Guidance Document

(Medical Devices Division)

Title	:	Guidance document on application for grant of Licence in Form-28 for manufacture of Medical Devices in India under CLAA Scheme
Doc No	:	CDSCO/MD/GD/CLAA/01/00
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CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
DIRECTORATE GENERAL OF HEALTH SERVICES
MINISTRY OF HEALTH & FAMILY WELFARE
GOVT. OF INDIA

Table of Contents

A. Preface

In India import, manufacture, sale and distribution of Medical devices is regulated under Drugs and Cosmetics Act, 1940; and Rules, 1945. At present following notified Medical Devices are regulated under the said Act.

S. No.	Name of Device
1.	Disposable Hypodermic Syringes
2.	Disposable Hypodermic Needles
3.	Disposable Perfusion Sets
4	In Vitro Diagnostic Devices for HIV, HBsAg and HCV.
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.

Manufacture for sale of Disposable Hypodermic Syringes, Disposable Hypodermic Needles, Disposable Perfusion sets and In-vitro Diagnostic Devices are regulated by the concerned State Drug Licensing Authority only.

However this document is applicable for following Devices only

S. No.	Name of Device
1.	Cardiac Stents.
2.	Drug Eluting Stents.
3.	Catheters.
4.	Intra Ocular Lenses.
5.	I.V. Cannulae.
6.	Bone Cements.
7.	Heart Valves.
8.	Scalp Vein Set.
9.	Orthopedic Implants.
10.	Internal Prosthetic Replacements.

The proposed requirements for the regulatory control over notified medical devices (Under CLAA Scheme) are being uploaded for the information of all stakeholders.

The document is intended to provide guidance for use in the manufacture of notified medical devices for sale in India.

This guidance document will be effective from **1st January 2013.** The common submission format may be used even before effective date (1st January 2013) for grant of manufacturing license.

SCOPE:

Manufacture of notified medical devices (Under CLAA Scheme) for sale in India, License in Form-28 is required under Drugs and Cosmetics Rules. The Rule 76 of Drugs and Cosmetics Rules describe the information/data required for grant of manufacturing license. This guidance documents has been prepared to specify the general requirements for grant of manufacturing license for sale in Form-28. This guidance will help the industry to submit the required documents in a more realistic manner, which in turn will also help reviewer of CDSCO and State Drugs Control officials to review such application in systematic manner. It is apparent that this structured application with comprehensive and rational contents will help the CDSCO and State Drugs Control Officials to review and take necessary actions in a better way and would also ease the preparation of electronic submissions, which may happen in the near future.

B. Requirements for Grant of Licence in Form-28 for Manufacture of Medical Devices in India

Application for the grant of licence for manufacture of Medical Devices in India shall be made in Form 27 to:-

i. The concerned State Drugs Licensing Authority, Address of all SLA are placed at **Annexure-I**.

ii. The concerned CDSCO Zonal/Sub-Zonal Office. Address of CDSCO offices are placed at **Annexure-II** and

iii. The Drugs Controller General of India CDSCO (HQ), FDA Bhawan, Near Bal Bhawan, ITO, Kotla Road, New Delhi-110002.

accompanied by the requisite fee in the form and manner as prescribed in the Drugs & Cosmetics Rules.

The following documents are required to be submitted in the following manner and order for grant of licence in form-28 for Manufacture of Medical Devices in India: -

1. **Covering Letter** – The covering letter is an important part of the application and should clearly specify the intent of the application. The list of documents that are being submitted (Index with page number) as well as any other important and relevant information may be provided in the covering letter. The covering letter should be duly signed and stamped by the authorized signatory, indicating the name & designation of the authorized signatory.

2. **An Authorization letter** in original issued by the Director/Company Secretary/Partner of the Indian Agent firm revealing the name & designation of the person authorized to sign legal documents such as Form-27 on behalf of the firm should be submitted at the time of submission of the application for grant/Renewal of licence. It should have validity period as per company's policies. Duly attested photocopies of the Authorization letter may be submitted at the time of submission of subsequent applications.

3. **A duly filled Form 27** as per the Performa prescribed in the Drugs & Cosmetics Rules, signed & stamped by the Indian Agent along with name & designation. Form 27 Performa is enclosed at **Annexure - III**.

