Overview on Online System for Medical Devices

Medical Device Rules,2017

- Medical Device Rules, 2017 have been published vide GSR 78 (E), dated 31.01.2017.

- New rules already effective from 01.01.2018.

Flow Chart

Registration on Online System for Medical Devices Portal (Corporate/Company etc.)

Submission of application as per the required application forms for Manufacturing & Import license

Processing of applications depending on the type of application.

Issuance of Licenses/Permissions

Applicant Registration

Applicant Details

Applicant Type:* Choose Applicant Type
Multiple Roles can be selected

User-Name:* Enter Corporate Email Id

Password:* Enter Password
Only Best Passwords are accepted

Confirm Password:* Confirm Password
Only Best Passwords are accepted

Name:* Mr. | First Name | Middle Name | Last Name

Mobile Number:* +91 0

Gender:* Male Female

Nationality:* Indian

ID Proof Details:* (Single PDF < 10 MB) Select One | Choose File No file chosen | ID Proof No.

Undertaking:* (Single PDF < 10 MB) Choose File No file chosen
Download,Fill and Sign this Undertaking PDF Template and Upload the same here (Undertaking) - Available in Enterable PDF Format

Designation:* Name of Designation

Alternate Email ID: Alternate Email ID

Registering for Division:* Choose Division
Multiple Divisions can be selected

Cancel | Capture

Continue....

Registered Indian Address *(This address will be referred in all the forms submitted to CDSCO office)*

Organization Name:* Name of Organization

Organization Type:* Select

CIN (Corporate Identification Number): CIN No

Address Line * Address Line 1

Country* India

State* Select

District* Select

City/Taluka/Mandal/Tehsil* City/Taluka/Mandal/Tehsil

Pin Code* 0

Contact No.* (Please include STD Code - Phone Number)

+91 STD Code - Contact Number

Multiple Contact Numbers can be added with comma separation

Fax No.* (Please include STD Code - Fax Number)

+91 STD Code - Fax Number

Multiple Fax Numbers can be added with comma separation

Upload Your Corporate Address Proof Details (Certificate of Incorporation):* (Single PDF < 10 MB) Choose File No file chosen

Copy of Manufacturing License or Wholesale Licenses (In case, you are first time applicant & not holding any licenses,please upload the justification for the same) :* (Single PDF < 10 MB) Choose File No file chosen

☐ **Please tick (✔) this option if you want to receive SMS alerts.**

87454

☐ **I agree to the terms, conditions and privacy policy laid down by Central Drugs Standard Control Organisation, DGHS, Ministry of Health & Family Welfare for availing the online services provided under this portal. ***

Previous | Submit | Cancel | Capture

Regulatory Authorities

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

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

Forms and Fees

Input Forms	Output Forms	Fees (As per second schedule of MDR 2017)
Licence to Manufacture Class A or Class B		
MD-3 : Application for Grant of Licence to Manufacture for Sale and Distribution of Class A or Class B	**MD-5** : Licence to Manufacture for Sale or for Distribution of Class A or Class B Medical Device	Manufacturing Site: **INR.5000** & **INR.500** for each distinct Medical Device
Grant of Loan licence		
MD-4 : Application for Grant of Loan Licence to Manufacture for Sale or for Distribution of Class A or Class B	**MD-6** : Loan Licence to Manufacture for Sale or for Distribution of Class A or Class B	
Licence to Manufacture Class C or Class D		
MD-7 : Application for Grant of Licence to Manufacture for Sale or for Distribution of Class C or Class D	**MD-9** : Licence to Manufacture for Sale or for Distribution of Class C & D	Manufacturing Site: **INR 50000 & INR.1000** for each distinct Medical Device
Grant of Loan		
MD-8 : Application for Grant of Loan Licence to Manufacture for Sale or for Distribution of Class C or Class D	**MD-10** : Loan Licence to Manufacture for Sale or for Distribution of Class C or Class D	

