valves
12.	Scalp Vein Set
13.	Orthopedic Implants
14.	Internal Prosthetic Replacements
15.	Ablation Devices
16.	Ligatures, Sutures and Staplers
17.	Intra Uterine Devices (Cu-T)
18.	Condoms
19.	Tubal Rings
20.	Surgical Dressings
21.	Umbilical tapes
22.	Blood/Blood Component Bags
23.	Organ Preservative Solution*
24.	Nebulizer (effective from 1 Jan.2021)
25.	Blood Pressure Monitoring Device(effective from 1 Jan.2021)

26.	Glucometer (effective from 1 Jan.2021)
27.	Digital Thermometer (effective from 1 Jan.2021)
28.	All implantable medical devices Equipment (effective from 1, April,2021)
29.	CT Scan Equipment (effective from 1, April,2021)
30.	MRI Equipment (effective from 1, April,2021)
31.	Defibrillators (effective from 1, April,2021)
32.	PET Equipment(effective from 1, April,2021)
33.	X-Ray Machine (effective from 1, April,2021)
34.	Dialysis Machine (effective from 1, April,2021)
35.	Bone marrow cell separator (effective from 1, April,2021)
36.	Disinfectants and insecticide specified in Medical Devices Rules, 2017
37.	Ultrasound equipment (effective from 1, November, 2020)

”

[F.No. X.11035/281/2018-DRS]

Dr. MANDEEP K. BHANDARI, Jt. Secy.

Note : The Medical Devices Rules, 2017 was published in the Official Gazette *vide* notification number G.S.R. 78(E), dated the 31st January, 2017 and last amended *vide* notification number G.S.R. 787(E), dated the 16th October, 2019.

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MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 11th February, 2020

S.O. 648(E).— In pursuance of sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby specifies the following devices intended for use in human beings or animals as drugs with effect from the 1st day of April, 2020, namely:—

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 specially 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 —

(i) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;

(ii) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;

(iii) investigation, replacement or modification or support of the anatomy or of a physiological process;

(iv) supporting or sustaining life;

(v) disinfection of medical devices; and

(vi) control of conception.

[F.No. X.11035/281/2018-DRS]

Dr. MANDEEP K. BHANDARI, Jt. Secy.

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Essential Principles Checklist

ESSENTIAL PRINCIPLES CHECKLIST

Document No. Issue Date:

Revision No. Revision Date: Effective Date

Purpose:

The document is prepared to identify, document and establish compliance with the Essential requirements, as specified in **Clause 6 of Medical Device Rule 2017** for { Product Name: } throughout the life-cycle. It involves identifying the applicability or non-applicability of related requirement, applicability of related standard / regulation, compliance or non-compliance and technical documentation to establish compliance.

Device description:

Intended use:

Detailed Listing of Products Covered by this Product Group:

	Essential Principle	Relevant Yes / No	Specification / Standard / Sub Clause / reference	Complies Yes / No	Documentation reference justification and / or comments
4	**Essential Principles applicable for all categories of medical devices** **General Principles**				
4.1	Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training, and the medical and physical conditions of intended users, they will perform as intended by the manufacturer and not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. .				

	Essential Principle	Relevan tYes / No	Specification / Standard / Sub Clause / reference	Complies Yes / No	Documentation reference justification and / or comments
4.2	The solutions adopted by the manufacturer for the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk(s) reduction is required, the manufacturer should control the risk(s) so that the residual risk associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed: - identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse; - eliminate risks as far as reasonably practicable through inherently safe design and manufacture; - reduce as far as reasonably practicable the remaining risks by taking adequate protection measures, including alarms; and - inform users of any residual risks.				
4.3	Medical devices should achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that, during normal conditions of use, they are suitable for their intended purpose				

	Essential Principle	Relevan tYes / No	Specification / Standard / Sub Clause / reference	Complies Yes / No	Documentation reference justification and / or comments
4.4	The characteristics and performances referred to in clauses (4.1), (4.2) and (4.3) should not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions				
4.5	Medical devices should be designed, manufactured and packaged in such a way that their characteristics and performances during their intended use will not be adversely affected by transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.				
4.6	All known and foreseeable risks, and any undesirable effects, should be minimised and be acceptable when weighed against the benefits of the intended performance of medical devices during normal conditions of use.				

	Essential Principle	Relevant Yes / No	Specification / Standard / Sub Clause / reference	Complies Yes / No	Documentation reference justification and / or comments
4.7	Every medical device requires clinical evidence, appropriate for its intended use and classification of the medical device, demonstrating that the device complies with the applicable provisions of the essential principles.				
5 **5.1** **5.1.1**	**Essential Principles applicable to medical devices other than IVD medical devices** Chemical, physical and biological properties: The devices should be designed and manufactured in such a way as to ensure the characteristics and performance. Particular attention should be paid to,- (a) the choice of materials used, particularly as regards toxicity, biodegradability and, where appropriate, flammability; (b) the compatibility between the materials used and biological tissues, cells, and body fluids taking account of the intended purpose of the device; (c) the choice of materials used, reflecting, where appropriate, matters such as hardness, wear and fatigue strength.				

	Essential Principle	Relevant Yes / No	Specification / Standard / Sub Clause / reference	Complies Yes / No	Documentation reference justification and / or comments
5.1.2	The devices should be designed, manufactured and packaged in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to patients, taking account of the intended purpose of the device. Particular attention should be paid to tissues exposed and to the duration and frequency of exposure.				
5.1.3	The devices should be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they should be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.				

	Essential Principle	Relevant Yes / No	Specification / Standard / Sub Clause / reference	Complies Yes / No	Documentation reference justification and / or comments
5.1.4	The devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that may leach or leak from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction.				
5.1.5	Devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate risks posed by the unintentional ingress or egress of substances into or from the device taking into account the device and the nature of the environment in which it is intended to be used.				
5.2 **5.2.1**	**Infection and microbial contamination:** The devices and manufacturing processes should be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to patients, users and, where applicable, other persons. The design should,-				

	Essential Principle	Relevant Yes / No	Specification / Standard / Sub Clause / reference	Complies Yes / No	Documentation reference justification and / or comments
	(a) allow easy handling, and, where necessary; (b) reduce as far as reasonably practicable and appropriate any microbial leakage from the device and/or microbial exposure during use; (c) prevent microbial contamination of the device or specimen, where applicable, by the patient, user or other person.				
5.2.2	Devices labelled as having a special microbiological state should be designed, manufactured and packaged to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.				
5.2.3	Devices delivered in a sterile state should be designed, manufactured and packaged in a non-reusable pack, and/or according to appropriate procedures, to ensure that they are sterile when placed on the market and remain sterile, under the transport and storage conditions indicated by the manufacturer, until the protective packaging is damaged or opened.				

	Essential Principle	Relevant Yes / No	Specification / Standard / Sub Clause / reference	Complies Yes / No	Documentation reference justification and / or comments
5.2.4	Devices labelled either as sterile or as having a special microbiological state should have been processed, manufactured and, if applicable, sterilized by appropriate, validated methods.				
5.2.5	Devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.				
5.2.6	Packaging systems for non-sterile devices should maintain the integrity and cleanliness of the product and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system should be suitable taking account of the method of sterilization indicated by the manufacturer.				
5.2.7	The packaging or labelling of the device should distinguish between				

	Essential Principle	Relevant Yes / No	Specification / Standard / Sub Clause / reference	Complies Yes / No	Documentation reference justification and / or comments
	identical or similar products placed on the market in both sterile and non-sterile condition.				
5.3	**Medical devices incorporating a substance considered to be a medicinal product or drug:**				
5.3.1	Where a medical device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product or drug as defined in the Drugs and Cosmetics Act, 1940 and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and performance of the device as a whole should be verified, as well as the safety, quality and efficacy of the substance in the specific application.				
5.4 **5.4.1**	**Medical devices incorporating materials of biological origin:** Where a medical device incorporates substances of biological origin, the risk of infection must be reduced as far as reasonably practicable and appropriate by selecting appropriate sources, donors and substances and by using, as appropriate, validated inactivation, conservation, test and control procedures.				

	Essential Principle	Relevant Yes / No	Specification / Standard / Sub Clause / reference	Complies Yes / No	Documentation reference justification and / or comments
5.4.2	For medical devices incorporating non-viable tissues, cells and substances of animal origin should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. The manufacturer is required to retain information on the geographical origin of the animals. Processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. Explanation: For the purpose of this clause, veterinary controls shall also include that an animal source should be tested and to be free from Transmissible spongiform encephalopathies (TSEs) and Bovine spongiform encephalopathy (BSEs)				
5.4.3	For medical devices incorporating cells, tissues and derivatives of microbial or recombinant origin, the selection of sources or donors, the				

	Essential Principle	Relevant Yes / No	Specification / Standard / Sub Clause / reference	Complies Yes / No	Documentation reference justification and / or comments
	processing, preservation, testing and handling of cells, tissues and derivatives of such origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.				
5.4.4	For medical devices incorporating non-viable human tissues, cells and substances, the selection of sources, donors or substances of human origin, the processing, preservation, testing and handling of tissues, cells and substances of such origin should be carried out so as to provide optimal safety. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.				
5.5	**Manufacturing and Environmental properties:**				

	Essential Principle	Relevan tYes / No	Specification / Standard / Sub Clause / reference	Complies Yes / No	Documentation reference justification and / or comments
5.5.1	If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system should be safe and should not impair the specified performance of the devices. Any restrictions on use applying to such combinations should be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer or mechanical coupling, should be designed and constructed in such a way as to minimize all possible risks from incorrect connection.				
5.5.2	Devices should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate: (i) the risk of injury to the patient, user or other persons in connection with their physical and ergonomic features; (ii) the risk of use error due to the ergonomic features, human factors and the environment in which the				

	Essential Principle	Relevant Yes / No	Specification / Standard / Sub Clause / reference	Complies Yes / No	Documentation reference justification and / or comments
	device is intended to be used; (iii) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature or variations in pressure and acceleration; (iv) the risks associated with the use of the device when it comes into contact with materials, liquids, and gases to which it is exposed during normal conditions of use; (v) the risk associated with the possible negative interaction between software and the environment within which it operates and interacts; (vi) the risks of accidental penetration of substances into the device; (vii) the risks of reciprocal interference with other devices normally used in the investigations or				

	Essential Principle	Relevant Yes / No	Specification / Standard / Sub Clause / reference	Complies Yes / No	Documentation reference justification and / or comments
	for the treatment given; risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.				
5.5.3	Devices should be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention should be paid to devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.				
5.5.4	Devices should be designed and manufactured in such a way that adjustment, calibration, and maintenance, where such is necessary to achieve the performances intended, can be done safely.				
5.5.5	Devices should be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.				

	Essential Principle	Relevant Yes / No	Specification / Standard / Sub Clause / reference	Complies Yes / No	Documentation reference justification and / or comments
5.6 **5.6.1**	**Devices with a diagnostic or measuring function:** Diagnostic devices should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended use, based on appropriate scientific and technical methods. In particular the design should address sensitivity, specificity, trueness, repeatability, and reproducibility, control of known relevant interference and limits of detection, as appropriate. .				
5.6.2	Where the performance of devices depends on the use of calibrators or control materials, the traceability of values assigned to such calibrators or control materials should be assured through a quality management system.				
5.6.3	Any measurement, monitoring or display scale should be designed in				

	Essential Principle	Relevant Yes / No	Specification / Standard / Sub Clause / reference	Complies Yes / No	Documentation reference justification and / or comments
	line with ergonomic principles, taking account of the intended purpose of the device.				
5.6.4	Wherever possible values expressed numerically should be in commonly accepted, standardized units, and understood by the users of the device.				
5.7 **5.7.1**	**Protection against radiation:** **General:** Devices should be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation should be reduced as far as reasonably practicable and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.				
5.7.2	**Intended radiation:** Where devices are designed to emit hazardous, or potentially hazardous, levels of visible or invisible radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks				

	Essential Principle	Relevant Yes / No	Specification / Standard / Sub Clause / reference	Complies Yes / No	Documentation reference justification and / or comments
	inherent in the emission, it should be possible for the user to control the emissions. Such devices should be designed and manufactured to ensure reproducibility of relevant variable parameters within acceptable tolerance. Where devices are intended to emit potentially hazardous, visible or invisible radiation, they should be fitted, where reasonably practicable, with visual displays or audible warnings of such emissions.				
5.7.3	**Unintended radiation:** Devices should be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as reasonably practicable and appropriate.				
5.7.4	**Ionizing radiation:** (a) Devices intended to emit ionizing radiation should be designed and manufactured in such a way as to ensure that, where reasonably practicable, the quantity, geometry and energy distribution (or quality) of				

	Essential Principle	Relevant Yes / No	Specification / Standard / Sub Clause / reference	Complies Yes / No	Documentation reference justification and / or comments
	radiation emitted can be varied and controlled taking into account the intended use. (b) Devices emitting ionizing radiation intended for diagnostic radiology should be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user. (c) Devices emitting ionizing radiation, intended for therapeutic radiology should be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the energy distribution of the radiation beam.				
5.7.5	The operating instructions for a medical device that emits radiation must include detailed information about the following matters: (a) the nature of the radiation emitted; (b) the means by which patients and users can be protected from the				

	Essential Principle	Relevant Yes / No	Specification / Standard / Sub Clause / reference	Complies Yes / No	Documentation reference justification and / or comments
	radiation; (c) ways to avoid misusing the device; and (d) ways to eliminate any risks inherent in the installation of the device.				
5.8	**Medical devices that incorporate software and standalone medical device software:**				
5.8.1	Devices incorporating electronic programmable systems, including software, or standalone software that are devices in themselves, should be designed to ensure repeatability, reliability and performance according to the intended use. In the event of a single fault condition, appropriate means should be adopted to eliminate or reduce as far as reasonably practicable and appropriate consequent risks.				
5.8.2	For devices which incorporate software or for standalone software that are devices in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, verification and validation.				

	Essential Principle	Relevant Yes / No	Specification / Standard / Sub Clause / reference	Complies Yes / No	Documentation reference justification and / or comments
5.9	**Active medical devices and devices connected to them:**				
5.9.1	For active medical devices, in the event of a single fault condition, appropriate means should be adopted to eliminate or reduce as far as reasonably practicable and appropriate consequent risks.				
5.9.2	Devices where the safety of the patients depends on an internal power supply should be equipped with a means of determining the state of the power supply.				
5.9.3	Devices where the safety of the patients depends on an external power supply should include an alarm system to signal any power failure.				
5.9.4	Devices intended to monitor one or more clinical parameters of a patient should be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.				
5.9.5	Devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks of creating electromagnetic				

	Essential Principle	Relevant Yes / No	Specification / Standard / Sub Clause / reference	Complies Yes / No	Documentation reference justification and / or comments
	interference which could impair the operation of this or other devices or equipment in the usual environment.				
5.9.6	Devices should be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.				
5.9.7	Devices should be designed and manufactured in such a way as to avoid, as far as reasonably practicable, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.				
5.10 **5.10.1**	**Protection against mechanical risks:** Devices should be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.				

	Essential Principle	Relevant Yes / No	Specification / Standard / Sub Clause / reference	Complies Yes / No	Documentation reference justification and / or comments
5.10.2	Devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.				
5.10.3	Devices should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.				
5.10.4	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle should be designed and constructed in such a way as to minimize all possible risks.				
5.10.5	Devices should be designed and manufactured in such a way as to reduce to the lowest practicable level, the risk of error when certain parts within the device are intended to be				

	Essential Principle	Relevant Yes / No	Specification / Standard / Sub Clause / reference	Complies Yes / No	Documentation reference justification and / or comments
	connected or reconnected before or during use.				
5.10.6	Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings should not attain potentially dangerous temperatures under normal conditions of use.				
5.11	**Protection against the risks posed to the patient or user by supplied energy or substances:**				
5.11.1	Devices for supplying the patient with energy or substances should be designed and constructed in such a way that the delivered amount can be set and maintained accurately enough to guarantee the safety of the patient and of the user.				
5.11.2	Devices should be fitted with the means of preventing and/or indicating any inadequacies in the delivered amount which could pose a danger. Devices should incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.				
5.11.3	The function of the controls and indicators should be clearly specified				

	Essential Principle	Relevant Yes / No	Specification / Standard / Sub Clause / reference	Complies Yes / No	Documentation reference justification and / or comments
	on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information should be understandable to the user and, as appropriate, the patient.				
5.12 **5.12.1**	**Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons:** Devices for use by lay persons should be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can reasonably be anticipated in the layperson‟s technique and environment. The information and instructions provided by the manufacturer should be easy for the lay person to understand and apply.				
5.12.2	Devices for use by lay persons should be designed and manufactured in such a way as to reduce as far as reasonably practicable the risk of error during use by the lay person in the handling of the device and also in				

	Essential Principle	Relevan tYes / No	Specification / Standard / Sub Clause / reference	Complies Yes / No	Documentation reference justification and / or comments
	the interpretation of results.				
5.12.3	Devices for use by lay persons should, where reasonably possible, include a procedure by which the lay person can verify that, at the time of use, the product will perform as intended by the manufacturer.				
5.13 **5.13.1**	**Label, direction or Instructions For Use (IFU):** Users should be provided with the information needed to identify the manufacturer, to use the device safely and to ensure the intended performance, taking account of their training and knowledge.				
5.13.2	This information should be easily understood and detailed information for labelling should be incorporated as provided in the Chapter VI: labelling of Medical device, of the Medical Device Rules, 2017.				
5.14	**Clinical evaluation:** For all medical devices, the demonstration of conformity with essential principles includes a clinical evaluation. The clinical evaluation should review clinical data in the				

	Essential Principle	Relevant Yes / No	Specification / Standard / Sub Clause / reference	Complies Yes / No	Documentation reference justification and / or comments
5.14.1	form of any, (a) clinical investigation reports; or (b) literature reports/reviews; or (c) clinical experience, to establish that a favorable benefit-risk ratio exists for the device.				
5.14.2	Clinical investigations: Clinical Investigations on human subjects should be carried out in accordance with the provisions of Medical Devices Rules, 2017. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results.				

Compiler/Reviewer/ Approver	Name	Designation	Signature	Date
Compiled By				
Reviewed By				
Approved By				

User Manual for Sugam Portal

Central Drug Standard Control Organization (CDSCO)

Applicant User Manual

For

Medical Device Portal

Version: 1.0

Release Date: 28/12/2017

Centre for Development of Advanced Computing
(A Scientific Society of the Ministry of Electronics and Information Technology, Govt. of India)
Anusandhan Bhawan, C-56/1, Institutional Area, Sector-62, Noida-201307
Phone: 91-120-3063311-14 Website:http://www.cdac.in

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1. Introduction

Online Portal for Medical devices enables applicant to submit online applications for Medical Devices regulatory process to CDSCO. It will also enable upload of supporting documents, respond to queries from CDSCO officials and track their application status. The user account lists out all the applications submitted and licenses/permissions held by them and provides the statistical analysis of the applications for various processes & licenses issued, suspended /cancelled, withdrawn.