4. **The requisite fee** as prescribed in the Drugs & Cosmetics Act & Rules viz. Licence fees of Rs.6000/- and an Inspection fees of Rs. 1500/- (Total Rs. 7500/- for 10 items for each category of Device) and additional fees at the rate of Rs.300/- for a each additional item of Device.

5. **Constitution Details** Documents relating to constitution of firm viz. partnership-deed, memorandum and article of association etc.

6. **Approved Manufacturing Premises Plan/Layout**. A copy of Plan/layout approved by the Drugs Licensing Authority should be submitted as stated in Site Master File at C-I

7. **Full particulars of competent and regular technical staff for manufacturing and testing of Medical Devices along with the copies of Educational Qualification, Experience Certificate, Appointment Letter, Acceptance Letter, Joining letter etc.**

8. **Site Master File** as per **Annexure-IV**

9. **Specific Environmental Requirements** as per **Annexure-V**

10. **Device Master File** as per **Annexure-VI for each category of device.**

11. **List of Medical Devices along with undertaking in prescribed pro-forma** as per **Annexure VII.**

12. **Details of Standards followed by the company for product evaluation**

13. **Promotional literature, package insert, device labels etc**

14. **ISO 13485:2003 Certificate (if any)**

15. **Full Quality Assurance Certificate (if any)**

16. **CE Design Certificate (if any)**

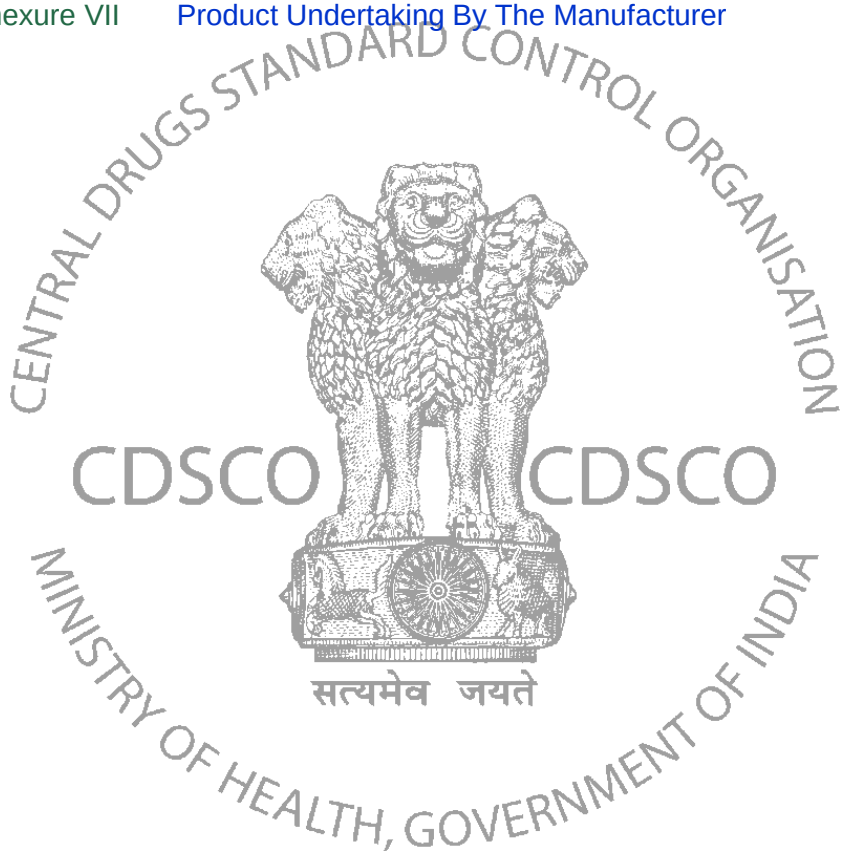
17. **Declaration of Conformity (if any)**

18. **Any other approvals (e.g. US FDA)**

Note:

- **All certificates submitted should be within the validity period.**
- **In case of New Devices/not yet approved in India, the applicant has to submit a copy of necessary permission/NOC from the Drugs Controller General (I) along with the application.**
- **In case the applicant intend to manufacture both SLA(Syringes, needles and perfusion sets) and CLAA (remaining devices) devices, separate applications should be made and separate licenses should be obtained from the concerned licensing authorities.**