Forms and Fees

Medical devices for clinical investigations, test, evaluation, examination, demonstration or training		
MD-12: Application for licence to manufacture medical device for purpose of clinical investigations, test, evaluation, examination, demonstration or training	**MD-13:** Licence to manufacture medical device for purpose of clinical investigations, test, evaluation, examination, demonstration or training	**INR 500** for each distinct Medical Device
Import Licences		
MD-14: Application for issue of import licence to import medical device.	**MD-15** : Licence to Import Medical Device	**Class A**: Manufacturing Site: USD 1000 and each distinct device USD 50 **Class B**: Manufacturing Site: USD 2000 and each distinct device USD 1000 **Class C& D**: Manufacturing Site: USD 3000 and each distinct device USD 1500
Import Licence for medical devices used for clinical investigations, test, evaluation etc.		
MD-16: Application for Licence to import medical devices for the purpose of clinical investigation, test, evaluation, examination, demonstration or training	**MD-17**: Licence to import medical devices for the purpose of clinical investigation, test, evaluation, examination, demonstration or training	**USD 100** for each medical device

Forms and Fees.....

Clinical Investigation of an investigational medical device		
MD-22: Application for Grant of permission to conduct Clinical Investigation of an investigational medical device	**MD-23:** Permission to conduct Clinical Investigation	INR 1,00,000
Permission to Conduct Clinical Performance Evaluation of new in vitro diagnostic medical device		
MD-24: Application for Grant of permission to conduct clinical performance evaluation of new in vitro diagnostic medical device	**MD-25:** Permission to conduct clinical performance evaluation of new in vitro diagnostic medical device	INR 25,000
Import device which do not have Predicate Medical Device		
MD-26: Application for Grant of permission to import/manufacture for sale or for distribution of medical device which does not have predicate medical device.	**MD-27**: Permission to import/manufacture for sale or for distribution of medical device which does not have predicate medical device.	INR 50,000
Permission to import or manufacture of new in vitro diagnostic medical device		
MD-28 : Application for Grant of permission to import or manufacture for Sale or for Distribution of new in vitro diagnostic medical device	**MD-29** : Permission to import or Manufacture new in vitro diagnostic medical device	INR 25,000

Checklist for Manufacturing License.

1. Covering letter
2. Constitution of the firm
3. The Establishment/Site ownership/Tenancy Agreement.
4. Copy of Duly notarized valid copies of Quality Certificate in respect manufacturing sites (s), if any
5. Copy of Certificate supporting quality managements system (ISO: 13485), if any
6. Plant Master file from the Manufacturer as specified in Appendix I of Forth Schedule of Medical Devices Rules.
7. Device Master File from the Manufacturer as specified in Appendix II (only for Medical Devices) of Fourth Schedule of Medical Device Rules.
8. Test Licences obtained for testing and generation of quality control data
9. Undertaking signed stating that the manufacturing site is in compliance with provision of fifth schedule.
10. Fee Challan
11. Legal Form

Checklist for Import License

1. Covering Letter
2. Power of Attorney (Original)
3. Self-attested copy of valid whole sale licence or manufacturing licence
4. Regulatory Certificate
5. Duly apostilled/notarized copy of Free Sale Certificate Marketing Authorization of the product from National Regulatory Authority of any of the following countries viz USA, EU, Canada, Japan, Australia.
6. copy of latest inspection or audit report carried out by Notified bodies or National Regulatory Authority or Competent Authority within last 3 years, if any.
7. Notarized copy of Duly notarized valid copies of Quality Certificate in respect of the legal and actual manufacturing site.
8. Notarized copy of Certificate supporting quality management system (ISO: 13485).

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11. Notarized Full quality Assurance Certificate/CE type examination Certificate/CE product quality assurance
12. Notarized CE design Certificate
13. Notarized Declaration of conformity
14. Plant Master file from the Manufacturer as specified in Appendix 1 of Forth Schedule of Medical Devices Rules
15. Device Master file from the Manufacturer as specified in Appendix II (only for medical Devices) of Forth Schedule of Medical Devices Rules.
16. Notarized copy of overseas manufacturing site or establishment or plant registration, by whatever name called, in the country of origin issued by the competent authority
17. Constitution details of domestic manufacturer or authorized agent require for Class B, C and D
18. Fee Challan
19. Legal Form

Mfg. License in Form MD-9

सत्यमेव जयते

FORM MD-9

[See sub-rule (1) rule 25]

Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

Licence Number: MFG/MD/2020/000003

1. M/s CENTENIAL SURGICAL SUTURE LTD., B-17, MIDC,MURBADThane, Thane, Maharashtra (India) - 421401 Telephone No.: 2224102876 FAX: 2224171261 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s CENTENIAL SURGICAL SUTURE LTD., B-17, MIDC, MURBAD,, Thane, Maharashtra (India) - 421401 Telephone No.: 02524-223200 FAX: 022-24161261
2. Details of medical device(s) [Annexed]
3. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s): As per records maintain by the manufacturer
4. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	Generic Name:ABSORBABLE HEMOSTAT OXIDISED REGENRATED CELLULOSE USP Model No.:NIL Intended Use:Absorbable Hemostat, Sterilised Oxidized Regenerated Cellulose (ORC) USP is used to stop capillary and venous bleeding. Adjunctively in surgical procedures to assist in the control of venous, capillary and small arterial hemorrhage when ligation or other conventional methods of control are ineffective or impractical. Absorbable Hemostat, Sterilised Oxidized Regenerated Cellulose (ORC) USP can be cut to size for use in endoscopic procedures and application in contaminated environment is not suitable. Class of medical device:Class D Material of construction:Oxidized Regenerated Cellulose Dimension(if any):2 INCHES X 3 INCHES, 4 INCHES X 8 INCHES,Etc Shelflife:2 YEARS Sterile or Non sterile:Sterilized Brand Name(if registered under the Trade Marks Act, 1999):CENTCEL

Place:

V G SOMANI

Import License in Form MD-15

FORM MD-15

[See sub-rule (1) of rule 36]

Licence to Import Medical Device

Licence No. IMP/MD/2018/000004

1. M/s M/s Boston Scientific India Pvt. Ltd., , C-41 Ground Floor, Okhla Industrial Area, Phase II, New Delhi , New Delhi, Delhi (India) - 110020 Telephone No.: 1244923300 FAX: 1244923333 E-Mail : is hereby licenced to import the medical device(s) manufactured by overseas manufacturer having manufacturing site as specified below.

2. Details of overseas manufacturer and manufacturing site under this licence

Sr. No	Name and Address of Manufacturer	Name and Address of Manufacturing Site
1	Legal Manufacturing Site : M/s Heraeus Medical Components, LLC, , 2605 Fernbrook Lane North, Suite J, Plymouth, MN 55447, USA , Country: United States Telephone No.: 1 763 559 4440 FAX: 1 763 559 7676 E-Mail : hmc-plymouth@Heraeus.com	Actual Manufacturing Site : M/s Heraeus Medical Components, LLC, , 2605 Fernbrook Lane North, Suite J, Plymouth, MN 55447, USA , Country: United States Telephone No.: 1 763 559 4440 FAX: 1 763 559 7676 E-Mail : hmc-plymouth@heraeus.com

3. Details of medical device(s):

S.NO	Medical Device Details
1	1. Generic Name :Guidewire 2. Brand Name(if registered under the Trade Marks Act, 1999) :NovaGold High Performance Guidewire 3. Notified Category :OthersEndoscopic Guidewire, single Use 4. Class of Medical Device :Class B 5. Shelflife :3 years 6. Sterilization:Sterilized 7. Contains Drugs:No 8. Medical Device Grouping Category : Single-MD 9. Grouping Description: Single MD 10. Intended Use :The NovaGold Guidewire is intended for use in selective cannulation of the biliary ducts including the common bile, pancreatic, cystic, right and left hepatic ducts, and to aid in the placement of diagnostic and therapeutic devices during endoscopic procedures.

Post Approval Changes

Major change

1. Material of construction;
2. Design which shall affect quality in respect of its specifications, indication for use; performance and stability of the
medical device
3. Intended use or indication for use
4. Method of sterilization
5. Approved Shelf life;
6. Name or address of:
(i) the domestic manufacturer or its manufacturing site;
(ii) overseas manufacturer or its manufacturing site (for import only);
(iii) authorised agent (for import only);
7. Label excluding change in font size, font type, color, label design;
8. Manufacturing process, equipment or testing which shall affect quality of the device;
9. Primary packaging material.

Minor Change

1. Design which shall not affect quality in respect of its specifications, indication for use, performance and stability of
the medical device;
2. Manufacturing process, equipment, or testing which shall not affect quality of the device;
3. Packaging specifications excluding primary packaging material.
4. Amendment/Corrections/others
5. Line Extension of Additional Model numbers or Model names

Thank you.