The following sections details about the various steps

1.1. User Login

- How to login into the system?
- User can login the system with the correct User Name and Password credentials,as shown in ***Figure 1.***

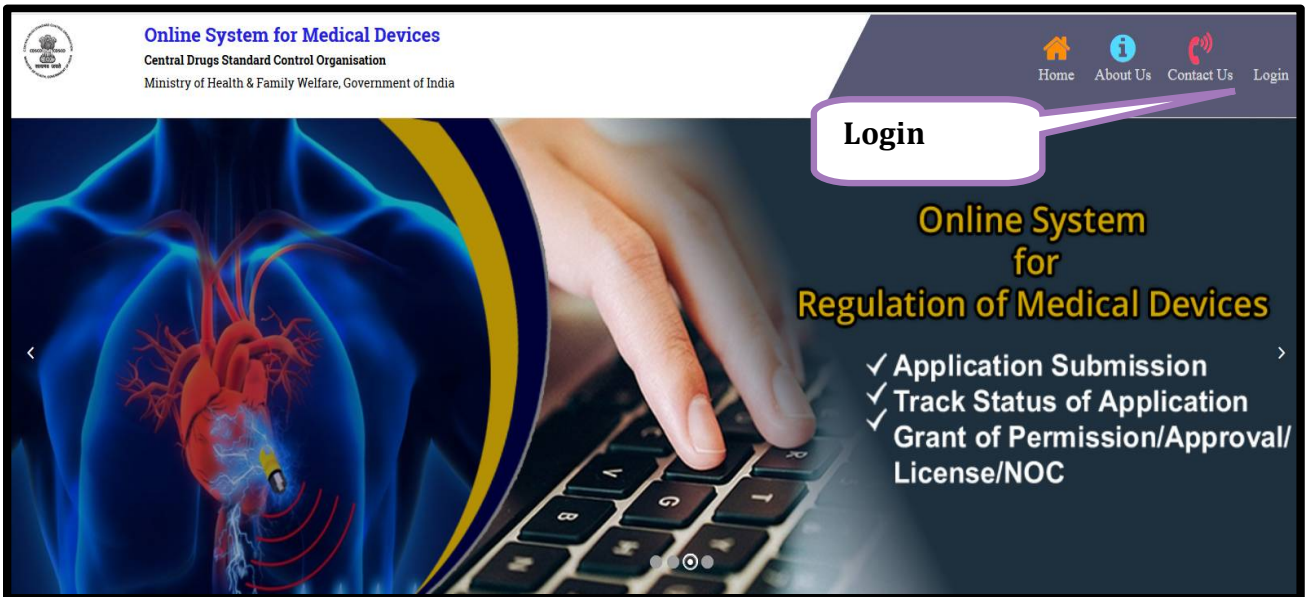


Figure 1: Login Screen

1.2. Dashboard

- **Dash Board Screen** : After successful login to the application the system will show a Dashboard there you can see the multiple informations,as shown in ***Figure 2.***

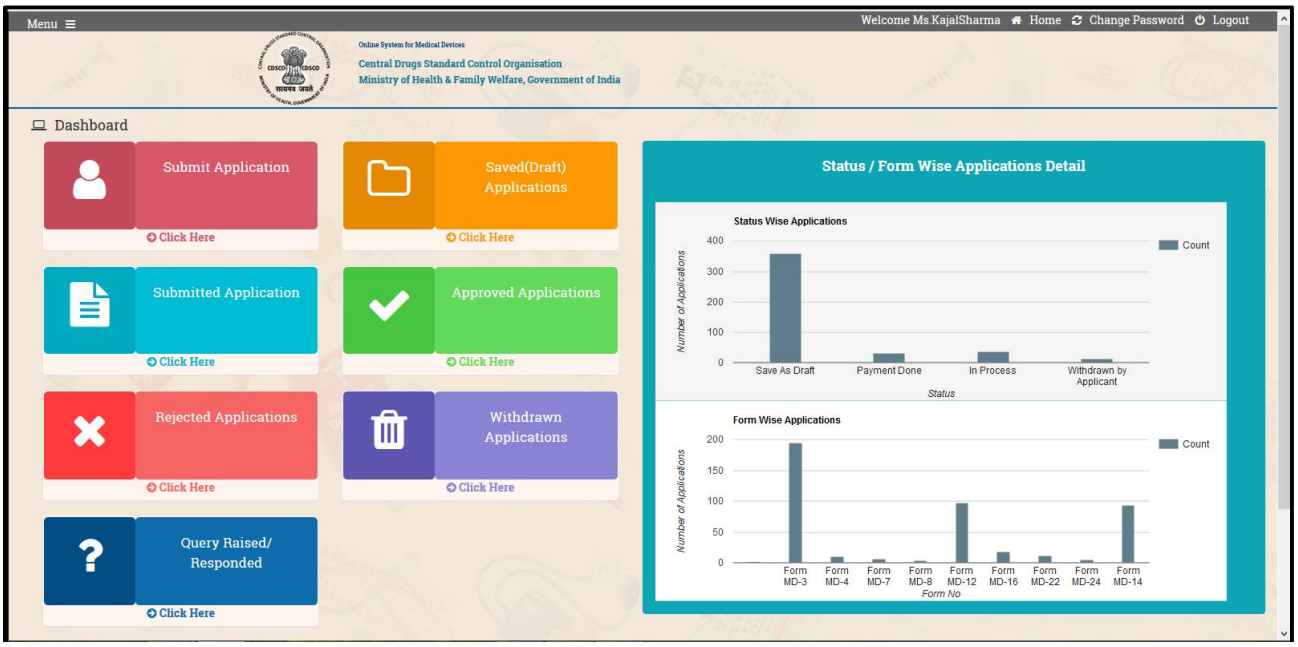


Figure 2 : Dashboard Screen

- Various options are available on the dashboard as described below :-

Table 1 : Dashboard Option

	**Submit application** - For Fresh Application Click on Submit Application Button.
	**Saved (Draft) Applications** - To view the pending/incomplete applications click on Saved (Draft) Applications.
	**Submitted Application:**To view the status of submitted applications click on "Submitted Application" link.
	**Approved Application:** This session used to store the Approved Application.
	**Rejected Application** : This interface is reserved for Rejected Applications
	**Withdrawn Application :**This link is to view all Withdrawn Applications
	**Query Raised/ Responded:**This link is to help query raised by CDSCO.

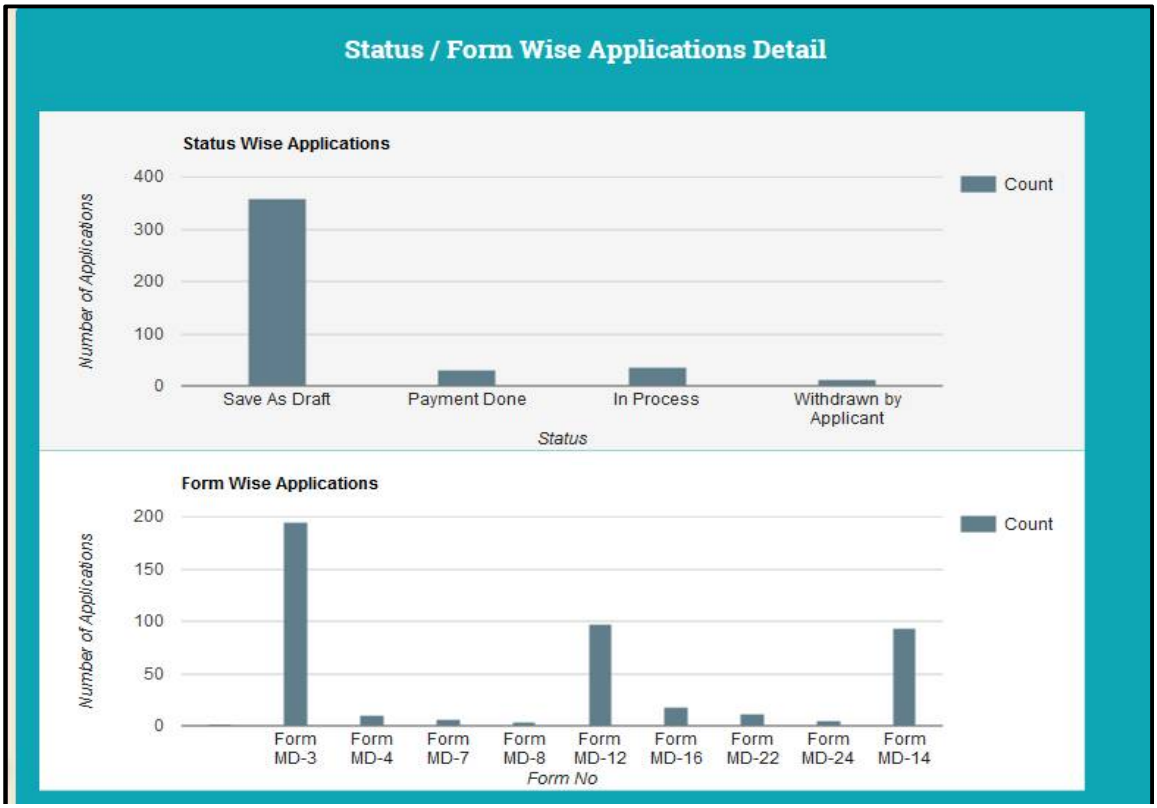


Figure 3 : Status / form Wise Application Detail

1.3. Change Password

- If the user want to change their password then they can click on 'Change Password' link, as shown in ***Figure 4.***

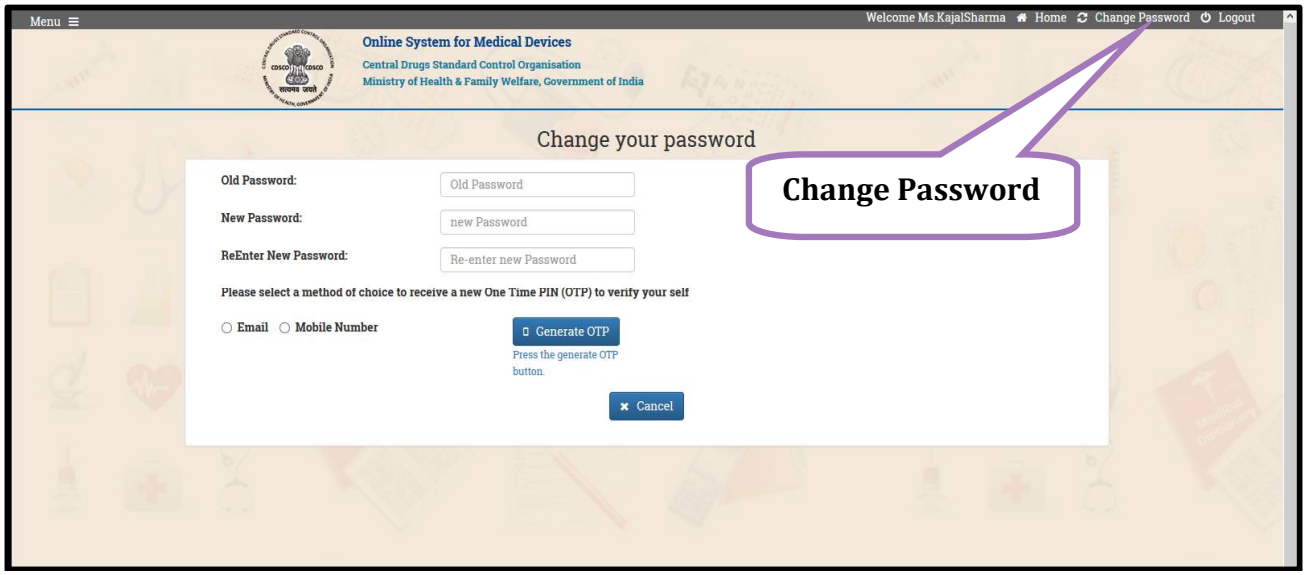


Figure 4 : Screen of Change Password Option

➢ After clicking the "Change Password" link you can see a new screen as shown in ***Figure 5*** where you can change the old password with the new one.

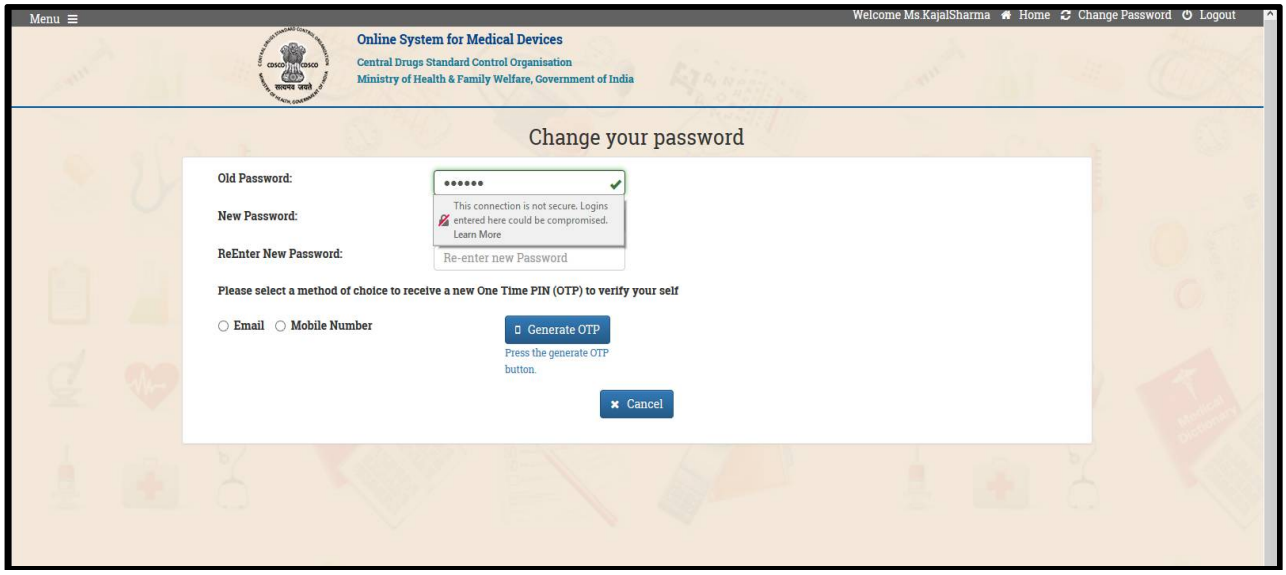


Figure 5 : Screen of change password (Continue)

Note

- After enter the new password click on "save" button and the password will be saved with the new one.

1.4. User Profile

➢ Click on Menu as Shown in the **figure 6.** After click on Menu Button it shows "User Profile", "Add Address", and "Online Payment".

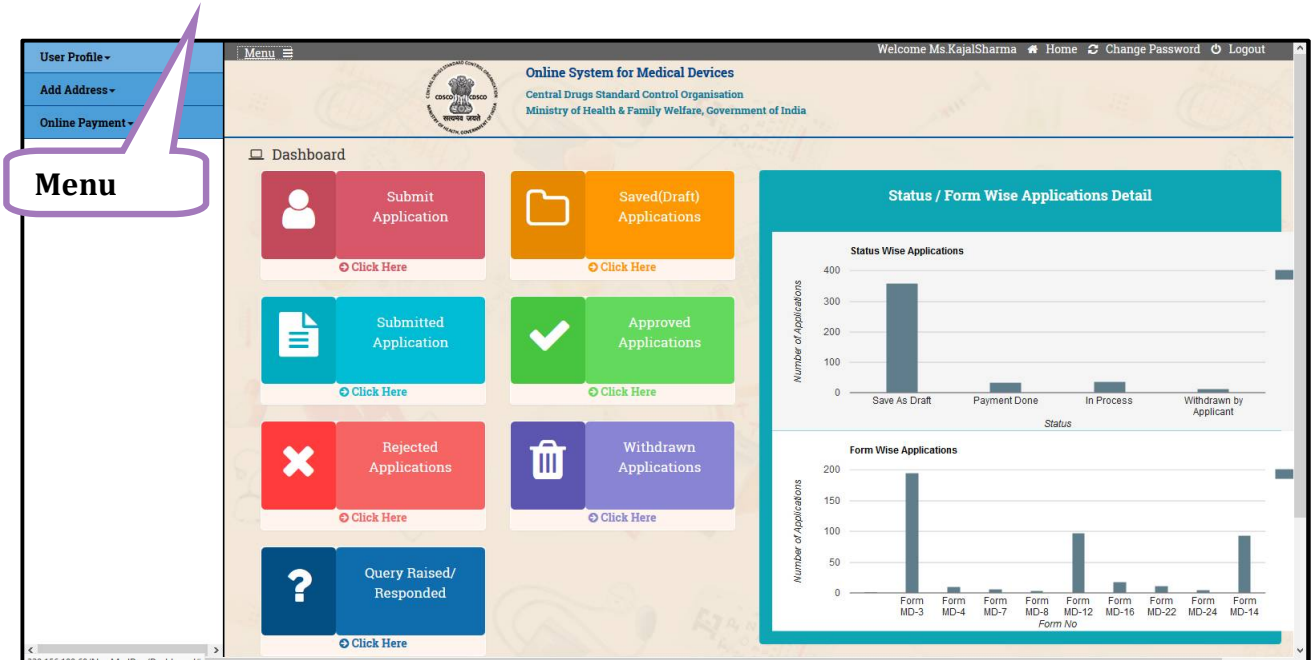


Figure 6 : Menu Button

➢ Click on User Profile as shown in **Figure 7.**

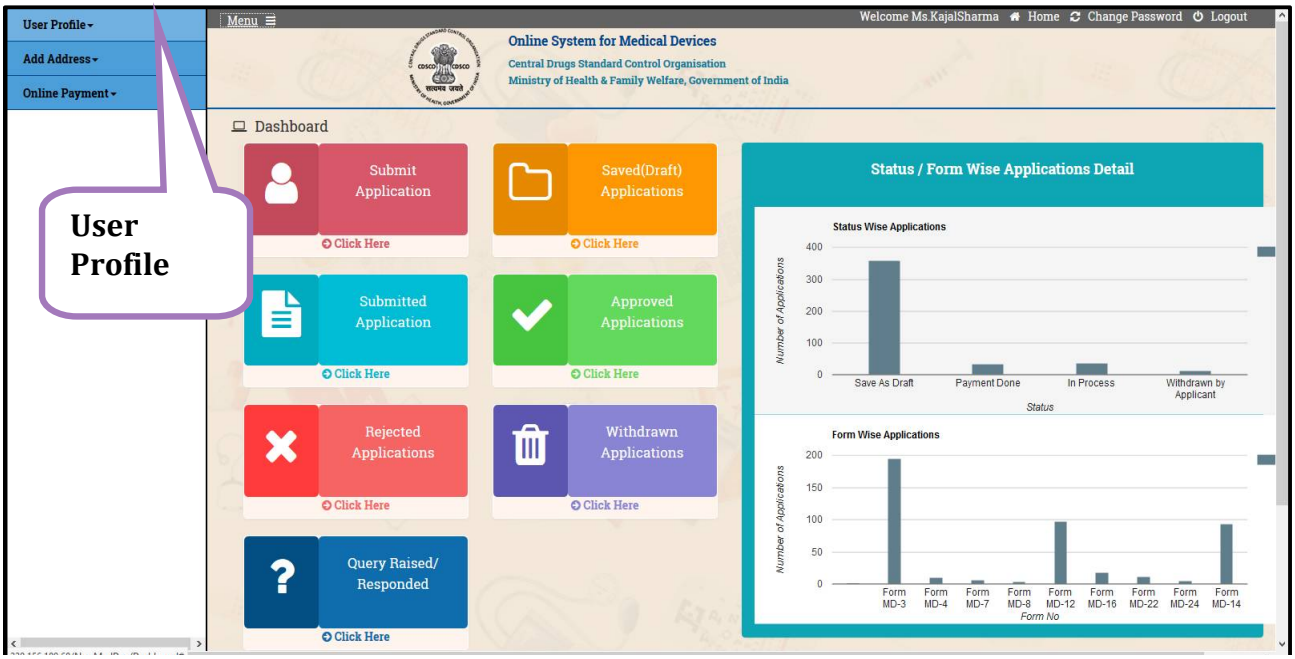


Figure 7 : User Profile

➢ After clicking the User Profile, click on "View Profile" Option. Then you will get below the mention screen i.e as shown in the **figure 8.**

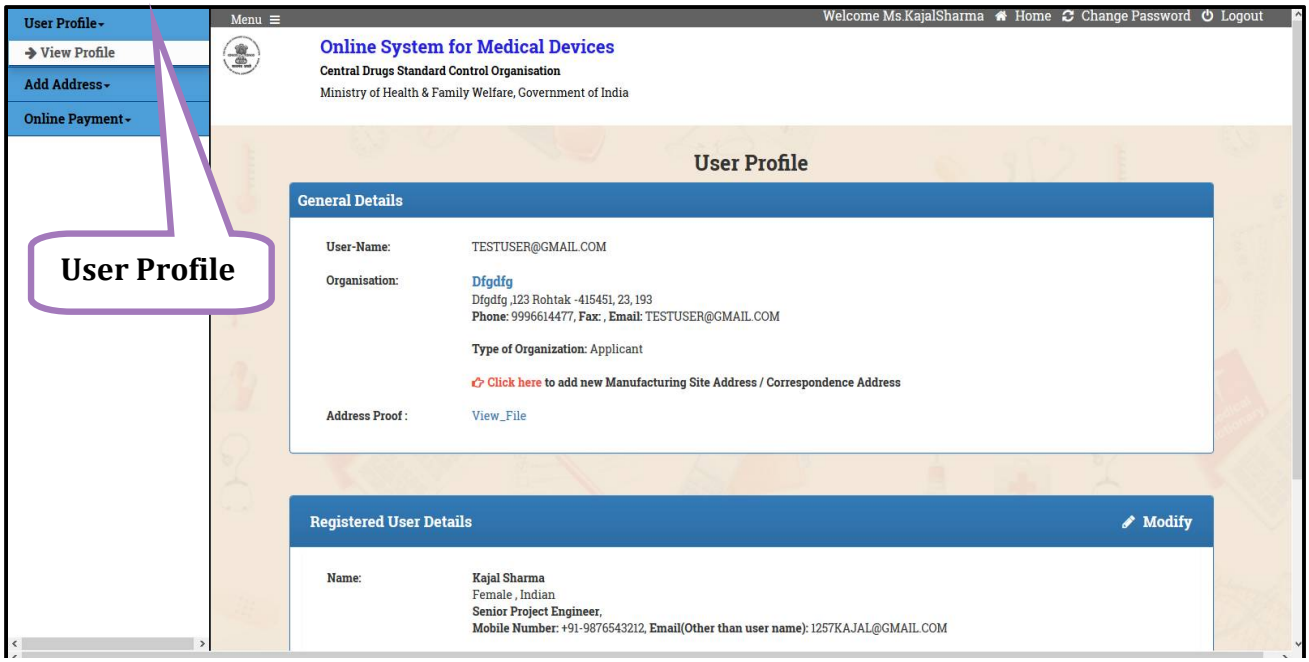


Figure 8 : Click on View Profile

1.5. Add Address

- There is two Option in Add Address (a) Add Correspondence and Site Address (b) Foreign Manufacturer address as shown in **figure 9.**