C. Annexures



ANNEXURE-I

List of State Licensing Authorities

S.No.	State	Address	Tel. Office.	Fax
1	**Andhra Pradesh**	Drugs Control Admn. Drugs Control Bhawan Vengalrao Nagar Hyderabad-500036. A.P.	23814119, 0944062731, 040-23713563 23814360. 23415006	040-23814360
2	**Arunachal Pradesh**	Drugs Controller, Dte. Of Health Services Neharlagun-791119 , Arunachal Pradesh	(0360)2244248	2244105
3	**Assam**	Drugs Controller, Dte. Of Health Services Hengrabari Guwahati (Assam)-38	0361-2265276	2261630
4	**Bihar**	Drugs Controller Bihar,Dte. of Health Services, 4th Floor, Vikas Bhavan, New Secretariat, PATNA-800001	0612-221110 , 09430218184	2224608
5	**Chhattisgarh**	Drugs Controller, Food and Drugs Admn.Chattisgarh, Old Nursing Hostel Campus,Near Mantralaya,Raipur-492001	(0771) 2235226 2221025	2235226
6	**Delhi**	Drug Control Administration, F17 Kakardooma Shahadra, Delhi-140 032 , Mr. P.P. Sharma	23967511 , 22393707 22393701 22393706	23392018, 22393704
7	**Goa**	Director,Directorate of Food and Drugs Administrator.,Old IPHB Bldg. Altinho, PANAJI-GOA-403001	(0832)2224639(Direct) 2220245/2430948	(0832)2224639

8	**Gujarat**	Commissioner, Food and Drug Control Admn., Gujarat,Block-8, Dr. Jivraj Mehta Bhavan,1st Floor, Gandhi Nagar-382010	(079)23253400 23253399, 09978405054	23253400 23252417
9	**Haryana**	Drugs Controller of Haryana, Food and Drugs Administration, Haryana SCO-94, Sector-5, Panchkula, Haryana	(0172)2551081 2551692	
10	**Himachal Pradesh**	DRUGS CONTROLL ADMINISTRATION, NEAR BUS STAND, SAI ROAD, BADDI, DISTT. SOLAN (H.P.)-173205	0177-2621842	221107
11	**Jharkhand**	Drugs Controller and Licensing Authority, Jharkhand, Dte. of Health Services, Jagannathpur High School Building, Sector 3, Dhurwan, RANCHI-834004		0651-2260361
12	**Jammu & Kashmir**	Drugs Controller, J&K,Drug and Food Control Admn.Patoli Magotrian, JAMMU TAWI-180001	(0191)2538527, 2597445,	
13	**Karnataka**	Drugs Controller, Drug Control Department, PB No.5377,Palace Road,BANGALORE-560001	(080)22262846, 22282789, 22256386, 9449818892	22286492
14	**Kerala**	Drugs Controller and Licensing Authority, Kerala, Public Health Laboratory Campur, Red Cross Road,Thiruvananthapuram-695035	(0471)2473256, 09447010210,09446048210	2473256
15	**Madhya Pradesh**	Drugs Controller, Food & Drugs Administration,Madhya Pradesh,Idgah Hill, BHOPAL –462001	(0755)2665385 2666058	2665385

16	**Maharashtra**	Jt Commissioner,Food and Drugs Admn.,Maharashtra,341 , Bandra Kulra Complex,Opp. RBI Building, Bandra (East) Mumbai-400 051	(022)26590548, 26591463	26591959
		Office of the Joint Commissioner (Kokan Division.) Food and Drug Administration, M.S., E.S.I.S. Hospital Bldg., 4th floor, Road No.33, Wagale Estate, THANE-400604.	+ 91 –022 - 25811988/25821245	+ 91 –022 - 25823189
		Office of the Joint Commissioner (Pune Division.) Food and Drug Administration, M.S., Lucky Bldg., 791/92, New Guruwar Peth, PUNE-411028	+ 91 –020 - 24470276	+ 91 –020 - 24477555
		Office of the Joint Commissioner (Nashik Division.) Food and Drug Administration M.S. Hall No 21 and 23, Udhyog Bhavan, Tryambakeshwar Road, NASHIK-422003.	+ 91- 0253 - 2351200 (D) & fax + 91- 0253 - 2351201/2	+ 91 – 0253 - 2351204
		Office of the Joint Commissioner (Nagpur Division.) Food and Drug Administration, M.S., Limbana Compound, 20 Mount Rd., Sadar, NAGPUR-440 001	+ 91 - 0712 - 2564347/2562204	+ 91 – 0712 - 2555120

		Office of the Joint Commissioner (Amravati Division.) Food and Drug Administration, M.S., Amaravati Javade Awar, Mal Tekadi Road, Near S.T. Stand, AMARAVATI-444602.	+ 91 –0721 - 2663273/2665892/ 2665891	+ 91 – 0721- 2663273
		Joint Commissioner (Aurangabad Division) Food and Drug Administration, M.S., Aurangabad, Nath Market, 2nd floor, Aurangapura, AURANGABAD-431001.	+ 91 –0240 - 2331268/2346810	+ 91 – 0240 - 2331268
17	**Manipur**	Addl. Director, Health Services, Manipur,Lamphlept IMPHAL-795004	0385-2414964	0385-2414964
18	**Meghalaya**	Asst. Drugs Controller,O/O Dy.Director of Health Services, Meghalaya,Nokrek Building,SHILLONG-793001	(0364)2225709	2228493
19	**Mizoram**	Drug Controller andDirector of Health Services,Mizoram, Dinthar, AIZWAL – 796001	0389-2323452	2320169
20	**Nagaland**	Joint Drugs Controller,Nagaland, Dte. of Health Services,KOHIMA-797001	(0370)2222626	2243887
21	**Orissa**	Drugs Controller, Orissa,New Nandan Kanan Road,Bhubaneshwar-751017 Nandan Kanan Road,Bhubaneshwar-751017	(0674) 2300494	2300494

22	**Punjab**	Drugs Controller, Punjab,Sector 34 A, CHANDIGARH-160016.	(0172)2603803	2609142
23	**Rajasthan**	Drugs Controller Shri D.K. Shringi,Drugs Controller Dte. of Medical Health Services, Swasthya Bhavan, Tilak Marg, JAIPUR-302005	0141-2221670	2337284
24	**Sikkim**	Dy.Drugs Controller,Dpt. Of Health & F.W.,Sikkim, Gangtok-737101	(03592)226238 Ext. 425	204481
25	**Tamilnadu**	Drugs Controller Tamilnadu, 259/261, Anna Salai, Chennai – 600006	(044) 24321830 ,9710142019, 044-24311830	044-24321830
26	**Tripura**	Dy.Drugs Controller and Licensing Authority, Tripura, Aushadh Niyantran Bhawan, Pt.Nehru Office Complex,PO - Kunjaben,AGARTALA – 799006	(0381) 2325868	2325868
27	**Uttar Pradesh**	Drugs Controller of UP,Swasthya Sewa Mahanideshalaya, Swasthya Bhawan, Aushadhi Kaksha,LUCKNOW-226006.	0522-2221115	0522-2621115
28	**Uttrakhand**	Drugs Controller , Directorate of Medical Health, Dada Lokhond , SahashtraDhara Road, Dehradun	09411014217	
29	**West Bangal**	Director, Drugs Control West Bengal, P-16, India Exchange Place Extn. Cit Building , KOLKATA -700073	(033) 22252215, 24778710, 9831261582, 09433038710	
30	**Andaman & Nicobar**	Dte. of Health Services, A&N Island, PORT BLAIR – 744104	(03192)233331 232910	232910

31	**Chandigarh admn.**	Drugs Controller and Licensing Authority, Chandigarh Administration, Sector 16, CHANDIGARH-160016	(0172) 780781	27500255
32	**Dadar & Nagar Haveli**	Asstt. Drugs Controller Civil Hospital, Dadra & Nagar Haveli SILVASSA-396230	(0260)2642940 2642120	26429061
33	**Pondicherry**	Asst. Commissioner, Food and Drugs Admn., Govt Hospital Building. Murunga pakkam, PONDICHERRY-605004	(0413) 2353647	
34	**Lakshadweep**	Director, Medical and Health Services, Lakshdweep, PO-Kavarati VIA KOCHI-682555	(04896)62316	62817
35	**Daman & Diu**	Drugs Licensing Authority, Dte. of Medical Health Services, Daman-396220	(0260) 2230470 2230847	2230570