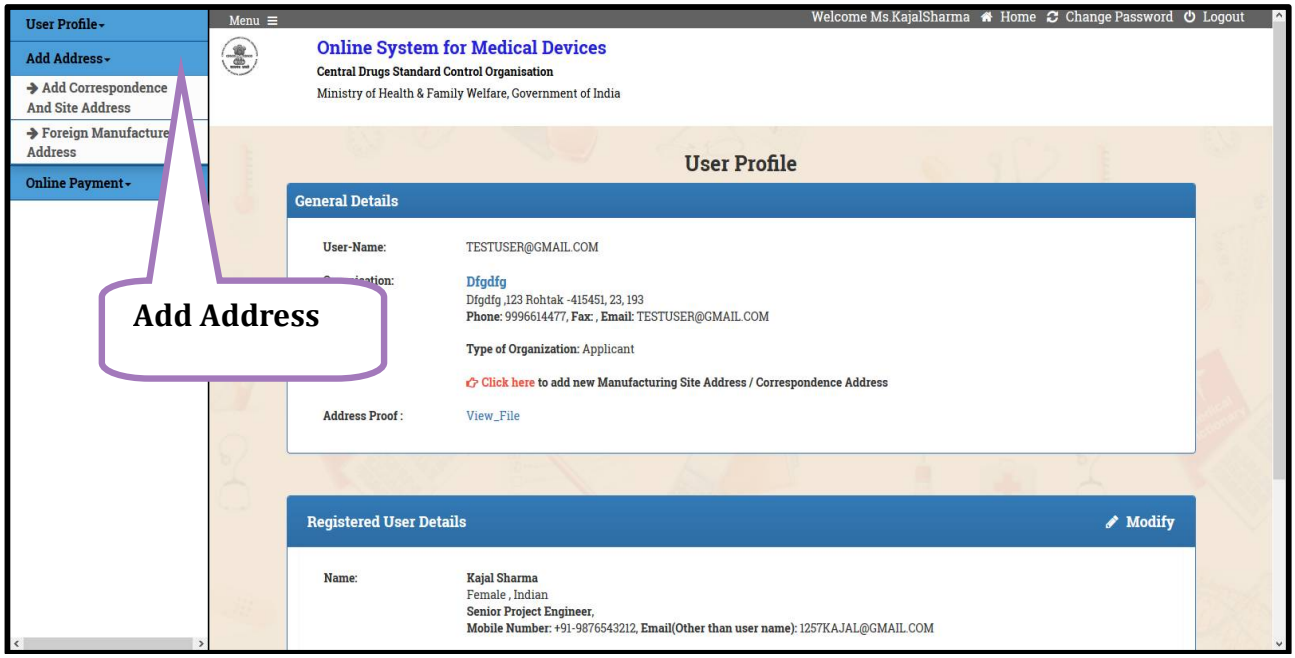


Figure 9 : Add Address

- Click on Add Correspondence and Site Address the screen will show as mention in **figure 10.**

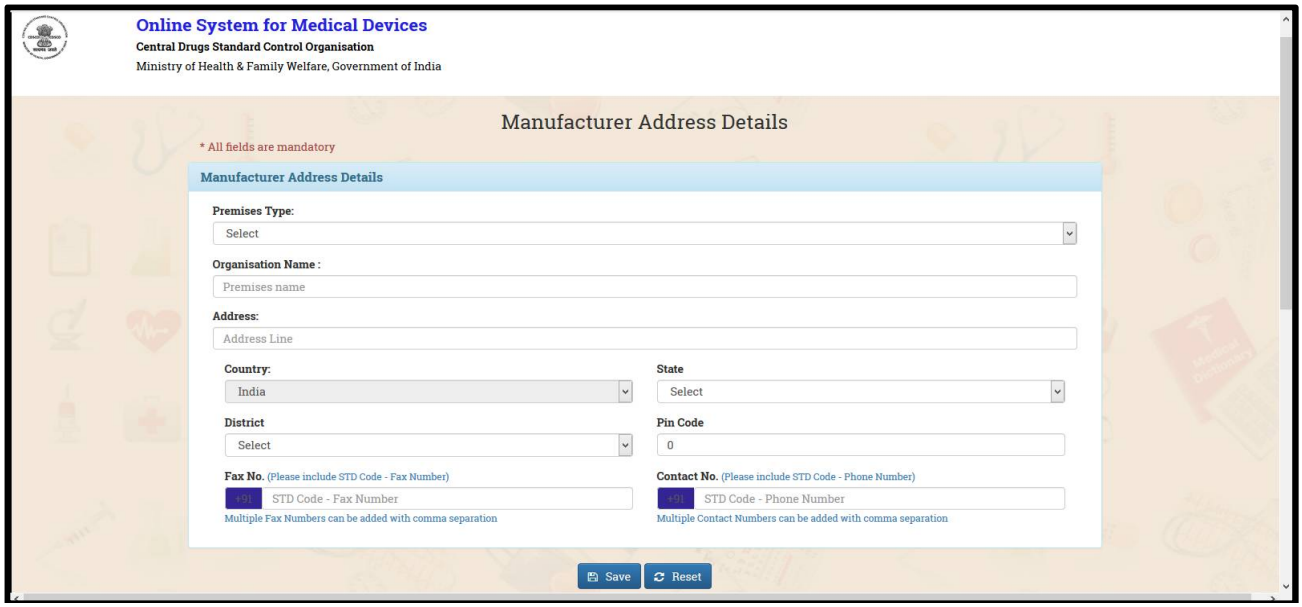


Figure 10 : Manufacturer Address Details

- Fill all the mandotory details (*) as shown in **figure 11**, and then after click on Save button.

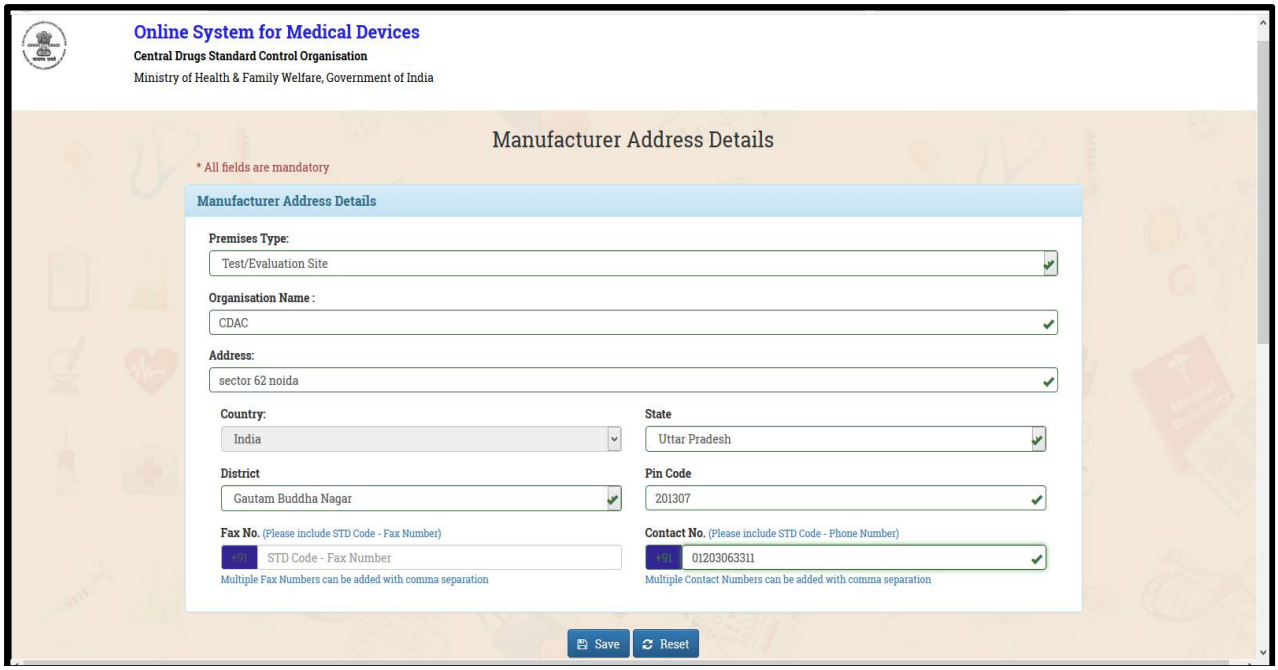


Figure 11 : Click on Save Button

- After click on save button, the list will shown as below the mention **Figure 12**. User can Edit with Edit Button or Delete the Address.

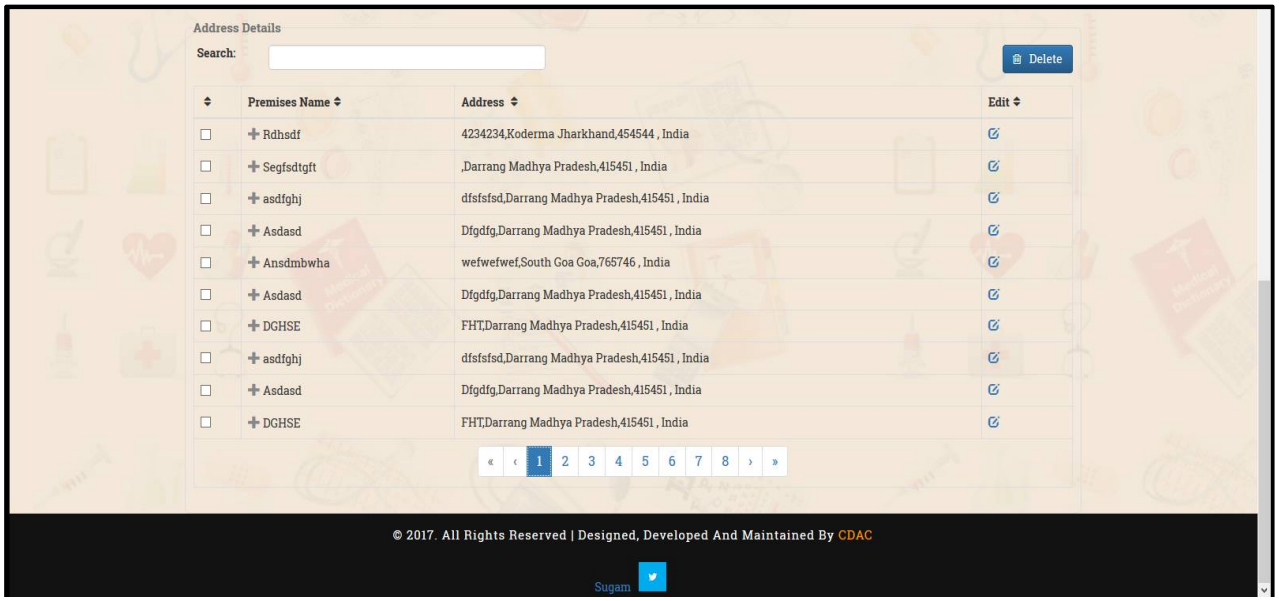


Figure 12 : Address Details

- After click on edit button user can modify or Reset the details.As shown in **figure 13.**

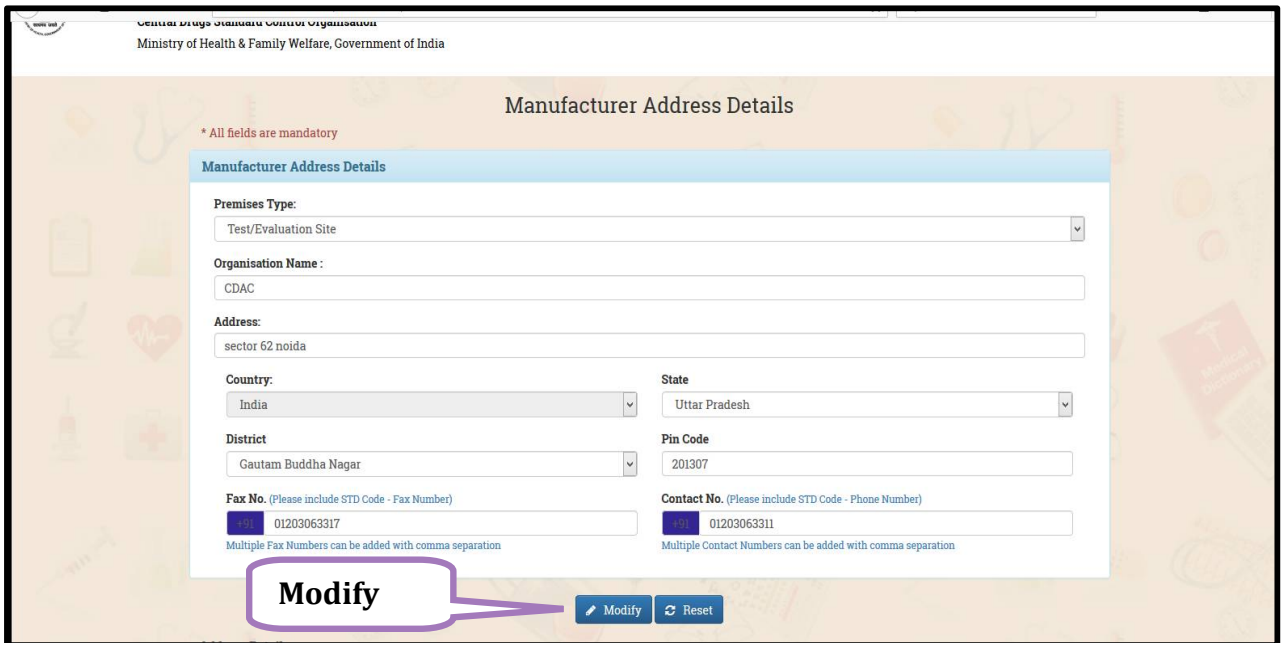


Figure 13 : Modify or Reset the Details

- If User wants to delete any address details, Select by Checklist button, and then click on Delete Button, After you clicked Delete Button, you can get Popup Message i.e "Do you Want to Delete" then click on OK button.

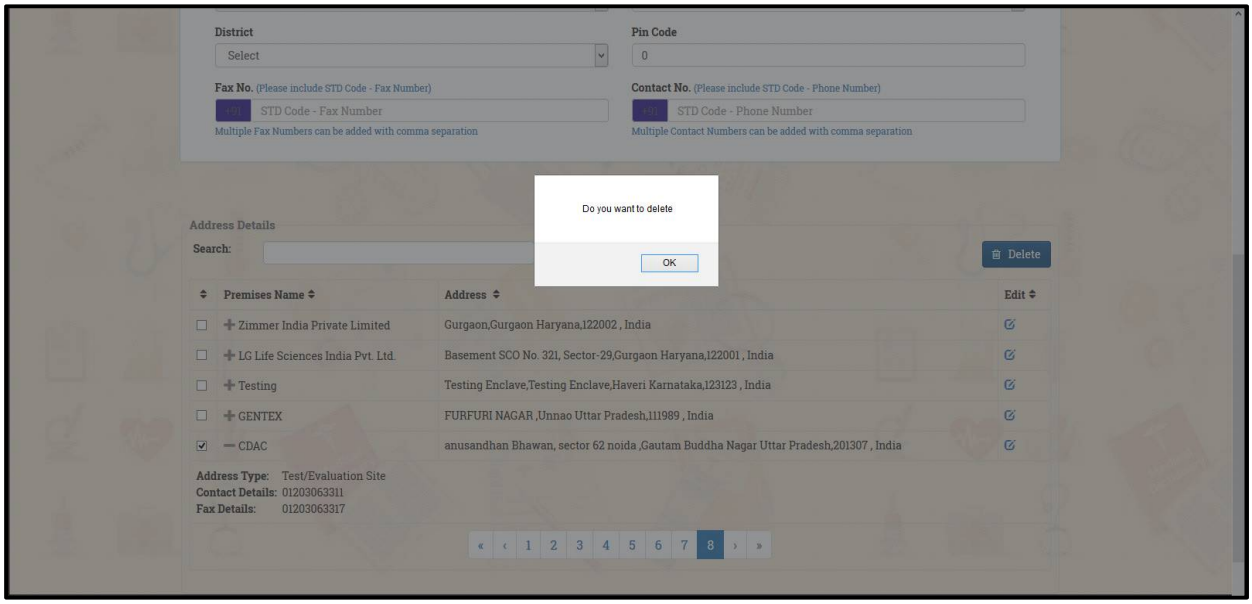


Figure 14 : Popup Message: Delete

- Now click on Foreign Manufacturer address Details, the screen will shown as figure 13. Fill all the required field as shown in **figure 15.**

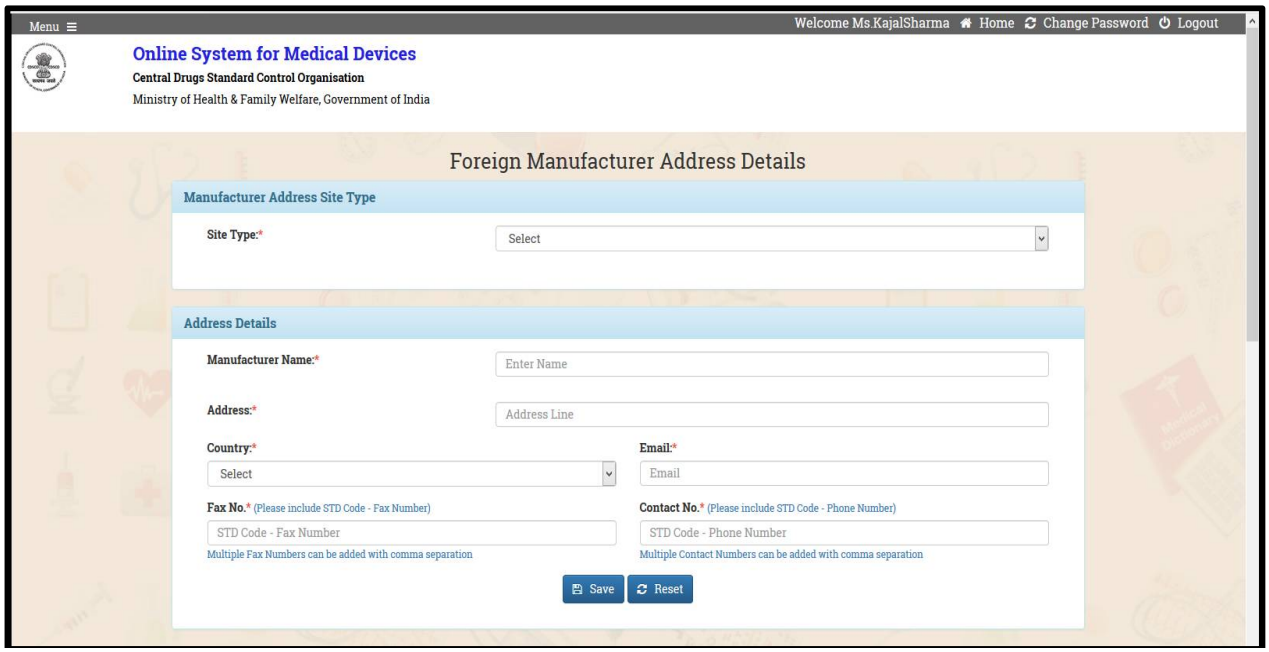


Figure 15 : Screen of Foreign Manufacturer address Details

- After fill all the details you can save information by clicking the Save Button. As shown in **figure 16.**

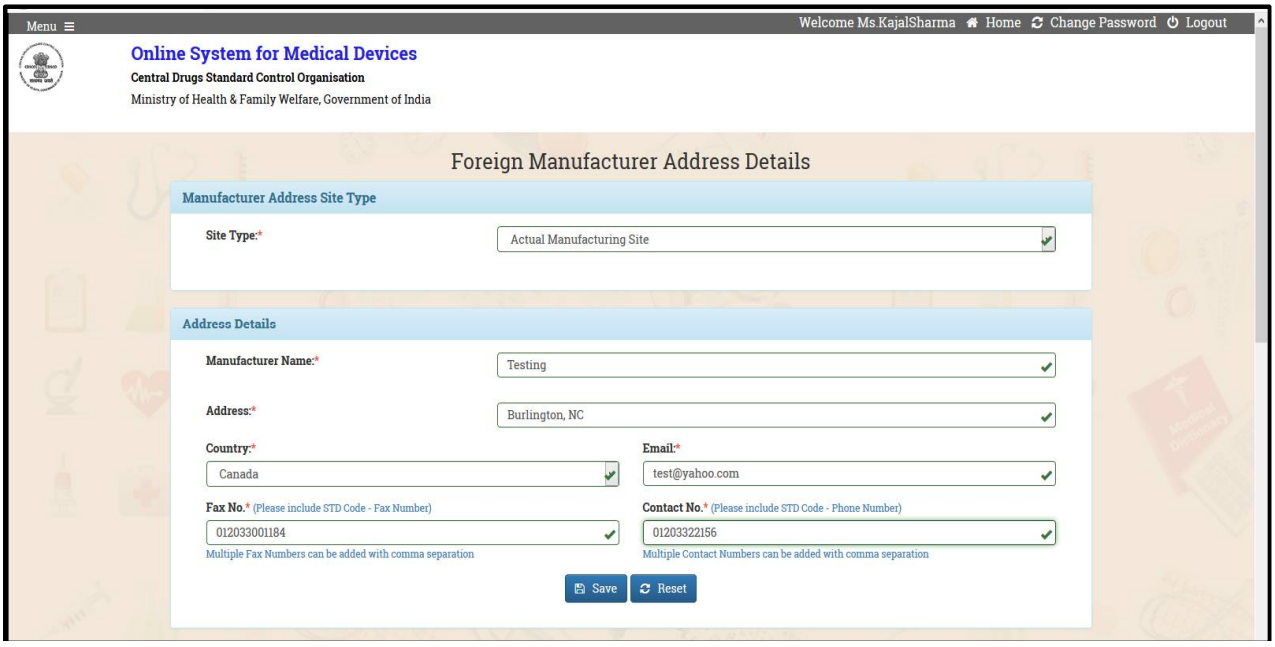


Figure 16 : Filled all Required Field

- After click on Save Button Address Details list will show, **figure 17,** user can Edit or Delete the address.