ANNEXURE-II

LIST OF ZONAL AND SUB-ZONAL OFFICES OF CENTRAL DRUGS STANDARD CONTROL ORGANISATION (CDSCO)

Sr. No	Zone	Address	Phone No./ Fax No	Name of States
1	East Zone	Dy. Drugs Controller (I) Central Drugs Standard Control Organization, (East Zone) C.G.O. Building, Nizam Place, 2nd Floor, 234/4 A.J.C. Bose Road, **Kolkata**-700020	Phone No.- 033 – 22870513 Fax : 033 - 22813806	Andaman and Nicobar Island, Arunachal Pradesh, Assam, Bihar, Jharkhand, Manipur, Meghalaya, Mizoram, Nagaland, Orissa, Sikkim, Tripura & West Bengal
2	West Zone	Dy. Drugs Controller, (I) Central Drugs Standard Control Organization, (West Zone) 4th Floor, Central FDA Bhawan, GMSD Compound, Bellasis Road, Mumbai Central **Mumbai**-400008	Phone No.- 91-22-23002279, 23002215, 23092971. Fax: 91 (22) 23002271	Chhattisgarh, Goa, Daman & Diu, Madhya Pradesh and Maharashtra
3	Ahmedabad Zonal	Dy. Drugs Controller, CDSCO Sub Zonal Ahmedabad, Air cargo Complex, Old Terminal Building, Airport **Ahmedabad**-380016	Tele Fax No. 079-22865244	Gujarat
4	North Zone	Dy. Drugs Controller (I), CDSCO (North Zone) 1st Floor, Central Govt. Office Building-I Kamla Nehru (Central Govt. Enclave), Hapur Road, **Ghaziabad**-201002.	Phone No.- 91 -120-2719483 Fax: 91 -120-27101927	Haryana, Himachal Pradesh, Jammu & Kashmir, Punjab, Rajasthan, Uttaranchal, Uttar Pradesh, N.C.T. of Delhi & Union Territory of Chandigarh
5	Sub-Zonal Chandigarh	Asstt. Drugs Controller (I), CDSCO Sub-Zonal Office, DGHS, Sector 39C, Chandigarh-36		

6	Sub-Zonal Jammu	Asstt. Drugs Controller (I), CDSCO Sub Zonal Office C/o DY. Drugs Controller Office, Muthi, Jammu Pin-181205	0191-2593338	Jammu & Kashmir
7	South Zone	Dy. Drugs Controller (I), CDSCO (South Zone), 2nd Floor, Shastri Bhawan Annexe, 26, Haddows Road, 1.0 **Chennai-**6	Phone No. - 044 - 28278186. Tele Fax : 044-28213079	Kerala, Pondicherry, Lakshadweep, Dadar & Nagar Haveli and Tamil Nadu
8	Hyderabad Zonal Office	Dy. Drug Controller (India), CDSCO, Zonal office, CDTL Building, Chest Hospital, S.R. Nagar, Hyderabad – 500 038.	Phone No. - 040 – 24008236. Fax : 040 – 24008270	Andhra Pradesh
9	Sub Zonal, Bangalore	**Subzonal Office-** Asstt. Drugs Controller (I) CDSCO, Sub Zonal Office, 2nd Floor Office for the State Drugs Controller of Karnataka Palace Road, **Bangalore**-560001	PhoneNo.- 080-23286492 Fax : 080-22341080	Karnataka

ANNEXURE-III

FORM 27

Application for grant or renewal of a [licence to manufacture for sale or for distribution] of drugs specified in Schedules C and C (1) [excluding those specified in Schedule XB and Schedule X]

1.1/ We .....hereby apply for the grant / renewal of a licence to manufacture on the premises situated at the undermentioned drugs, being drugs specified in Schedules C and C (1) 2[excluding those specified in Schedule XB and Schedule X] to the Drugs and Cosmetics Rules, 1945.

Names of drugs……..…….
(each item to be separately specified).

2. The names, qualifications and experience of the expert staff responsible for the manufacture and testing of the above mentioned drugs.

(a) Name (s) of staff responsible for test.....

(b) Name (s) of staff responsible for manufacture.....

3. The premises and plan are ready for inspection
will be ready for inspection on

4. A fee of rupees.....and an inspection fee of rupees ……has been credited to Government under the head of account……..

Date.....

Signature……

Designation…..

Note-The application shall be accompanied by a plan of premises.

ANNEXURE – IV

Site Master File

NOTE: The manufacturer shall submit the duly signed information pertaining to Manufacturing premises in the following format. It is expected that the information submitted in the form of hard copy shall also be submitted in the form of soft copy. The applicant shall submit a succinct document in the Form of "Site Master File" containing specific and factual information about the production and/or control of manufacturing process carried out at manufacturing premises. It shall contain the following information but not limited to:

Sr. No	Requirements	Information
A	GENERAL INFORMATION	
I	**Brief information on the site (including name and address), relation to other sites**	In not more than 250 words, outline the company's activities, other sites (if any)
II	**Manufacturing activities**	1. Indicate whether the site has been approved by national authority, or any foreign Competent Authority 2. Quote the relevant document (licence) as issued by the Competent Authority. State the period of validity of licence/certificate document (if the validity of the document is given in the country concerned). Any conditions and/or restrictions should be stated.
III	**Any other operations carried out on the site**	This covers both medical device related and non-medical device (including medicinal products) related activities.
IV	**Name and exact address of the site, including telephone, fax numbers, web site URL and e-mail address**	1. Name of company, site address and mailing address (if different from site address) 2. Telephone, fax nos. and email address of contact person
V	**Type of medical devices handled on the site and information about specifically toxic or hazardous substances handled, mentioning the way they are handled and precautions taken**	1. Quote the type of medical devices handled, specifying if the medical device is handled under a contractual agreement with a contract giver. 2. Note any toxic, hazardous, highly sensitising substances handled e.g. antibiotics, hormones, cytostatics. Note whether special precautions were taken for such medical devices. (List the appropriate licence numbers where applicable)

<table>
<tr><td>VI</td><td>Short description of the site (size, location and immediate environment and other activities on the site)</td><td colspan="3">1. Provide a map indicating the location of the site(s) and the surrounding area. Mark the site(s).

2. Other activities on the site.</td></tr>
<tr><td rowspan="2">VII</td><td rowspan="2">Number of employees engaged in Production, Quality Control, warehousing, and distribution</td><td>Area of Operation</td><td>No of Permanent/regular employees</td><td>No of Contractual employees</td></tr>
<tr><td>1. Production
2. Quality Control
3. Warehousing
4. Storage
5. Distribution
6. Technical & Engineering Support Services
Total of the above</td><td></td><td></td></tr>
<tr><td>VIII</td><td>Use of outside scientific, analytical or other technical assistance in relation to the design, manufacture and testing</td><td colspan="3">For each work process outsourced or sub-contracted (including contract delivery companies), give:-

1. Name, address, telephone no. and fax, no. of contractor

2. Brief outline of the activity being undertaken in not more than 250 words.</td></tr>
<tr><td>IX</td><td>Short description of the quality management system of the company</td><td colspan="3">(Not more than 750 words).
1. State the company's Quality Policy
2. Define the responsibility of the Quality Assurance function
3. Describe the elements of the QA system e.g. organisational structure, responsibilities, procedures, processes
4. Describe the audit programmes (self-inspection or audits by external organisations undertaken).
5. Describe how results are reviewed to demonstrate the adequacy of the quality system in relation to the objective i.e. quality, efficacy and safety of the product.
6. Describe vendors qualification/validation policy. When suppliers of critical starting materials and packaging materials - actives, excipients, containers, closures and printed packaging materials are assessed, give details of how this is done
7. Record if the company has been certified to industry standards (e.g. ISO9000, ISO 13485:2003)
8. Describe the release for sale procedure for finished products</td></tr>
</table>