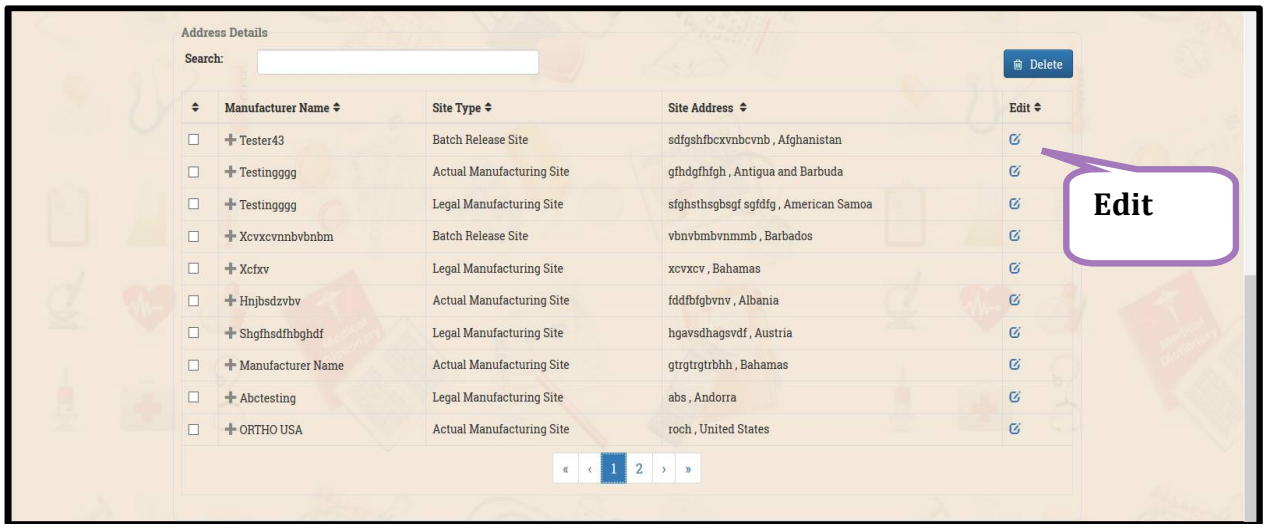


Figure 17 : List of address Details

1.6. Submit Application

- Click on show, 

Submit Application then below the mention screen will **Figure 18.**

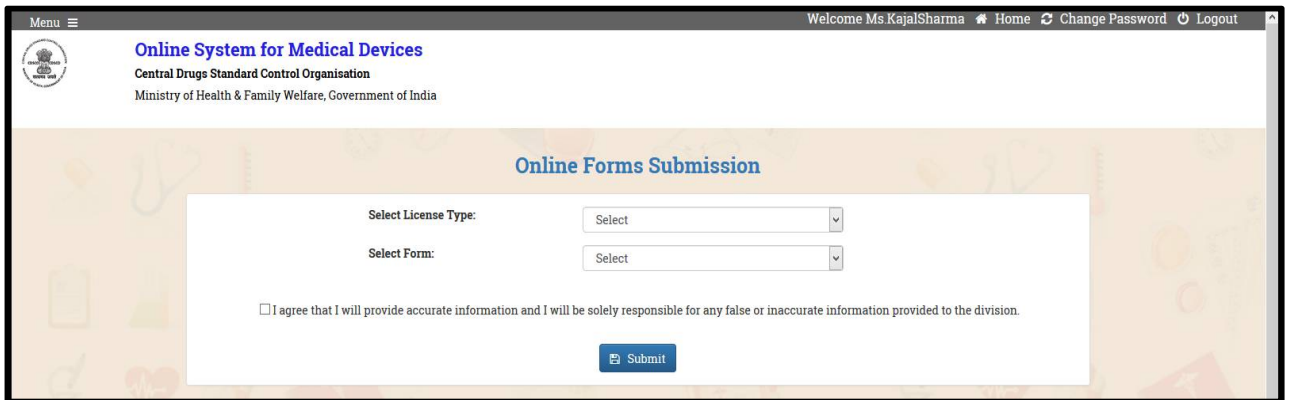


Figure 18 : Screen of after Click on Submit application

- Fill all the details using Dropdown Menu List like Selet License Type, Select Forms then after click on Submit Button for Online Form Submission. As shown in **figure 19, 20, 21, 22.**

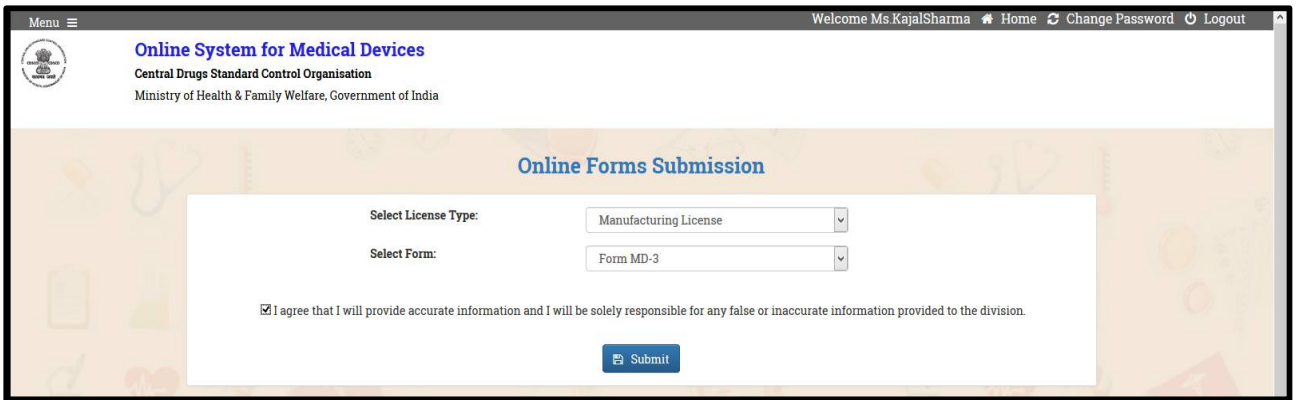


Figure 19 : Submit application (Continue)

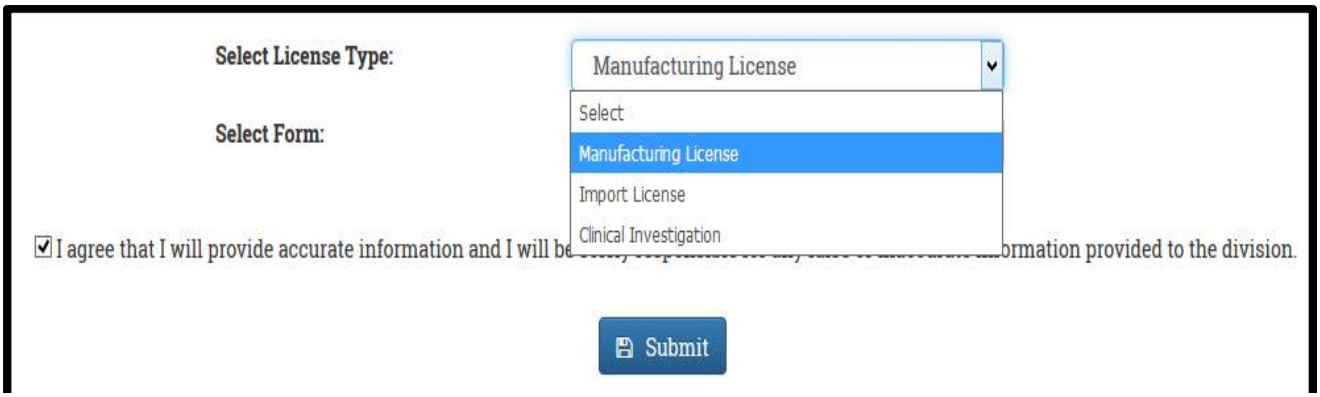


Figure 20 : Three Options - Manufacturing License, Import License, Clinical Investigation

- Select any Form from Dropdown List like – (a) Form MD- 3 (b) Form MD- 4 (c) Form MD- 7 (d) Form MD- 8. As shown in **figure 19.**

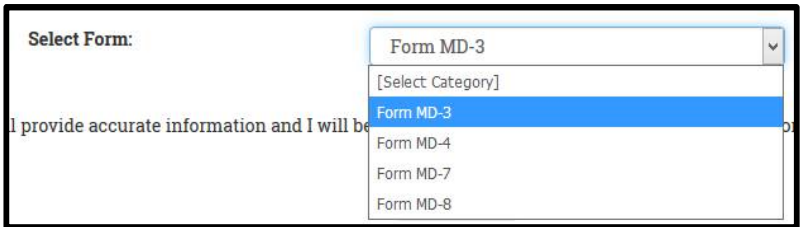
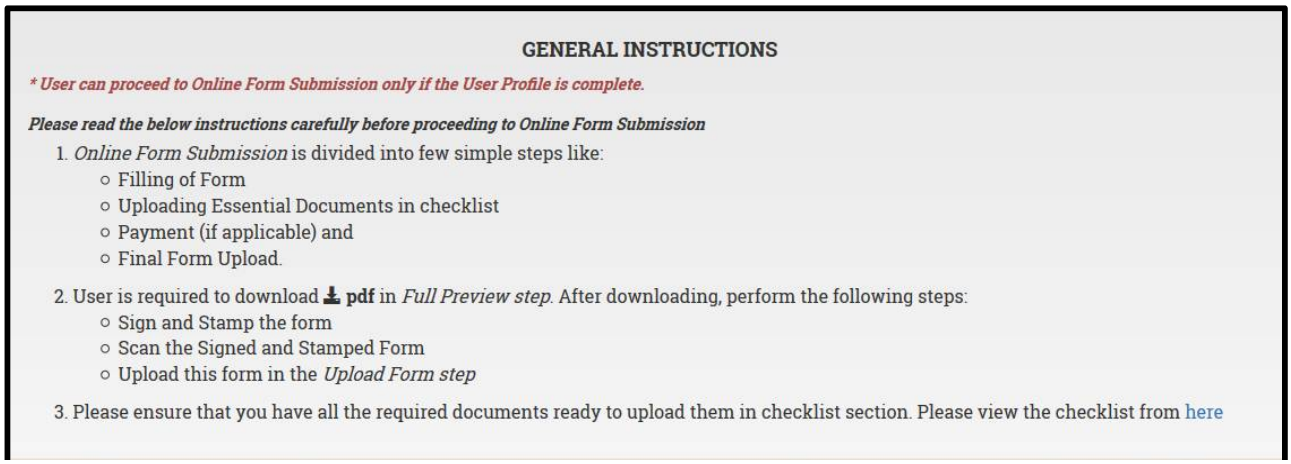


Figure 21 : Form Type

- Read carefully General Instructions then after Proceed. As Shown in **Figure 20**.



GENERAL INSTRUCTIONS

** User can proceed to Online Form Submission only if the User Profile is complete.*

Please read the below instructions carefully before proceeding to Online Form Submission

1. *Online Form Submission* is divided into few simple steps like:
   - Filling of Form
   - Uploading Essential Documents in checklist
   - Payment (if applicable) and
   - Final Form Upload.
2. User is required to download **pdf** in *Full Preview step*. After downloading, perform the following steps:
   - Sign and Stamp the form
   - Scan the Signed and Stamped Form
   - Upload this form in the *Upload Form step*
3. Please ensure that you have all the required documents ready to upload them in checklist section. Please view the checklist from here

Figure 22 : General Instructions

- After click on Submit Button screen will show in **figure 23& figure 24**.

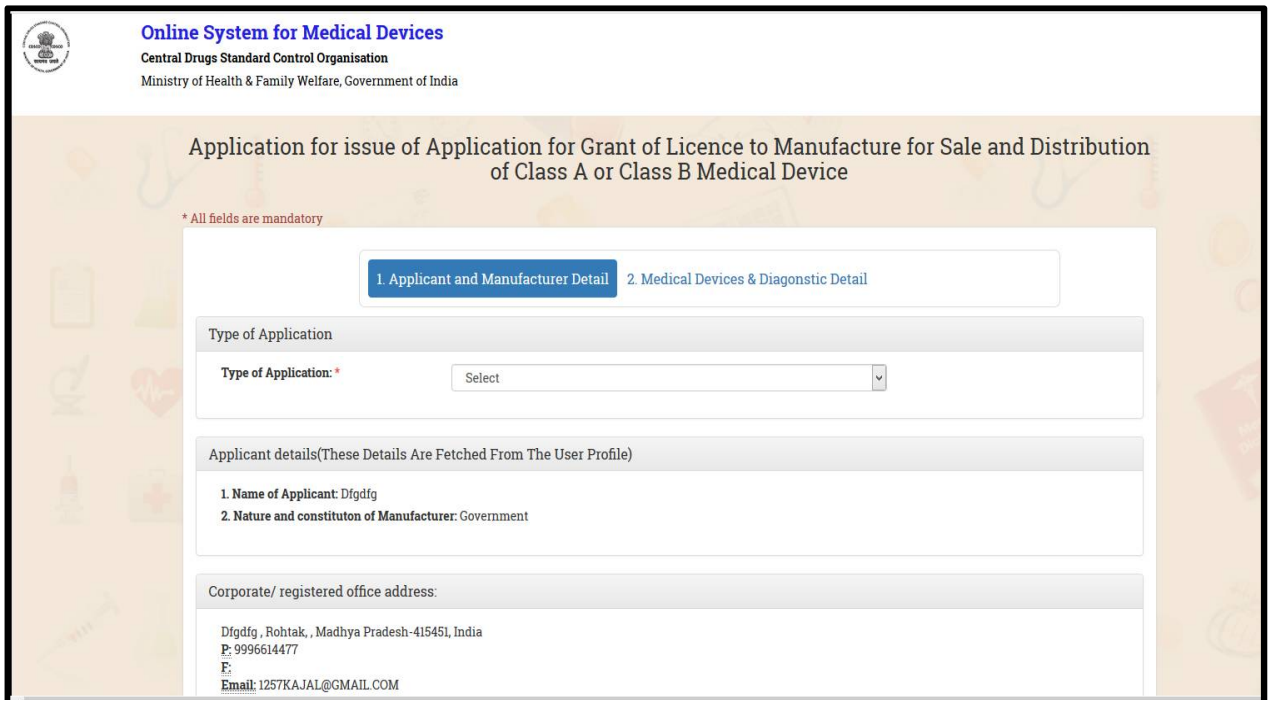


Figure 23 : Screen of After Click on Submit Button

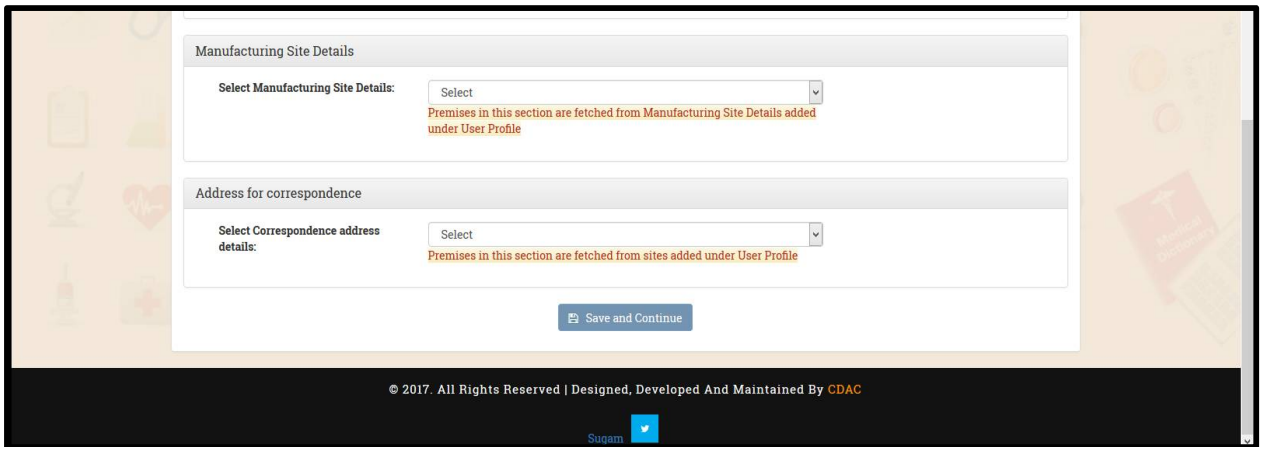


Figure 24 : Screen of After Click on Submit Button (Continue)

- Select Type of Application, Select Manufacturing Site Details and Select Correspondence address details then click on Save and Continue. As shown in the figure

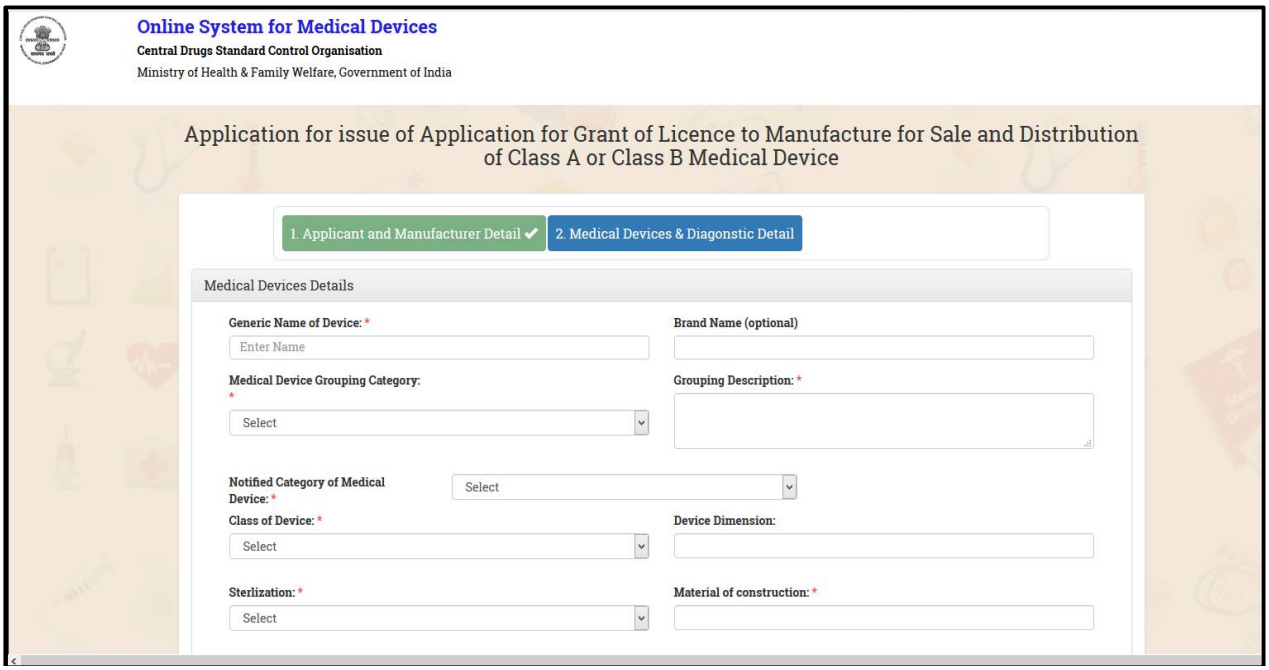


Figure 25 : Screen of after click on Save and Continue

- **Medical Device Details** : After click on save button then fill Medical Device Details like Generic Name of Device, Medical Device Grouping Category, Grouping Description, Notified Category of Medical Device, Class of Device, Sterlization, Product Description etc. as shown in the **figure 24.**

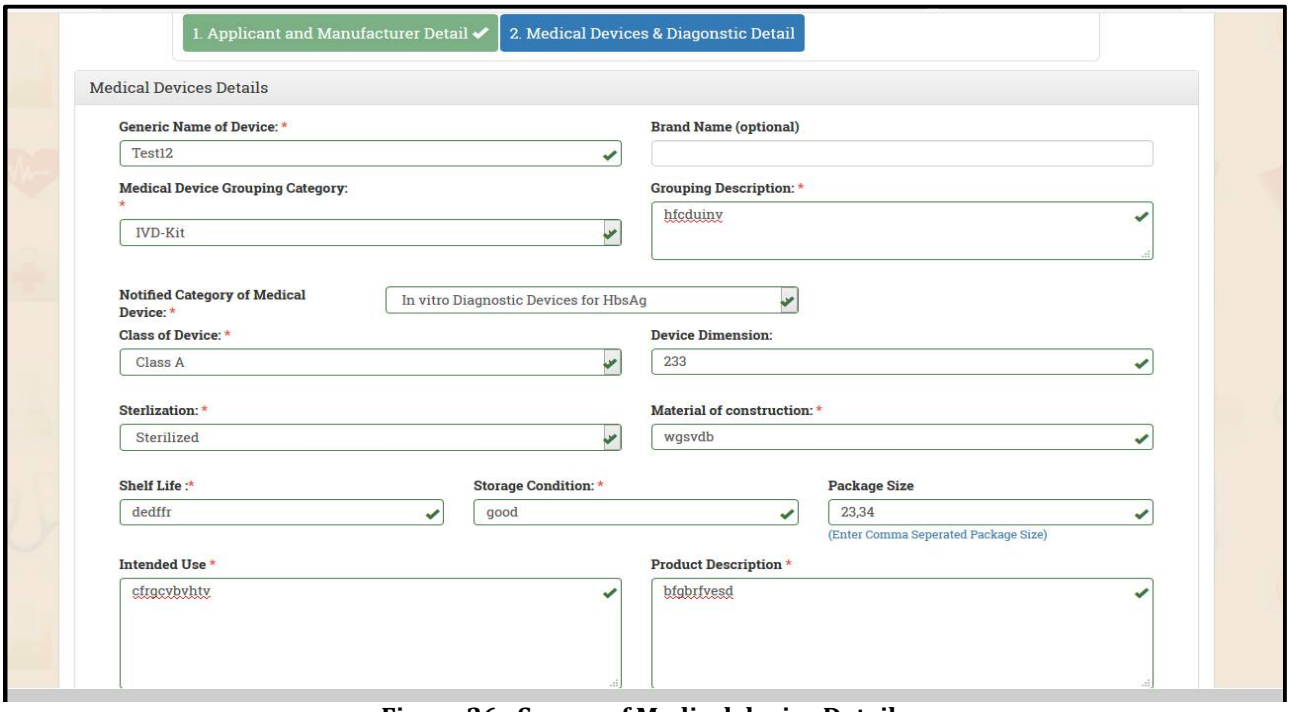


Figure 26 : Screen of Medical device Details

- **Accessories/Components :**User can Add(+) or Remove (-) the field. Refer **figure 25.**

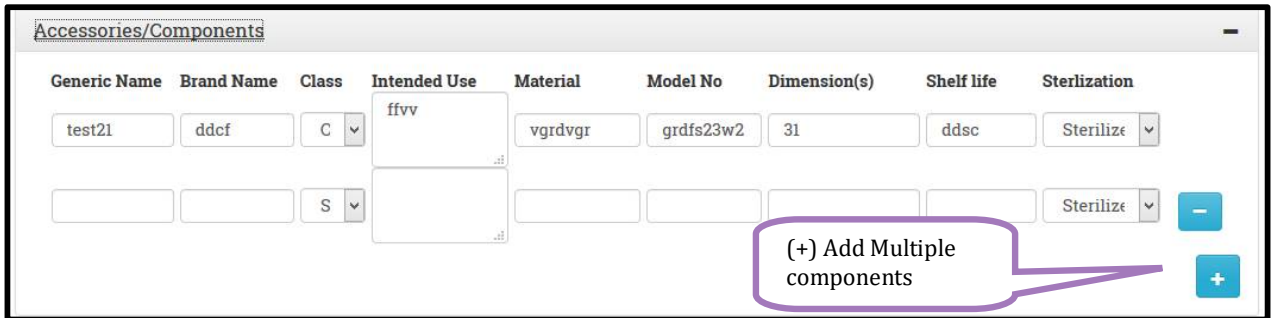


Figure 27 : Accessories/Components

- **Models :** User can "Add Model " or "Remove Model" with the help of Buttons. As shown in figure 26

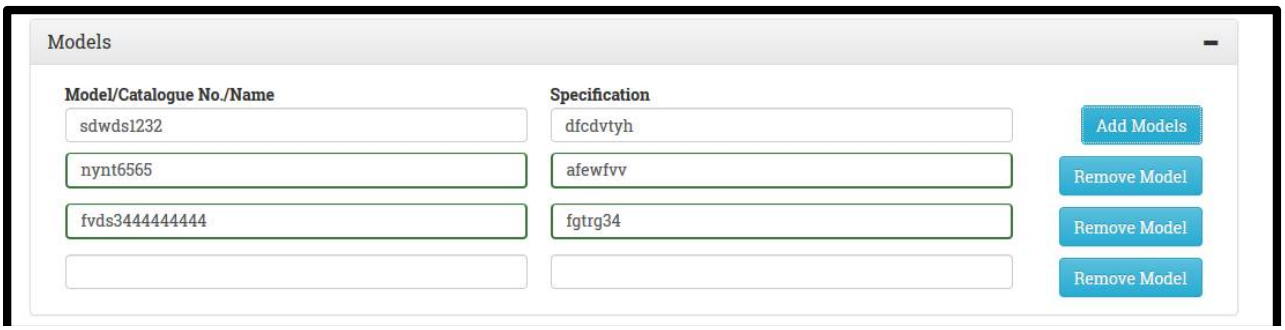


Figure 28 : Fill Model Details

- Fill all the details click on Save Button, After Save the information screen will show in this **figure 27.** Shows device details, user can Edit or delete the device details.

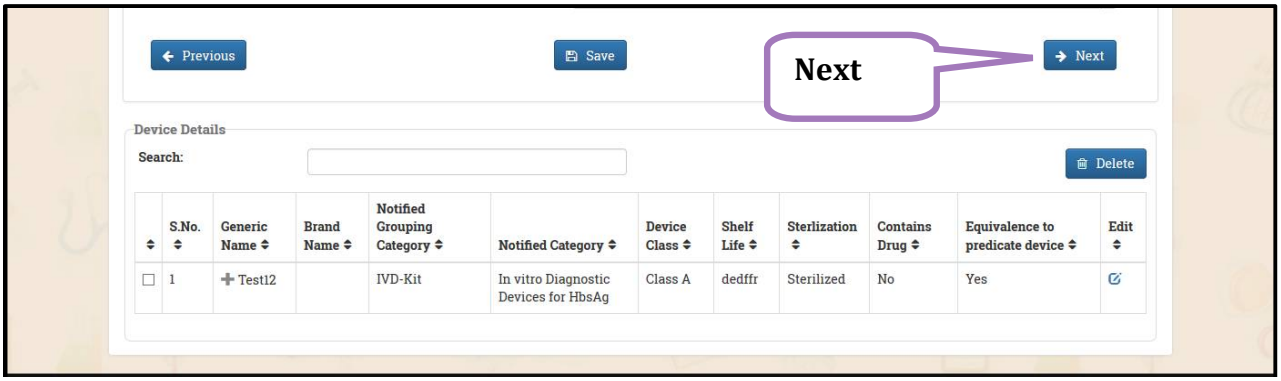


Figure 29 : List of Device Details

- Then click on NEXT Button, screen will show in **figure 28.**User can Edit Form or Proceed to Cheklist.

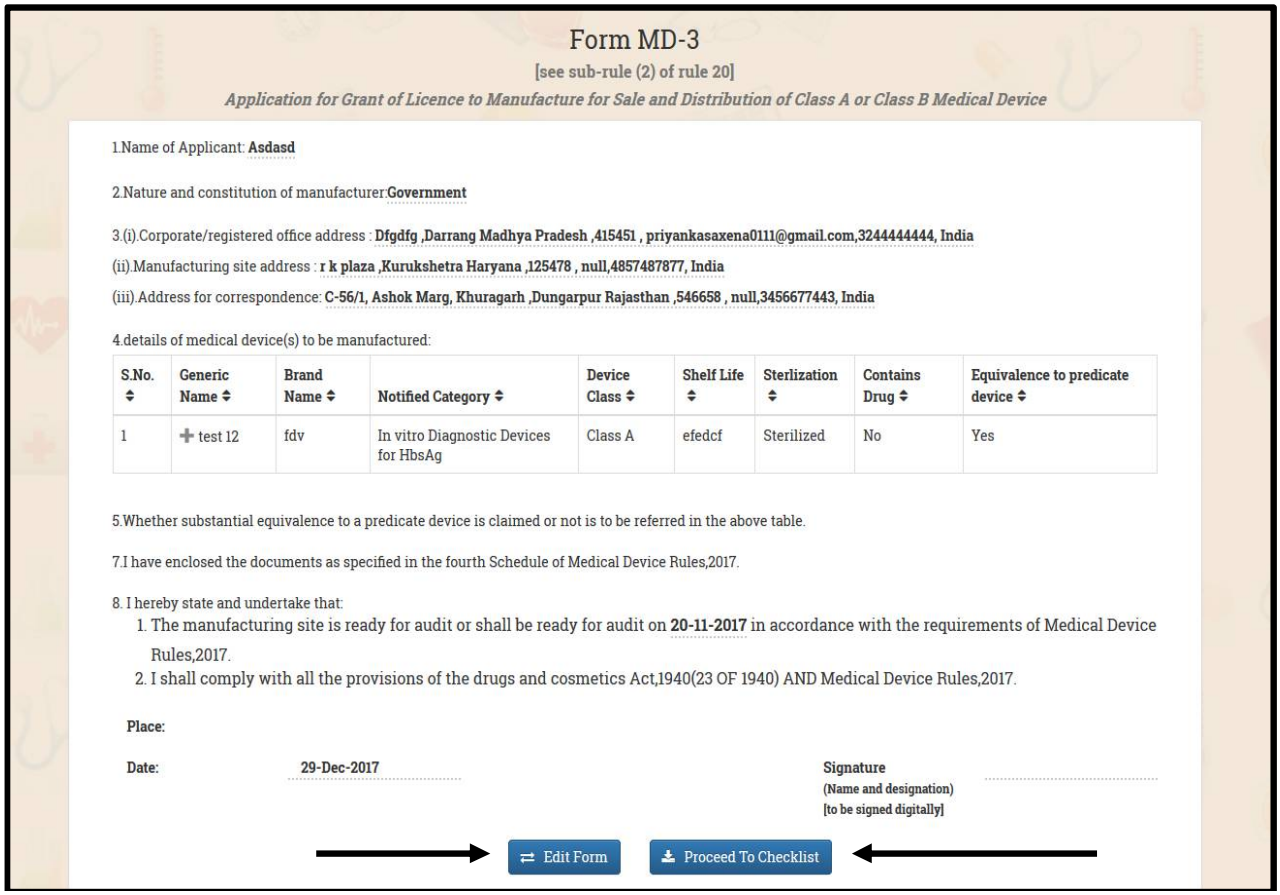


Figure 30 : Form MD - 3

- After Click on Proceed to Cheklist, screen will show like **figure 29.**

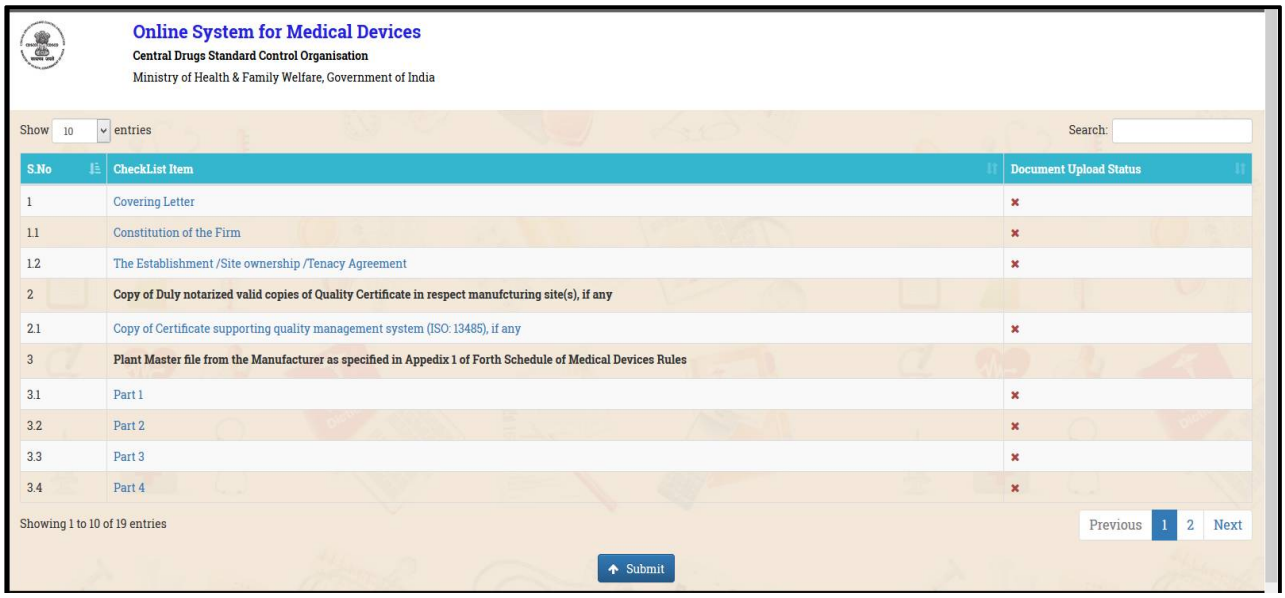


Figure 31 : Checklist Item

- Then User can upload the Documents, View the documents and Reset the Document.
- **For Upload the document :** User can click any "Cheklist Items" like – Covering Letter, Constitution of the firm, The Establishment /Site ownership /Tenacy Agreement etc.
- After click on Covering Letter or The Establishment /Site ownership /Tenacy Agreement. The screen will show like **figure 30.**

Figure 32 : Upload document for Covering Letter

- Then Submit the Upload Documents, If user wants to view the document or can change the upload document, he can do so. As shown in the **figure 31.**

Figure 33: View Upload Document or change file

- After upload, all the documents, "**documents Upload status**" will show as **figure 33.** Uploaded documents will show,Mark as Green colour.

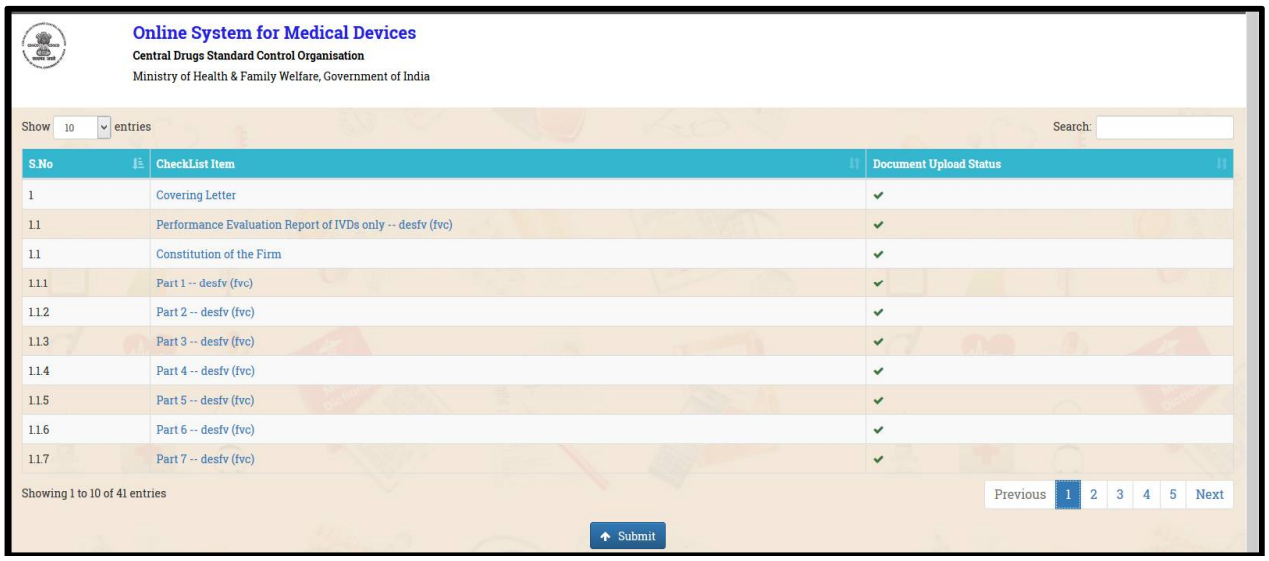


Figure 34 : Screen of "Documents Upload Status"

- After Click on Submit Button the screen will show in this **figure 33**.

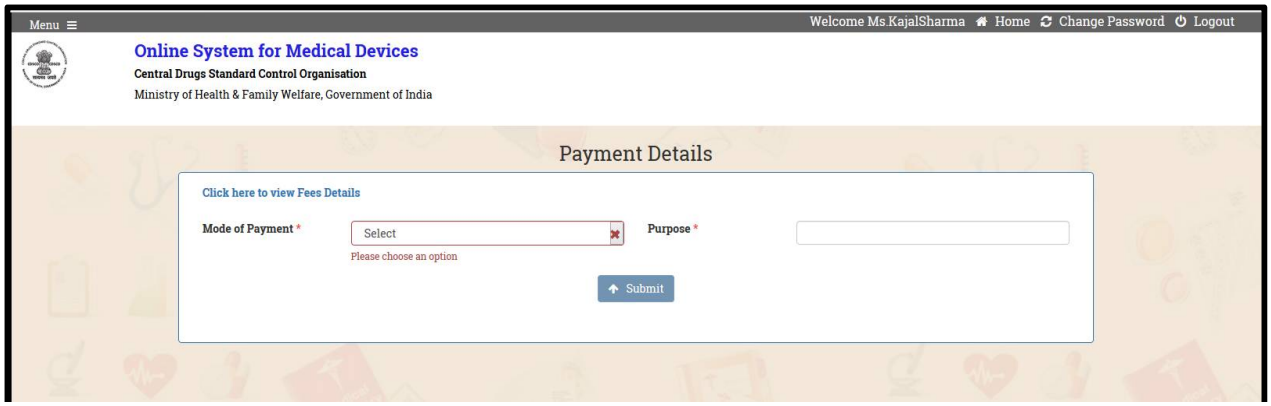


Figure 35 : Payment Detail Screen

- Select Mode of Payment Challan, Fill Challan Details Like Challan No., Date, Amount, Bank Name, Branch Code, and Upload Challan.

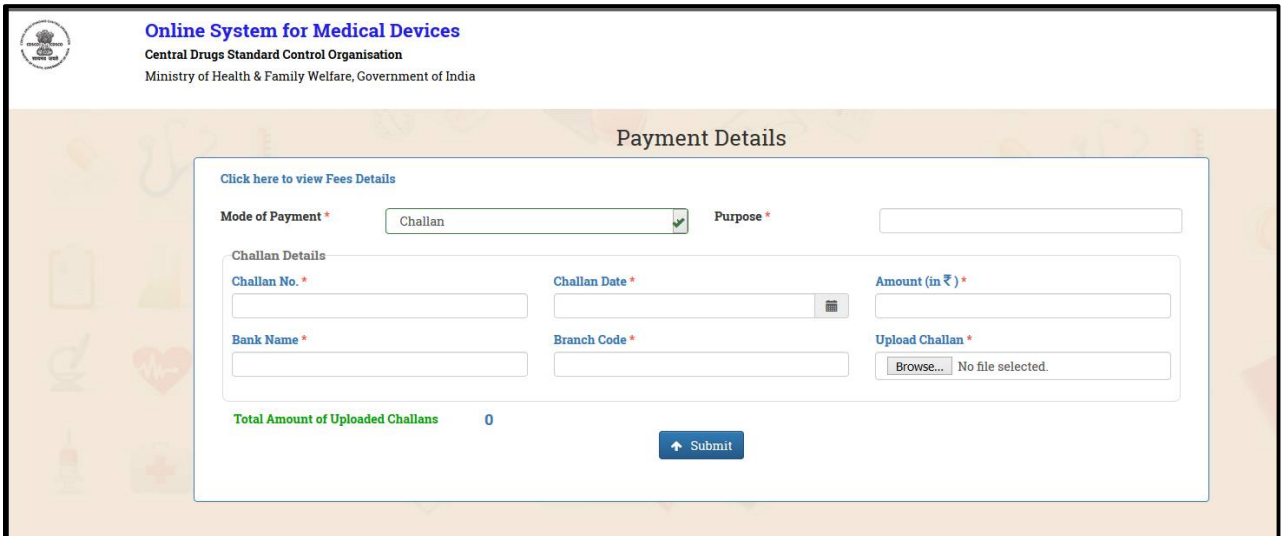


Figure 36 : Payment Details (Continue)

- After Fill all the details, then Click on Submit Button.