X	**Devices details registered with foreign countries**	State name of the devices along with the name of the countries where the device is approved/registered.
B	**PERSONNEL**	
I	**Organisation chart showing the arrangements for key personnel**	Organogram listing key personnel (Quality Assurance, Production, and Quality Control) has to be constructed. Record senior managers and supervisors only.
II	**Qualifications, experience and responsibilities of key personnel**	1. Brief details of qualifications and years of relevant experience since qualifying. 2. Job descriptions for the key personnel
III	**Outline of arrangements for basic and in-service training and how records are maintained**	Give brief details of the training programme and include induction and continuous training, as follows:- 1. Describe how training needs are identified and by whom. 2. Give details of training relative to GDP (Good Documentation Practices) requirements. 3. State the form of training e.g. in-house, external, and how practical experience is gained and which staff are involved. 4. Explain training evaluation procedures. 5. Explain how retraining needs are identified. 6. Give brief details of training records kept.
IV	**Health requirements for personnel engaged in production**	Give brief details of the following: 1. Who is responsible for checking health of employees? 2. Is there a pre-employment medical examination? 3. Are employees routinely checked from time to time depending on the nature of their work? 4. Is there a system for reporting sickness or contact with sick people before working in a critical area? 5. Is there a system of reporting back after illness? 6. Are those who work in clean areas (Grade A-D) subject to additional monitoring?
V	**Personnel hygiene requirements, including clothing**	Give brief details of the following: 1. Are there suitable washing, changing and rest areas? 2. Is the clothing suitable for the activity undertaken? Briefly describe the clothing 3. Are there clear instructions on how protective clothing should be used and when it should be changed? Is in-house or external laundry used?

C	**PREMISES AND FACILITIES**	
I	**Layout of premises with indication of scale**	Layout of premises 1. Manufacturing Plant Layout with men and material flow, Clean room classification (e.g.as per ISO 14644-1). 2. Describe the controls available to prevent unauthorized access. 3. Provide a simple plan of each area with indication of scale. Label areas and annotate plan with names. 4. Plans should be legible
II	**Nature of construction, finishes/fixtures and fittings**	Nature of construction should include type of flooring, walls, roof, doors, windows etc. Details should be provided for all processing areas, packaging areas and critical storage areas.
III	**Brief description of ventilation systems. More details should be given for critical areas with potential risks of airborne contamination (including schematic drawings of the systems). Classification of the rooms used for the manufacture of sterile products should be mentioned**	Brief description of ventilation systems etc. Note 1: More details should be given for critical areas with potential risks of airborne contamination. Note 2: To reduce the narrative, schematic drawings should be used. The following data should be given:- 1. Design criteria e.g. • Specification of the air supply • Temperature • Humidity • Pressure differentials and air change rate • Single pass or recirculation (%) 2. Filter design and efficiency e.g. • Bag 99% efficiency • HEPA 99.997% efficiency • Details of any alarms on the ventilation system should be given. 3. The limits for changing the filters should be given. 4. Give the frequency of revalidation of the system
IV	**Special areas for the handling of highly toxic, hazardous and sensitizing materials**	Follow the same layout as above for description of areas specially designated for the handling of highly toxic, hazardous and sensitising materials.
V	**Brief description of water systems (schematic drawings of the systems are**	Brief description of water system, including sanitation should include following: 1. The schematic drawing must go back to the city supply system

	desirable) including sanitation	2. The capacity of the system (maximum quantity produced per hour). 3. Construction materials of the vessels and pipework 4. Specification of any filters in the system must be given 5. If water is stored and circulated, the temperature at the point of return 6. The specification of the water produced (Chemical, Conductivity and microbiological) 7. The sampling points and frequency of testing 8. The procedure and frequency of sanitation
VI	**Maintenance (description of planned preventive maintenance programmes for premises and recording system)**	Maintenance Note: For the purpose of this guide, "maintenance" is carried out by the company and "servicing" is by an outside contractor. 1. Describe the planned preventive maintenance programme. 2. Are there written procedures and contractual details for outside work? 4. Are there written procedures and suitable reporting forms for maintenance and servicing? Do the documents record type/frequency of service/checks, details of service, repairs and modifications? 5. Have the maintenance routines that could affect medical device quality been clearly identified? 6. Are the reports made known to the users?
D	**EQUIPMENT**	
I	**Brief description of major production and quality control laboratories equipment (a list of the equipment is required)**	*Makes and model numbers of the equipment are not required*. However the following points should be addressed: 1. The parts of production equipment that come into contact with the product shall not be reactive, additive or adsorptive to an extent that would affect the quality of the product. 2. Is the equipment designed with ease of cleaning in mind? 3. A brief general description is required. If the equipment has additional devices, these should be recorded 4. In particular give brief information on the use of computers, microprocessors etc. in the premises.
II	**Maintenance (description of planned preventive maintenance programmes and recording system).**	Following points should be addressed: 1. Who is responsible for maintenance and servicing? 2. Are there written procedures and contractual details for outside work? 3. Are maintenance routines which could affect product quality clearly identified? 4. Are records kept of: • type and frequency of service/check • details of service repairs and modifications 5. Are reports made known to the users?