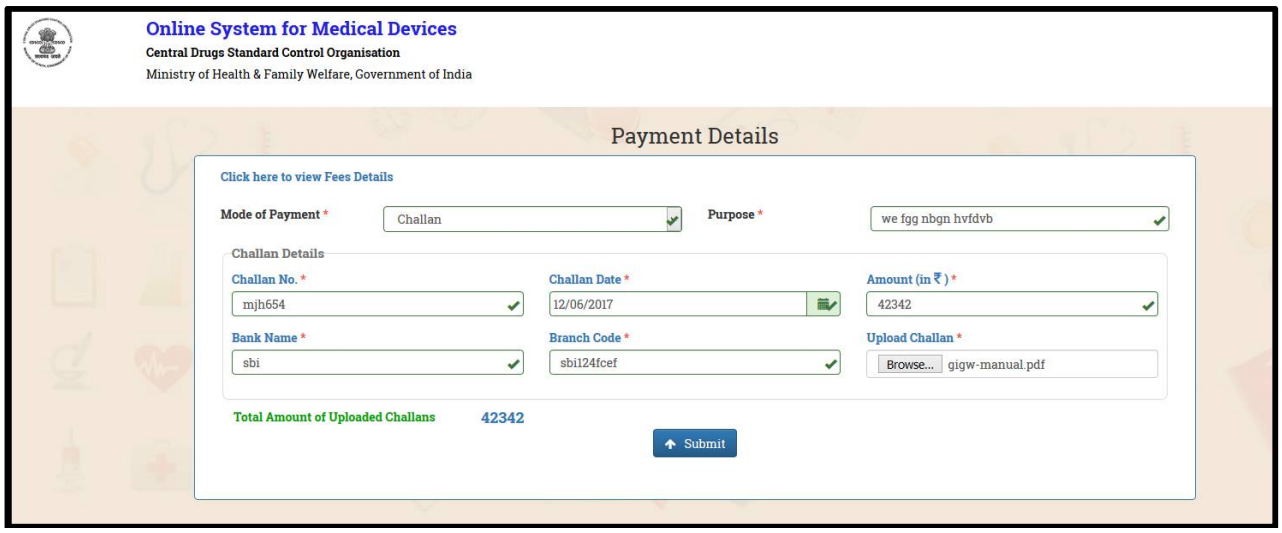


Figure 37 : Payment Details (Continue)

- After click on Submit the screen will show as **figure 36.** In this shows **Download PDF** or click on **Next** Button for Continue.

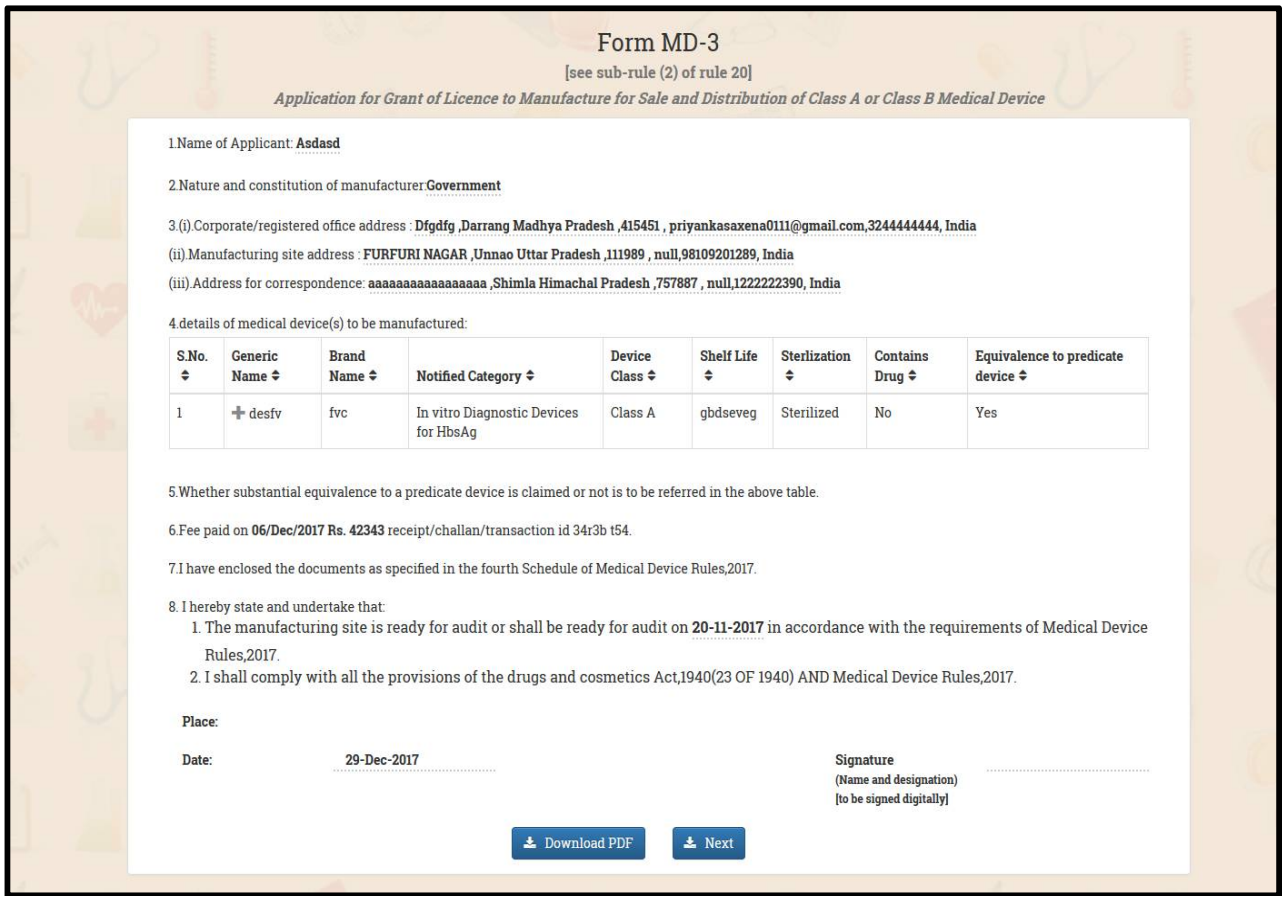


Figure 38 : Preview of Form MD- 3

- After Click on Next Button the screen will show as **figure 37.**

Figure 39 : Upload Form

- After Click on Submit Button, below the mention screen will show, **figure 38** and Message will show i.e " Your Application has been submitted Successfully", note your File no. **MFG/MD/2017/915.**

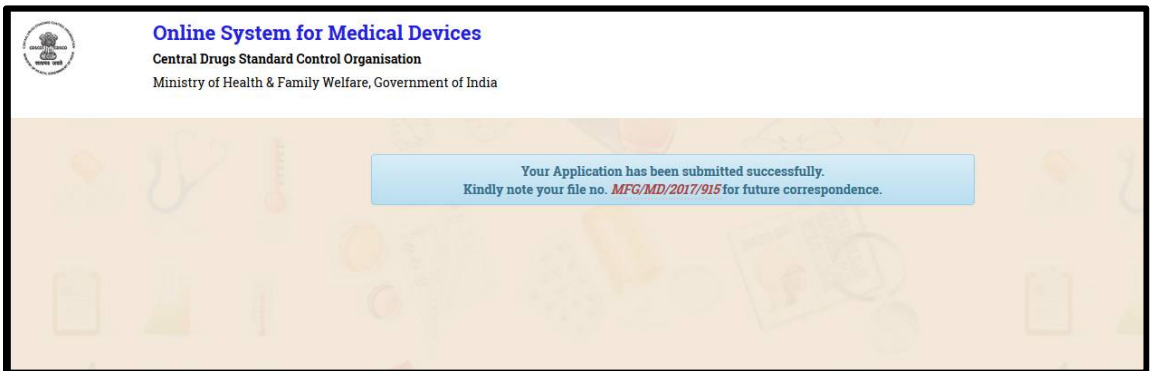


Figure 40 : Screen of Application Successfully Submitted

1.7. Save as Draft

1.8. Submitted Application

- Click on Submitted Application under the dashboard screen,
- To view the status of submitted applications. In this you can Withdraw the application as shown in the **figure 39.**

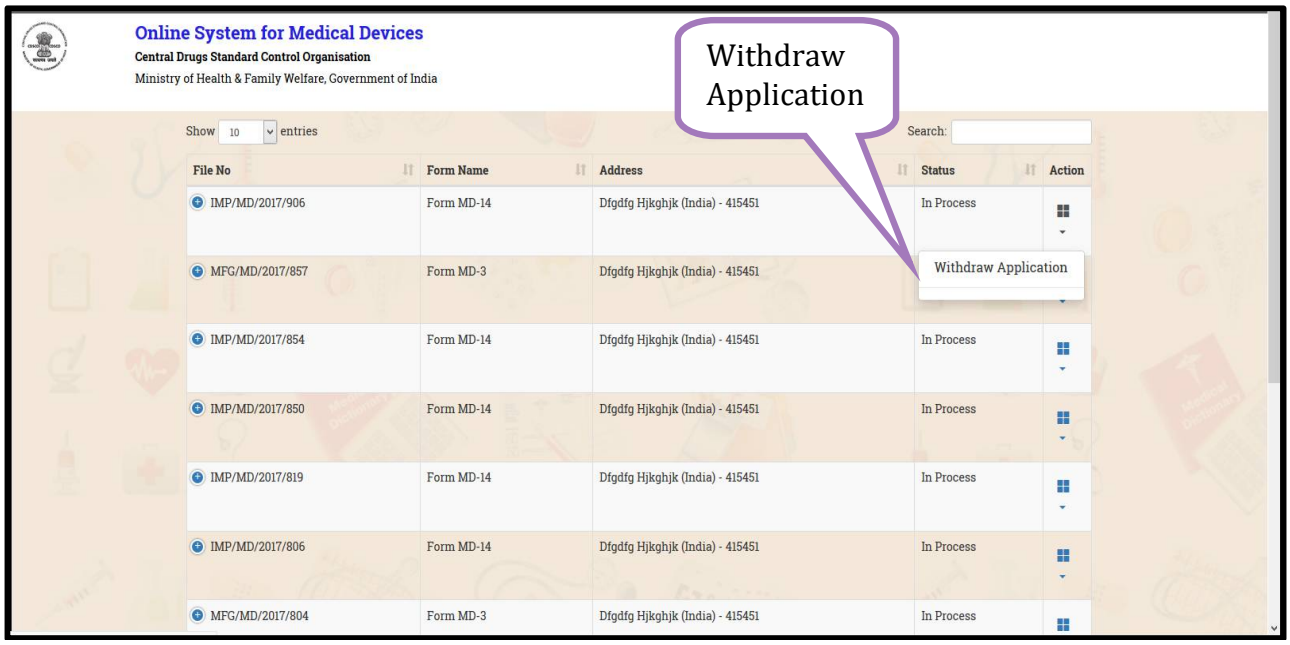


Figure 41 : Screen of after click on Submitted Application

- After Click on Withdraw Application Confirmation message will show. As shown in the **figure 42.**

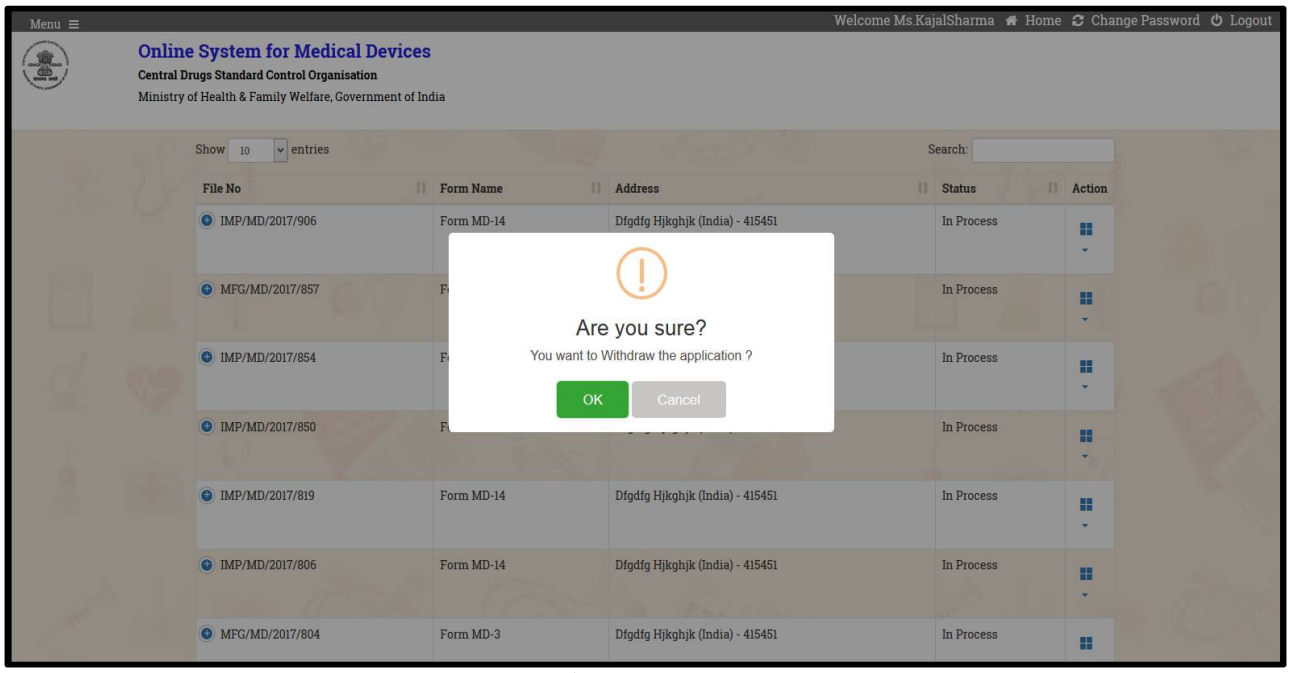


Figure 42 : Popup Message: 'You want to withdraw the Application."

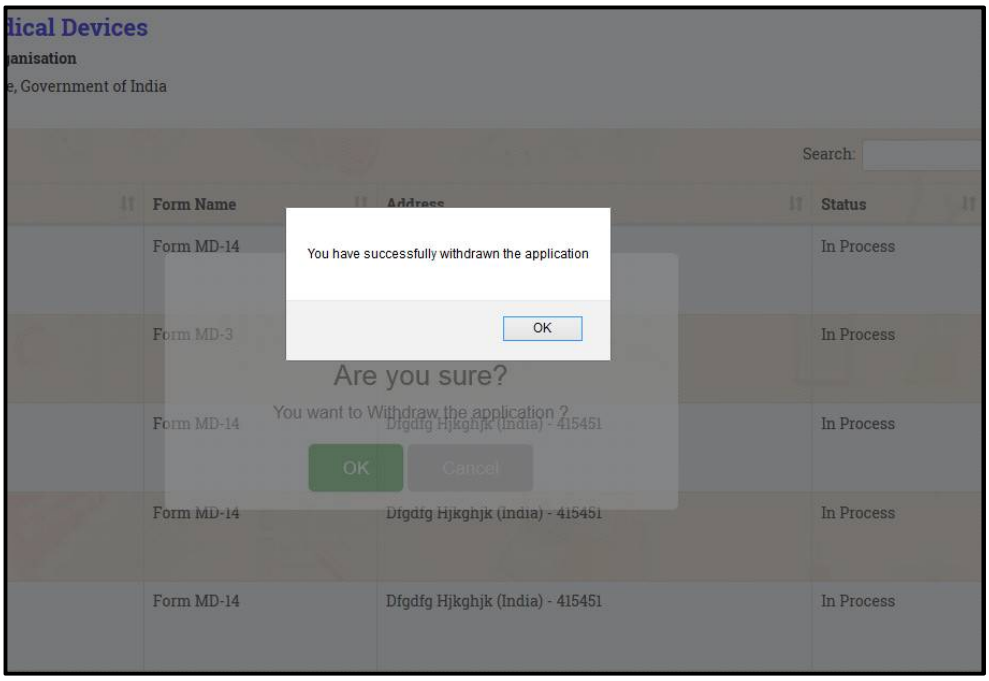


Figure 43 : Popup Message- Successfully Withdraw the application

Frequently Asked Questions

Frequently Asked Questions on Medical Device Rule, 2017

1. **If a license is granted in Form 25 or Form 28 before or after publication of GSR 1337(E) dated 27.10.2017, what will be validity period of such license?**

   As per notification, GSR 1337(E), dated 27.10.2017 the license issued under Form 25 or 28, unless sooner suspended or cancelled, shall remain valid perpetually.

2. **What will be status of application for renewal of license issued in Form 25 or Form 28 which are pending for approval by licensing authority or central licensing approving authority on or after 27.10.2017?**

   As per notification, GSR 1337(E), dated 27.10.2017, the Drugs and Cosmetic Rules, As per provisions in Rule 75 and Rule 76 the word "renewal" is omitted however, the licensee shall deposit license retention fee and documents as per the provisions of Current Medical Device Rules 2017.
   It is advised to all manufacturers of medical devices for compliance with the conditions and with the requirements of Medical Devices Rules, 2017 by online processes before the due date of the payment of applicable license retention fee.

3. **What will be the status of the application for grant of license are applied before 01.01.2018 but are still in process and not granted the license?**

   The application for grant of license which are applied before 01.01.2018 but are still in process and not granted the license, the applicant will need to pay balance fees and also reapply on the online portal as per the Current Medical Device Rules 2017.

4. **What will be the status of manufacturing license / additional product issued by State Licensing Authority before 01.01.2018 and sent for approval to CLAA?**

   Manufacturing licenses of a medical devices covered under CLAA scheme and signed for granting by State Licensing Authority before 31.12.2017, may be considered for approval by CLAA with the condition that licensee shall fulfill requirements of Medical Devices Rules, 2017 after 01.01.2018. Further, if such licenses are signed by State Licensing Authority after 27.10.2017, it shall be granted in accordance with GSR 1337 dated 27.10.2017 and those which are signed by SLA before 27.10.2017 shall be granted as per earlier provisions with validity period.

2. **What will be procedure to obtain additional products on existing valid licenses, in similar category of Medical Devices/IVD's after 01.01.2018?**

   Application form, fees and documents will have to be submitted on new Medical Device

portal as per MDR-2017 to obtain the new license.

6. **What will be status of those applicants for import, who applied for registration or Import License before 01.01.2018 on old Sugam, but could not get it, due to incompletion of document or query raised?**

   Such applicants shall re-apply in new CDSCO MD online portal with additional balance fees and documents as per Medical Devices Rules, 2017 which may include new application form, new Power of Attorney, covering letter detailing the sequence of event & proofs thereof including proof of old fees paid. Such old applications on old Sugam may get advantage of old submissions/ fees till 30.07.2018 based on Medical Devices Rules, 2017.

7. **What will be applicability /utility of old sugam for applicants, with respect to existing Registration Certificate/ import Licenses?**

   Old sugam will remain operative for post approval changes of existing Registration Certificate and Import Licenses (as on 1.1.2018) till their expiry or till 30.07.2018, whichever is later as per Medical Devices Rules, 2017.

8. **For importing of raw materials / components intended to be used for further manufacture of Finished Medical Devices under a valid manufacturing license issued under the provisions of Drugs and Cosmetic Act and Rules thereunder, whether the importer needs to obtain the import license for such raw materials / components?**

   As per existing practices and circulars, in such cases, no import license is required.

9. **What will be the status of competent person existing on the license before 01.01.2018 for manufacturing and testing?**

   As per the saving clause of Rule 97 prescribed in Medical Devices Rules, 2017 those competent persons will continue to remain so.

   Note: *The first nine questions and answers applies to IVD's also*

10. **By when will the revised Notified Medical Device listing be made available?**

    As per Medical Device Rules 2017,

    (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);

    (ii) substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified under sub-clause (ii); and

    (iii) 15 classes of Medical 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) Government of India may notify more devices under section 3 (b) (iv) of the Drugs and Cosmetics Act, 1940 in due course of time which will be displayed on the CDSCO website.

11. Will business continuity be considered for devices already in market, but not yet notified, if they are brought under the list of notified devices?

Once devices are brought under notified categories, the manufacturer / importer has to comply with Medical Device Rules 2017.

12. What would be the transition timeline given to manufacturers and importers w.r.t grandfathering of already existing devices?

If the device is already in the market and government of India notify the same under 3(b)(iv) of Drugs and Cosmetics Act, 1940 (23 of 1940) then the device will be regulated under the Medical Device Rules 2017.

13. In which form permission to import small quantities of medical devices for personal use can be obtained?

A patient can apply in Form MD-20 with all requisite documents and permission can be given in Form MD-21.

14. What is the process for classification verification with CDSCO or notified body prior to submission?

The Central Licensing Authority shall, classify medical devices referred to in Rule 2, based on their intended use and other parameters specified in the First Schedule. Based on the classification referred to in sub-rule (3), class wise list of medical devices shall be published on the website of the Central Drugs Standard Control Organization (CDSCO): Provided that the Central Licensing Authority may, from time to time, make additions or deletions in such list of medical devices or modify the class of any medical device. CDSCO has already displayed the list of medical devices with classification, which is dynamic in nature.

15. What if the classification of a product being imported is different in GHTF countries from the classification in India?

In such cases, the higher class of Medical device will be considered.

16. Where can we get a list of authorized Notified bodies?

The list of the registered Notified bodies with CDSCO will be made available on the website.

17. What are the requirements to be a registered Notified body?

The requirements are laid down in Part I of Third Schedule of Medical Devices Rules, 2017.

18. Will the manufacturer have an option to choose Notified body?

The Notified body accredited under sub-rule (1) of Rule 13 shall be competent to carry out an audit of manufacturing sites of Class A and Class B medical devices to verify their conformance with the Quality Management System and other applicable standards as specified under these rules in respect of such medical devices as and when so advised by the State Licensing Authority.

19. If Notified body is not having competency to evaluate specific class(es) of devices, what would be the process?

As per the Medical devices Rules 2017, the National Accreditation Board for Certification Bodies (NABCB) shall lay down the conformity assessment activities for Accreditation of Notified bodies prior to registration with CDSCO.

20. For devices, already in market and notified later, would the requirement of local clinical investigation/evaluation be waived off?

The medical device on the basis of their intended use will be deliberated on case to case basis & data available, to substantiate their safety and effectiveness. The matter may also be placed before SEC.

21. Sub- clause (ii) lists 'insecticides' as notified under sub-clause (ii) of the 'Drugs' definition under clause (b) of Section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) will be regulated under the Medical Device Rules 2017. In most cases, these are currently regulated as 'Drugs' and have FF-Finished Formulation Registration Certificates. Please clarify that under the new Rules, these product categories would also migrate to medical devices?

As per the medical device definition the substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified under sub-clause (ii) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) are included in the definition of medical devices.

22. Sub- clause (ii) lists 'Insecticides' as notified under sub-clause (ii) of the 'Drugs' definition under clause (b) of Section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) will be regulated under the Medical Device Rules 2017. In most cases, these are currently regulated as 'Drugs' and have FF-Finished Formulation Registration Certificates. Please clarify that under the new Rules, these product categories would also migrate to medical devices?

As per the medical device definition the substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified under sub-clause (ii) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940).

23. In the event CDSCO considers any devices to be regulated beyond the notified devices as additional devices or as subset of device, what will be the process of regulating such device?

The devices which are already notified or to be notified by Government of India shall be regulated as per Medical Device Rules 2017.

24. Will a list of products classified into Class A, B, C and D be released by CDSCO or the companies have to do a self-classification of the products as per their understanding of the definition of the risk factors?

List of devices based on risk classification is published on the CDSCO website which is dynamic in nature.

25. If the list will be provided by CDSCO then would it be classified according to their therapeutic specialty (Cardiovascular, Dental etc.) to provide ease of location of the product?

Yes, the devices are classified as per the Risk based classification which is at par with the classification adopted in other countries is already displayed on the CDSCO website.

26. Will the risk-based classification be harmonized with the already existing and established global classification systems?

Yes.

27. Will a single import license fee apply to a grouped submission?

Any person who intends to apply for grant of license in respect of medical devices for - (i) import; (ii) manufacture for sale or for distribution; and may group all or any medical device in accordance with the guidelines to be issued from time to time by the Ministry of Health and Family Welfare in the Central Government, by taking into consideration the technological changes or development in the field of medical devices and in vitro diagnostic medical devices. If the principle technology, platform, intended use and product specification are different then separate fees needs to be submitted.

28. If a manufacturing firm is complying with ISO/IEC standards, would it still need to follow BIS standards?

(i) The medical device shall conform to the standards laid down by the Bureau of Indian Standards established under section 3 of the Bureau of Indian Standards Act, 1985 (63 of 1985) or as may be notified by the Ministry of Health and Family Welfare in the Central Government, from time to time.

(ii) Where no relevant standard of any medical device has been laid down under sub- rule (1), such device shall conform to the standard laid down by the International Organization for Standardization (ISO) or the International Electro Technical Commission (IEC), or by any

other pharmacopoeial standards.

(iii) In case of the standards which have not been specified under sub-rule (1) and sub-rule (2), the device shall conform to the validated manufacturer's standards.

29. Will a Notified body with two years auditing experience, outside India, be eligible for registering as a Notified body for carrying out audit of Class C & D medical devices?

Yes, they have to be registered with NABCB and CDSCO before being considered for auditing.

30. What is the timeline for carrying out the inspection for class C & D and grant of license?

For class C and class D the inspection will be carried out by Central Licensing Authority within a period of 60 days from the date of application and Central Licensing Authority may grant license if satisfied that the requirements of these rules have been complied within a period of forty five days from the date the inspection report has been received.

31. In case of Multi pack of a medical device is it sufficient to provide a single IFU (Instructions for use) if the medical devices are to be used by Health Care Professionals?

The medical device when offered for sale shall be accompanied by either its package inserts or user manual.

32. Will e-IFU (electronic Instructions for use) be permitted under the new regulations?

In Medical Device Rules 2017, e-IFU is not specified.

33. Several low-risk medical devices are supplied without an IFU. Where such a low-risk device is offered for sale, an IFU is not applicable and may not be supplied. Will this be allowed if a justification is submitted to the licensing authority (LA) at any time of registration?

The medical device when offered for sale shall be accompanied by either its package insert or user manual as per Rule 26 part (x) of Medical Device Rules 2017.

34. Could there be multiple importers for the same product (i.e. same legal & actual manufacturer)?

Yes, an authorized agent having license to manufacture for sale or distribution or wholesale license for sale or distribution under these rules, shall make an application for grant of import license for medical device to the Central Licensing Authority through an identified online portal of the Ministry of Health and Family Welfare in the Central Government in Form MD-14 for obtaining a license.

35. In case of multiple importers for same product:

a. For subsequent applications to obtain import license for already registered product & site by another agent under Medical Devices Rules, 2017 do all the documents related to site and product need to be submitted?

The new agent has to submit the legal documents like MD-14, new Power of Attorney, fees, wholesale/manufacturing licenses, Label, IFU and copy of import license issued to earlier agent along with the undertaking from the manufacturer stating that there is no change in the Device master file, Plant master file and other regulatory documents submitted to CDSCO by the earlier agent (name, address & Import License number) for registration.

b. How will Post Marketing Surveillance (PMS) be managed? Who will have reporting responsibility?

PMS is the responsibility of the licensed holder/authorized agent.

c. In case of new medical device, does each applicant need to obtain investigational device approval or once first importer obtains the investigational device approval the subsequent importers can simply obtain Import license?

Every applicant viz. authorized agent or manufacture has to obtain separate investigational device approval for new medical devices.

36. Would there be a provision to list multiple sites for a specific product on an existing certificate which has multiple products?

For the import of additional product from different manufacturing site the Indian agent has to submit fee for additional site as well as for the product and, the import license will be issued with fresh validity. In case the importer desires to get endorsed the additional product then product fees is required to be submitted and the import license will be issued with the same validity as of the existing license.

37. If yes, then what will be the procedure to endorse an additional manufacturing site (legal or actual) into an existing license?

As explained in Q no. 34.

38. What is the timeline for grant of approval for additional products from same site (in Form MD-15-Licence to import medical device)?

As per Rule 36 sub-rule (1), the Central Licensing Authority may, on being satisfied, grant license in Form MD-15 or, may reject such application for which reasons shall be recorded in writing, within a period of nine months from the date of application.

39. What is the timeline for grant of approval for additional manufacturing site?

As explained in Q no. 38.

40. In the event of an inspection of an overseas manufacturing facility, what is the expected timeline subsequent to date of submission?

On receipt of an application under sub-rule

(i) of Rule 34, the Central Licensing Authority, may cause an inspection of the overseas manufacturing site either by itself or by any other person or body to whom the power has been delegated for the purpose.
(ii) The applicant shall be liable to pay a fee as specified under the Second Schedule in respect of expenditure required in connection with the visit to the overseas manufacturing site under sub-rule (1).
(iii) The Central Licensing Authority may, on being satisfied, grant license in Form MD-15 or, may reject such application for which reasons shall be recorded in writing, within a period of nine months from the date of application.

41. After completion of inspection of an overseas manufacturing facility what will be the Central Drugs Standard Control Organization's timeline for submitting their findings?

The Central Licensing Authority may, on being satisfied, grant licence in Form MD-15 or, may reject such application for which reasons shall be recorded in writing, within a period of nine months from the date of application.

42. If product is manufactured in countries other than the ones listed in Rule 36 sub-rule (3) – will clinical investigation in India be waived off for all classes?

As per Rule-36 sub-rule (4) where a medical device is imported from countries other than those referred to in sub-rule (3), the license in case of Class C and Class D medical devices may be granted after its safety and effectiveness has been established through clinical investigation in India as specified under provisions of Chapter VII of these rules.

Where a medical device, is imported from countries other than those referred to in sub-rule (3), the license in case of Class A or Class B medical devices may be granted after its safety and performance has been established through published safety and performance data or through clinical investigation in the country of origin and a free sale certificate from the country of origin is furnished.

43. Does the license retention fee need to be accompanied with any support documentation? If yes, what are these documents?

The Firm needs to comply all the conditions laid down in the import license as per Rule 38.

44. Can Importer affix the India specific details as a sticker on retail pack in India or would the manufacturer be required to do so prior to shipping to India?

As per Rule-44 (n) importer can provide the label, in case of imported devices, by way of stickering, when such details are not already printed, includes import license number, name and address of the importer, address of the actual manufacturing premises and the date of manufacture.

45. Can the date of manufacture/sterilization/expiry be mentioned as DD/MM/YY or M/YY?

As per Rule- 44 (e) the date of expiry shall be in terms of the month and the year and it shall mean that the medical device is recommended till the last day of the month and the date of expiry shall be preceded by the words "Expiry date" or "Shelf Life".

46. Are labeling rules applicable on transparent covers or any wrapper, case or other covering which is used for the purpose of packing/transport or delivery?

As per Rule-44 the 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.

47. What are the satisfactory evidences to be provided to get approval for Shelf Life more than 5 years?

Satisfactory accelerated and real time data as per international norms on the products including field samples should be provided.

48. To import a medical device which does not have a predicate would the clinical trial be waived off in the event of CE marking?

No. The results of clinical investigation in India may not be required to be submitted where the investigational medical device is approved by the regulatory authorities of either the United Kingdom or the United States of America or Australia or Canada or Japan and the said device has been marketed for at least two years in that country and the Central Licensing Authority is satisfied with the data of safety, performance and pharmacovigilance of the device.

49. Will licenses currently valid but expiring immediately after 1st Jan 2018 be considered valid until 31st July 2018 or 30th June 2019 as per Rule 97 'Savings'?

As per Rule 97 (i) The license or registration certificate, issued under the provisions of the Act and the Drugs and Cosmetics Rules, 1945, prior to commencement of these rules, shall be deemed to be valid till its expiry or for a period of eighteen months from the date these rules are notified, whichever is later, under the corresponding provisions of these rules.

50. Will the license issued in 2017 having validity up to 2020 be valid till 2020 as per new Medical Device Rule 2017?

As per Rule 97 (i) The license or registration certificate, issued under the provisions of the Act and the Drugs and Cosmetics Rules, 1945, prior to commencement of these rules, shall be

deemed to be valid till its expiry or for a period of eighteen months from the date these rules are notified, whichever is later, under the corresponding provisions of these rules.

51. For licenses expiring in early 2018 does the firm need to submit renewal 9 months in advance or simply pay retention fee, on expiry, as specified in new rules?

As per Rule 34 (1) An authorized agent having license to manufacture for sale or distribution or wholesale license for sale or distribution under these rules, shall make an application for grant of import license for medical device to the Central Licensing Authority through an identified online portal of the Ministry of Health and Family Welfare in the Central Government in Form MD-14 for obtaining a license.

52. How would the import license (with different RC holders) transit into the new system?

As per Rule 34 sub-rule (1) Individual import licenses have to be applied with requisite fees and documents.

53. What would be the mechanism for adding the new products in the existing registration certificate which will be valid after 1st Jan 2018 till 2020?

As per Rule 34 sub-rule (1) An authorized agent having license to manufacture for sale or distribution or wholesale license for sale or distribution under these rules, shall make an application for grant of import license for medical device to the Central Licensing Authority through an identified online portal of the Ministry of Health and Family Welfare in the Central Government in Form MD-14 for obtaining a license.

54. Will there be any provision to grant extended validity to the existing licenses by paying the fee difference, few relevant undertakings and certificates instead of submitting the complete Device Master File (DMF) & Plant Master File (PMF)?

As per Rule 34 sub-rule (1) an authorized agent having license to manufacture for sale or distribution or wholesale license for sale or distribution under these rules, shall make an application for grant of import license for medical device to the Central Licensing Authority through an identified online portal of the Ministry of Health and Family Welfare in the Central Government in Form MD-14 for obtaining a license.

55. What fee would be applicable for the manufacturing site, if the importers wish to register devices belonging to multiple classes (A/B/C/D)?

As per the second schedule the Firm needs to submit the fee for different classes of the products. If the manufacturer is manufacturing all classes of the product then fees pertaining to higher class needs to be submitted.

56. For cases, where real-time data is not available at the time of submission of application, accelerated stability for how many weeks or months to be submitted to support the claimed shelf life initially? Can we submit three months accelerated stability data as compliant with

relevant ISO standards?

As per Fourth Schedule, part III, Appendix II (7.8); if available, real-time aging data shall be submitted to support the claimed shelf life. However, if real-time data is not available, accelerated stability data shall be submitted to support the claimed shelf life. Such a provisional claimed shelf life may be approved provided that the manufacturer immediately initiates real-time stability testing to validate the proposed shelf life. After completion of the real time stability analysis, real-time stability data shall be submitted in support of the claimed shelf life.

57. Does the requirement in the fourth schedule which specifies that the manufacturers have to submit an undertaking that they comply with the provisions of the fifth schedule applicable to application for license to manufacture?

Undertaking signed stating that the manufacturing site is in compliance with the provisions of the Fifth Schedule needs to be submitted in case of manufacture of Class B, C and D medical devices.

58. Is Fifth Schedule applicable for importers?

Fifth Schedule is applicable for manufacturers.

59. Whether any change in labeling which is not among the details mentioned under Chapter- Labeling of medical devices (Rule 44) need to be notified? For e.g., if the label is universal for India and Philippines and there is change of manufacturing of license no. In the Philippines label part as per their local regulations, need to be notified?

Label excluding change in font size, font type, color, label design is a major change as per Sixth Schedule and prior approval needs to be taken from Central Drugs Standard Control Organization.

60. Will change in authorized Agent require fresh License?

Change in Indian agent will require fresh License

61. Whether GMP compliance and GMP certification is applicable to medical devices and IVDs as per Medical Devices Rules, 2017 as it asks for compliance to Quality Management System (QMS) & there is no mention of need for compliance to GMP?

As per Medical Devices Rules, 2017, there is no mention of requirement for compliance to GMP, but there is need for compliance to QMS and other rules. Therefore, now, there is no requirement of GMP certificates for Medical Devices & IVDs.

62. Despite no mention in rule for domestic purposes, if requested by importing country, who will issue the WHO GMP certificate for medical devices and IVDs?

Licensing Authority who has issued the valid license to manufacture for sale will continue to issue WHO GMP certificate (Only on the request of importing country).

63. Who will issue the other certificates like Non-Conviction Certificate, Validity Certificate, Market Standing certificate etc. which are not mentioned in rules but are required on request of procurement / tendering agencies?

The Licensing Authority who has issued license shall issue such certificates.

64. Who shall issue Free Sale Certificate of notified regulated medical devices and IVDs?

As per Medical Devices Rules, 2017, Central Licensing Authority (CLA) shall issue Free Sale Certificate of notified regulated medical devices and IVDs.

65. What are the surgical dressings covered under regulations?

Surgical dressings including bandages which are intended to be used on wound or injured skin or tissues are covered under regulation.

66. In the light of New Medical Device Rules 2017, how absorbent cotton will be regulated? Whether as Drug or Medical device and in which class?

Absorbent cotton will be regulated as a part of surgical dressings as a Medical Device under Risk class A as per the provisions of Medical Device Rules, 2017.

67. Whether bandages which do not come in contact with wound or used for providing support/compression are regulated?

Bandages which do not come in contact with wound or injured skin or tissue or used for providing support/compression are not covered under the category of surgical dressings.

68. Whether casting tapes or splints are regulated?

Casting tape/Splints intended to be used for external immobilization of fractures/sprains as prescribed by doctor are regulated.

69. What is regulatory expectation to ensure quality of components (raw materials which are to be used for further manufacturing of finished medical devices including In vitro diagnostic medical devices under the valid license for manufacturing?

With respect to quality of components/raw materials to be used for further manufacturing of finished medical devices under the valid license for manufacturing, it is required that these components need to qualifying quality standards and Quality Management System (ISO 13485) and, if imported, need to have Free Sale Certificate of their finished product in the GHTF countries. The documentary evidence of the same shall be submitted to the licensing authority (who is issuing manufacturing license) at the time of grant of license & subsequently, as &

when required. Further, it shall also be available for audit/inspection, whenever required.

70. Is there any provision for issue of GLP certificate in MDR-2017 under Drugs & Cosmetics Act?

There is no provision in MDR-2017 under Drugs and Cosmetics Act for issue of GLP certificate.

71. Is there any provision for exemption of Annexure A of Fifth schedule in Medical Device Rules, 2017 in respect of environmental requirements for catheters/ Ablation Device/ IV Cannulae/ Scalp Vein Set/ Hypodermic Syringes/ Hypodermic Needles/ Perfusion sets, if the product is supplied non-sterile to be subjected to a cleaning process prior to sterilization or its use?

As per Fifth Schedule of MDR 2017, Clause 7.5.1.2 regarding control of production and service provision — Specific requirements and clause 7.5.1.2.1 regarding cleanliness of product and contamination control.

The manufacturer shall establish documented requirements for cleanliness of product if:-
(a) Product is cleaned by the manufacturer prior to sterilization or its use; or

(b) Product is supplied non-sterile to be subjected to a cleaning process prior to sterilization or its use.

Further, it is clarified that, if the product is cleaned in accordance with clause (a) or clause (b) above, the requirements content in clause (a) and (b) of sub-paragraph 6.4 do not apply prior to the cleaning process.

72. Whether separate GMP/QMS is issued by CLA/SLA for Medical Device & In vitro Diagnostic products for the purpose of tender/procurement

The Existence of manufacturing license under Medical Device Rules 2017 indicate conformance of fifth schedule (Quality Management System) of MDR-2017 & Separate GMP/QMS are not prescribed for issuance by CLA/SLA under Medical Device Rules-2017.

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Speaker Profiles

Dr V G Somani
Drugs Controller General of India,
Central Drugs Standard Control Organization

Dr V G Somani is appointed as Drugs Controller General of India through All India open selection held by UPSC on 10th July 2019. Earlier, he had already worked as Drugs Controller General (India) in 2011 on additional charge. Dr V G Somani was lastly working as Joint Drugs Controller (India) having 21 years of vast experience in Central Drugs Standard Control Organisation (CDSCO).

He is highly qualified and well experienced in the field of GMP, GCP, GRP, GDP, Dossier Review, GLP etc. and worked on all posts in the hierarchy of Central Drugs Control Department including as Drugs Controller General of India. He is a well-known speaker and trainer of various national and international/ WHO scientific bodies.

He has done his M. Pharm and full time PhD on UGC Fellowship in Pharmaceutical Sciences and has presented various papers in national and international conferences. Being meritorious student, he was awarded scholarship/fellowships since schooling days i.e fourth standard till completion of PhD in various forms.

He has been selected and now working as Chairman of WHO's Member State Mechanism (MSM) of 194 countries on substandard and falsified medical products at Geneva, Switzerland vide World Health Assembly (WHA) resolution 65.19 which is very prestigious post for India to safeguard India's interest for making affordable generic medicines acceptable in the world inspite of opposing lobby from the western world.

He was an expert for Bihar Public Service Commission for selection of Drugs Controller of Bihar. He had been panellist speaker on Rajya Sabha TV as Drugs Controller General of India, in programme 'Sarokar on fake medicines', which is available on YouTube. He is known for simplification of complex regulatory processes to ensure access to safe, efficacious and quality medicines including generic and innovative products.

Dr. Ravi Kant Sharma
Deputy Drugs Controller (India),
Ministry of Health and Family Welfare, Govt. of India

Dr. Ravi Kant Sharma, Ph.D is working as Deputy Drugs Controller (India) at CDSCO (HQ), FDA Bhawan New Delhi. At present he is dealing with the work related to the manufacturing, import and registration of Medical Devices and in-vitro diagnostic kits. He was actively involved in drafting the Medical Device Rules 2017 which is already implemented from 1st January 2018. He was also leading the International Cell established at CDSCO (HQ) and is involved in collaboration with the Regulators of other countries in the areas of training, sharing of best practices, and observer during audit, harmonization of standards and other information exchange.

He has more than 25 years of experience in CDSCO and has worked in different fields like approval of IND, New Drugs, Import and Registration of Pharmaceuticals, Blood Products and was also involved in Airport and zonal office activities. He actively participated in nationwide drug survey and quality risk based inspections carried out in India. He played vital role for implementation of SUGAM- portal for on-line submission of applications pertaining to import and registration of Medical Devices and in-vitro Diagnostics. Under his supervision Medical Device Division got ISO-9001 Certification.He participated in many National and International seminars/workshops in various areas of Drugs Regulations and has undergone training from USFDA, PMDA & WHO.

Mr. Amrit Garg
GS1 Representative

Mr. Amrit Garg has been engaged in driving adoption of global standards and best practices in India which facilitate universal identification, track & trace, recalls management and information exchange between trading partners across Industry sectors.

He has been associated with GS1 India for over 8 years now and is actively working with the Healthcare industry in India in driving the adoption of global standards. Closely working with the

Healthcare community including regulators to facilitate implementation of global healthcare supply chain standards in the areas of Track and trace and product recalls.

He has been instrumental in the implementation of DGFT requirements and DAVA portal reporting requirements. He has conducted several workshops for pharma companies, solution providers and participated in industry forums for domestic and export regulations awareness.

Prior to this he has over 7 years of experience with firms such as Bharti Airtel, Max New York, Apollo Munich across services sector in varied responsibilities.

Mr. Amrit Garg is an Computer graduate from Indraprastha University, Delhi and an Executive Masters in Business Administration (Dual-Operations & Marketing) from Institute of Management Technology, Ghaziabad.

Mr. Mrutunjay Jena, Director, NABCB

He is currently Director, National Accreditation Board for Certification Bodies (NABCB), a constituent Board of the Quality Council of India (QCI), which is India's national accreditation body and is part of an international system of equivalence of accreditations and certifications. NABCB accredits certification bodies for ISO 9001, ISO 14001, ISO 20000-1, ISO 22001, OHSAS 18001, ISO 45001, ISO 27001, ISO 13485, ISO 16363, ISO 39001, ISO 50001, Product certification, Personnel certification and Inspection bodies as per applicable international standards and has accredited more than 100 certification bodies in India.

He holds Master's degree in Business Administration from Guru Jambheshwar University of Science and Technology, Hisar and Post-Graduation Diploma in Industrial Safety after his Engineering degree in Electrical Engineering from IGIT- a government Engineering College, Talcher. Now he is pursuing research in Management.

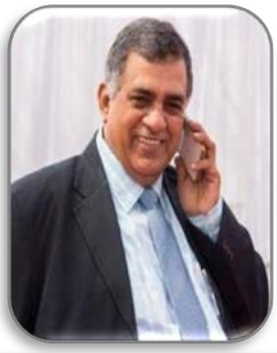
He has Overall 26 years of experience in the field of Quality, working in management systems product certification and inspection sector for 10 plus years in National Accreditation Body (NABCB). Developed third party evaluation mechanisms for regulators such as Petroleum and Natural Gas Regulatory Board, National Horticulture Board and Warehousing Development and Regulatory Authority. He is involved in various policy matter of NABCB accreditation including that of medical devices sector for Notified Bodies as per MD Rules - 2017.

Actively participated and contributed as a member of technical committee in development of QCI voluntary certification scheme "ICMED 9000" & "ICMED 13485" for medical device manufacturers - a unique and first such scheme in the world.

Actively involved in various ISO technical mirror committee for development of ISO standards of BIS like CHD 34, MED 39 etc in development and review of management/technical standards. Also involved in drafting of ISO 50003 standard on Energy Management Systems for auditor competency as an expert to ISO/TC 242.

Successfully developed and operated various management system accreditation schemes including OHSMS as per OHSAS 18001, MDQMS as per ISO 13485, ISMS as per ISO 27001, EnMS as per ISO 50001, ITSMS as per ISO 20000-1, RTSMS as per ISO 39001, TDRMS as per ISO 16363, BCMS as per ISO 22301.

He has been an empaneled assessor with United Nation Framework Convention on Climate Change (UNFCCC) for CDM assessments since, 2010.



Mr. Prakash Bachani
Scientist E & Head
Medical Equipment & Hospital Planning Department
Bureau of Indian Standards, the National Standards

Mr. Prakash Bachani, Scientist E & Head (Medical Equipment & Hospital Planning Department). He has 34years experience in Bureau of Indian Standards, the National Standards Body of India, having worked in Standard Formulation, Laboratory and Certification Activities. At the Technical level, he has overseen Product Certification, System Certification (QMS), Hallmarking of Gold and Silver, Standards Formulation (Electrotechnical and Medical Equipment & Hospital Planning), Laboratory Management. He has participated in various international seminars and meetings organized in the country in the field of electrotechnical as well as in Medical Equipment and Devices. He has also presented several papers on Standardization, Certification etc. in the field of Electrical Engg. and Medical Equipment at various National and International meetings / seminars. He is GOLD MEDALIST in MIE (Electrical Engg.), Institution of Engineers, India.

Dr. Purnima Sharma
Managing Director,
Biotech Consortium India Limited, New Delhi

Dr. Purnima Sharma is the Managing Director of Biotech Consortium India Limited (BCIL), New Delhi. BCIL is a public limited company promoted by the Department of Biotechnology, Ministry

of Science and Technology, Government of India and the all India financial institutions for facilitating biotechnology commercialization. The company has been in existence for more than two decades and has made a significant contribution to biotech sector by providing valuable services in areas such as technology evaluation and transfer, IP management, consultancy, biosafety, capacity building and manpower development to the Central and State Governments, academia, research institutions and industry.

Dr. Purnima Sharma is a doctorate in Experimental Medicine from Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh, the prestigious autonomous institution and deemed Medical University of national importance of the Ministry of Health, Government of India with Post Doctoral experience from IIT, Mumbai, and has to her credit many awards for excellence in academics.

She has more than 25 years of experience in the area of technology evaluation and transfer, management of IPR, project consultancy including DPRs for setting up Incubators and Science Parks, managing start-up ecosystem, public-private partnership funding schemes, entrepreneurship development etc. She has coordinated transfer of more than 50 technologies in various sectors of life sciences. She has also conducted a number of sectoral studies and market research studies on different biotech products.

She is a member of a number of national and state level committees responsible for biotech development and commercialization and also a member of The National Academy of Sciences, India (NASI), the first science academy of the country dedicated towards cultivation and promotion of science & technology in the country.

Dr. Suchita Markan
Assistant General Manager,
Biotech Consortium India Limited, New Delhi

Dr. Markan is working as Assistant General Manager in Biotech Consortium India Limited (BCIL). She has done PhD from Department of Experimental Medicine and Biotechnology, Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh and Executive General Management from IIM, Lucknow. She is leading management of techno-legal activities of School of International Biodesign for more than eleven years and Heading the Technology Transfer Activities at BCIL.

She has extensive experience and expertise in the Biomedical Device sector. She is a thought leader in the biomedical device innovation space assisting Government and policy makers to draft appropriate policies for boosting this sector. She has been leading the techno-legal and fellowship management of Department of Biotechnology, Government of India supported flagship program for boosting biomedical device innovation-Stanford India Biodesign programme, renamed as

School for International Biodesign for more than eleven years. She is providing strategic IP management, business plan development, licensing advisory and mentorship to more than 125 entrepreneurs and about 20 start-ups in the medtech domain. She has managed number of strategic collaborative programs aimed at fostering biomedical device innovation and entrepreneurship development with AIIMS, IIT Delhi, Stanford University, USA, QUT Australia, Tottori University, Japan, Hiroshima University-Japan, J&J-COSAT USA, Siemens etc.

She is member of number of national level committees for biotech development and commercialization and has numerous international publications to her credit.

Mr. Rajiv Chhibber
Vice President External Affairs,
Sahajanand Medical Technologies

Mr. Rajiv Chhibber is a Senior Corporate Affairs, Policy, Communications and Media Strategist with experience across Pharmaceuticals/Medical Devices Industry, Development Sector (Health, Environment, Climate Change, Energy and Sustainable Development) and Education Industry.

At SMT, Mr. Chhibber is responsible for driving strategic priorities and business vision with the Central and State governments, Regulatory agencies, Industry bodies, NGOs and Associations in addition to advising on policy matters, advocacy, managing complex reputational issues, Outreach and stakeholder engagement for the adoption of portfolio products while working closely with the senior management and global leadership.

Mr Chhibber hold a master's degree in Journalism and Mass Communication and a bachelor's degree in English Literature from Delhi University. He has a post-graduate diploma in Newspaper and Feature writing (Montgomery College, University of Maryland, USA) and pursued a Public Health Leadership in-professional course in NCDs from Emory University, Atlanta USA (2014-15) and a Communications Development Programme in Public Health Engagement by Wellcome Trust, UK at the London School of Hygiene and Topical Medicine (LSHTM), UK, (March 2016).

He was awarded an Honorary Doctorate from Aztec's University (UNESCO), Mexico in the year June 2019 the field of "Global Public Health Communication and Policy".He is a member of various government committees / sub-committees in areas of public health advocacy, nutrition, tobacco control, NCDs, and climate change in addition to being on various committees of CII, FICCI, USIBC and American Chambers of Commerce (AmCham).

He is a Member of Asia-Pacific Association of Communication Directors (APACD), Hong Kong, (2014-2020), the International Society for Disease Surveillance, CDC Atlanta, USA and the on the Advisory Board of the International Human Rights Council representing India. He is a Founding Member of Public Relations Society of India and the Founding Member of Climate Action

Network, South Asia (CANSA), a civil society led South Asia Chapter of a global platform that advocates on climate change, energy, power and related issues on sustainable development.

Mr. Rajiv Nath
Managing Director
Hindustan Syringes & Medical Devices Ltd.
& Forum Coordinator, AiMeD

Mr. Rajiv Nath is Managing Director of Hindustan Syringes & Medical Devices Ltd. which is having a turnover of over 600 Crores. He is President of All India Syringes & Needles Mfg. Association. (AISNMA). He is also the Founder and Forum Coordinator – Association of Indian Medical Device Industry (AiMeD) with over 350 Members nationwide whereby Medical Device Manufacturers of all types of technologies have been attracted nationwide on one Platform. He was born in 1962 and entered his family business i.e. Hindustan Syringes & Medical Devices Ltd. (HMD) soon after he finished his college in 1984.

Mr. Nath has started from the scratch i.e started his career on the shop floor of HMD to have first-hand technical experience of all the ground realities & learning basic production techniques of Medical Devices Industry. HMD has capacity of manufacturing over 6 Billion Disposables per annum. HMD's turnover has grown from a mere Rs. 2 crores to over Rs. 600 crores in the year 2017, an impressive growth rate of over 300 times in less than 35 years. Mr. Rajiv Nath has dared to challenge the rules of the market & wrote his own script with respect to syringe design, packaging and presentation. HMD created a niche for their disposable syringe "DISPOVAN" which is today the most popular brand in Syringe market in India with over 60% market share and thereby displaced renowned MNC's – an inspirational case study for other Indian Entrepreneurs. As Forum Coordinator of AiMeD,

Mr. Nath has taken many initiatives of establishing a collaborative framework with various Dept. of the Govt. and Media to bring to their attention issues troubling the industry and attract investments into India in his quest to make India as the Preferred Manufacturing Destination and the leading supplier of Medical Device worldwide. AiMeD is an Umbrella Association of Indian Manufacturers of Medical Devices covering all types of Medical Devices including consumables, disposables, equipment's instruments, Implants, electronics and diagnostics. With a Primary Membership of over 350 Manufacturers and additionally of over 200 Associate Members representing the interest of over 700 Manufacturers of Medical Devices to address the manufacturer's problems. (www.aimedindia.com).

Mr. Pardeep Kumar Sareen
CGM – Marketing
Hindustan Syringes & Medical Devices Ltd.
Technical Officer – AiMeD

Mr. Pardeep Kumar Sareen has broad knowledge in medical device manufacturing with a total experience of 41 years (5 years in pharma and rest in medical devices) including 36 years with HMD Group of Companies. He is the CGM – Marketing of Hindustan Syringes & Medical Devices Ltd. Also, he is the Technical Officer – Association of Indian Medical Device Industry (AIMED). He was born in 1954 and is a Science Graduate from Delhi University. A people's person with an affable personality,always comes up with fresh thoughts, unique insights and a bucket full of passion to the organization.

Ms. Malini Aisola
Health researcher,
co-convener of All India Drug Action Network (AIDAN)

Ms. Malini Aisola is a researcher and public health advocate working on policies impacting affordability and access to medicines and other health products. As a Co-Convenor of the All India Drug Action Network (AIDAN) she works on regulations that relate to pricing of drugs and devices, irrational use of drugs and intellectual property barriers to access. She is a vocal advocate for patient safety and needed regulatory reforms along with the patients of faulty J&J hip implants. She is also affiliated with the Campaign for Dignified and Affordable Healthcare, a forum of that advocates for regulation of the private healthcare sector and greater scrutiny of systemic unethical practices through reforms, for ethical and respectful treatment of patients. She is a member of Jan Swasthya Abhiyan (People's Health Movement in India) and Medico Friend Circle. Malini has previously worked with Knowledge Ecology International (Washington DC), the Public Health Foundation of India, Lawyers Collective and Oxfam India. She is an alumna of the University of Delhi, University of Illinois at Urbana-Champaign, University of Wisconsin-Madison, London School of Hygiene and Tropical Medicine and London School of Economics and Political Science, and is currently a student of law.

Mr. Rajeev Chhabra
Founder Orthocare
& Jt. Coordinator, (Orthopedic Vertical Group), AiMeD

Mr. Rajeev Chhabra, Founder of Ortho Care, took up the business in trading and manufacturing of Medical Equipment and Instruments in 1985. After the inception of Ortho Care, he was dedicated to Orthopaedic Implants and Instruments. Rajeev is the Founder member of AIMED and first president of Orthopaedic Implants Manufacturers' Association (OIMA) in India and also closely works with CDSCO, NPPA and the Ministry of Pharmaceuticals for the betterment of Orthopaedic Industry in India.

Mr. Gurmit Singh Chugh
Managing Director, Translumina Therapeutics and
Jt. Coordinator, Implants, AiMeD

Mr. Gurmit Singh Chugh, is the Managing Director of Translumina Therapeutics, A company that truly resonates the 'make in India" spirit. The company was recently in national Headlines for acquiring its parent company Translumina Germany for whom his company worked as a distributor 10 years back. His company has also created the longest safety and efficacy data of Drug Eluting Stents in the World which was a big surprise to the Med tech fraternity as they never expected a Indian company reaching such heights.

He is a Master in International trade from the prestigious IIFT, Delhi. He started his career as a Medical Representative in Schering Plough USA and left his last professional engagement as Marketing Head of Boston Scientific in 2004 after gaining rich experience in the field of High and Medical Devices

Translumina Therapeutics was started in 2011 with a facility in Dehradun with an objective to manufacture high End Medical Device for Cardiac Treatments with highest level of quality and clinical evaluation at an affordable price. To compete at global scale, he created close partnerships with various med tech companies and Large Hospitals around the world to get access to clinical and engineering support.

Mr. Gurmit, who represented his state in basketball, has a keen interest to mentor and lecture young Indian entrepreneurs in the Med Tech field by discussing his struggle while he trekked his tough journey with immense prejudice and discrimination of Indian made products in Indian and global markets.

Mr. Vivek Mangalwedhkar
Managing Director, S H Pitkar&
Jt. Coordinator (HWG – Regulations)

Mr. Vivek Graduate mechanical engineer-1984. Started working for Sales of Orthopaedic medical devices in 1987. Joined S H Pitkar Orthotools P Ltd as director in 1991. He has been responsible for overall growth of the company since then. Primarily responsible for Sales, Marketing, finance, HR, and regulatory. Working closely with various departments to regulate medical devices over 10 years.

Mr. Jatin Mahajan
Managing Director
J Mitra & Company

A global leader in diagnostic solutions, my mission is to preserve human lives through technological innovations in the healthcare and medical diagnostics space.
My vision is to reach out to the remotest of patients with our world-class diagnostic solutions. I believe that the relevance of state-of-the-art modern healthcare solutions lies in its ability to mitigate the distance gap between patient and solutions; make them cost-effective and potent. Driven by aggressive R&D, I aim to make significant breakthroughs in the biotechnology space

Mr. Tarun Arora
Founder and Managing Director
Infinity Mediquip India Pvt Ltd

Tarun Arora is the Founder and Managing Director of Infinity Mediquip India Pvt Ltd which is a Startup India Initiative ,recognized by DIPP. He is a Pharmacist and has 20 Years experience of

Medical Devices, He has Passed through a long journey of being a trader to an Importer and was then inspired by make in India program and choose to Transform his organization from an import based company in to a Manufacturing Company. He understands the grass root problem of smes and has pragmatic solutions for Importers and startups to pass through Transition phase of MDR to promote Manufacturing in India for Electronic Medical devices.

Mr. Anil Jauhri
Former Chief Executive Officer, NABCB

Mr. Anil Jauhri was the Chief Executive Officer of the National Accreditation Board for Certification Bodies (NABCB).

Mr. Jauhri began his career in 1980, when he joined the Bureau of Indian Standards (BIS) as an Assistant Director and gradually rose to the level of Scientist F. He was head of the division of Management Systems when he quit BIS. He is a trained Environment and Quality Management Systems auditor as per ISO 14000 and ISO 9000.

Mr. Jauhri also worked as an Adviser in the Export Inspection Council of India (EIC) in 2000 for 3 years on deputation from BIS. He joined the NABCB in January 2006, as Adviser and was appointed Director in 2010 and CEO in February 2013.

He manages the accreditation programs for Management Systems certification bodies for QMS, EMS, FSMS, OHSMS, ISMS, and Medical Devices QMS, Inspection bodies and product certification bodies.

Mr. Jauhri has been actively engaged in the National Quality Campaign, assigned to the Quality Council of India (QCI) in various sectors such as public services, food safety, GAP, etc. He has helped develop systems of conformity assessment to support regulations using accreditations for regulators, including the Food Safety and Standards Authority of India (FSSAI), in addition to support towards various government bodies in developing programmes for voluntary certification as well.

Mr. Jauhri is also an active Member of the CDM Accreditation Panel under UNFCCC, Bonn since July 2007.

Mr. Madan R Krishnan
Vice President & Managing Director
Indian Sub-Continent (South Asia) at Medtronic

International leader with emerging and developed market general management experience. Proven expertise in market entry, growth acceleration, M&A, corporate finance, SFE-marketing effectiveness, organizational transformation, channel strategy and talent development. Specialties: Medical Devices-Pharmaceuticals, Consumer Durables, FMCG, Chemicals & Plastics, Audit, Restructuring, SAP, Analytics.

Mr. Rajesh Maheshwari
CEO of National Accreditation Board for Certification Bodies (NABCB)

Rajesh Maheshwari, CEO of National Accreditation Board for Certification Bodies (NABCB), a constituent Board of Quality Council of India (QCI) w.e.f. 01 Aug 2019., and responsible for accreditation schemes for Certification, Inspection and Validation & Verification Bodies. Earlier to this was the Director of Project Planning & Implementation Division of QCI, and responsible for Conceptualization, Planning & Management of various projects being executed by QCI. Previously was responsible for managing Inspection Body Accreditation Program of NABCB as Joint Director. Working for QCI since Feb 2012.

Had earlier worked for National Accreditation Board for Testing & Calibration Laboratories (NABL), then under the Department of Science & Technology (DST) for more than a decade, managing the Testing and Medical Laboratory Accreditation Programs of NABL. Prior to this, had worked in Specialty Chemicals Manufacturing Industry for about a decade.

Holds Masters in Chemistry (with specialization in Organic Chemistry) and MBA.

Having almost 3 decades of experience in industrial manufacturing as well as in standards, technical regulations, accreditation & conformity assessment. Has multi-disciplinary experience in Quality Assurance & Management, Production & Process Control, Product Development, Project Management etc. Also has experience in International Evaluations & Mutual Recognition Arrangements, Technical Cooperation in Accreditation with international bodies like UNIDO, World Bank, PTB - Germany, ITC – Geneva etc.

Internationally, an APAC Evaluator for peer evaluation of Accreditation Bodies. Also, was WADA Assessor for assessment of Dope Testing Laboratories. Evaluated Accreditation Bodies in USA, Russia, Sri Lanka etc. Also, have done projects as an Expert on Accreditation with international organizations like IAEA, UNIDO etc.

Mr. Bodhisatya OM
Associate Vice President - Healthcare
Northgate Public Services

Bodhisatya Sarkar is leading the healthcare business in India for Northgate Public Services (NPS) as Associate Vice President. NPS is one of the leading software solution providers headquartered in the UK and have been providing healthcare solution for the NHS in the UK for the past two decades

Bodhisatya is a product management professional having worked managing software solutions for multiple industries like Public Safety, Healthcare, Hospitality and Semiconductors. He started his career in Germany as semiconductor chip designer. He has also worked as business strategy consulting manager for PwC in India and abroad.

He has done his MBA from Indian Institute of Management (IIM) Bangalore and Masters in science from Indian Institute of Technology (IIT) Bombay.

सत्यमेव जयते

औषध विभाग

Department of

Pharmaceuticals