III	**Qualification and calibration, including the recording system. Arrangements for computerized systems validation.**	Following points should be addressed: 1. Briefly describe the company's general policy and protocols for qualification and validation (prospective and retrospective). 2. Is there regular revalidation of critical equipment? 3. An outline of process validation may be given here or cross-referenced to Production 4. Describe the system for the release for sale or supply of development and validation batches. 5. What are the arrangements for computer validation, including software validation? 6. Describe equipment calibration policy and records kept
E	**SANITATION**	
I	**Availability of written specifications and procedures for cleaning the manufacturing areas and equipments**	Cleaning procedures for the manufacturing areas and equipments should include: 1. Are there written procedures for cleaning and specifications for cleaning agents and their concentration for the method of cleaning and the frequency? 2. Are cleaning agents changed from time to time? 3. Have the cleaning procedures been validated and what was the method of evaluating the effectiveness of cleaning? 4. Are cleaning methods monitored routinely by chemical and/or microbiological methods? 5. What are the cleaning methods (and their frequency) for the water system, air handling system and dust extraction system?
F	**PRODUCTION**	
I	**Brief description of production operations using, wherever possible, flow sheets and charts specifying important parameters**	Describe the production operations using flow charts. The following points should be addressed: 1. Describe the operations capable of being carried out at the site with the existing facilities and specify the types of medical devices 2. When only packaging is undertaken, give a brief description only, e.g. labelling, filling etc. and the nature of containers used 3. When only packaging is undertaken, give a brief description only, e.g. labelling, details of packaging materials used etc.
II	**Arrangements for the handling of starting materials, packaging materials, bulk and finished products,**	The following points should be addressed: 1. Control of manufacturing • Checks on key parameters during manufacture • Records of key parameters • In-process checks

	including sampling, quarantine, release and storage.	• Records of in-process checks • Compliance with the Marketing Authorization 2. Packing • Release of bulk, semi-finished products, packing materials • Confirmation of identity and line clearance checks 3. Quarantine and release of finished products; compliance with Marketing Authorization. 4. Explain the role of the Authorized Person(s).
III	**Arrangements for reprocessing or rework**	What arrangements are in place for reprocessing or reworking batches of products?
IV	**Arrangements for the handling of rejected materials and products**	The following points should be addressed: 1. Are rejected materials and products clearly labelled? Are they stored separately in restricted area? 2. Describe arrangements for disposal. Is destruction recorded?
V	**Brief description of general policy for process validation**	An outline of process validation policy only is required
G	**QUALITY CONTROLS**	
I	**Description of the Quality Control system and of the activities of the Quality Control Department. Procedures for the release of finished products**	The following points should be addressed: 1. Describe the activities of the QC system e.g. specifications, test methods, analytical testing, packaging, component testing, biological and microbiological testing and other quality related data collection. 2. Outline the involvement in the arrangements for the preparation, revision and distribution of documents in particular those for specification test methods, batch documentation and release criteria.
H	**STORAGE**	
I	**Policy on the storage of medical device**	The following points should be addressed: 1. How are the medical devices stored e.g. pallet racking? 2. Describe any special storage or handling conditions such as cold chain management.
E	**DOCUMENTATION**	
I	**Arrangements for the preparation, revision and distribution of necessary documentation, including storage of master documents**	Arrangement for the preparation, revision and distribution of documentation should include:- 1. Is there a description of the documentation system? 2. Who is responsible for the preparation, revision and distribution of documents? 3. Where are the master documents stored? 4. Is there a standard format and instruction of how documents are to be prepared?

		5. How is the documentation controlled? 6. For how long are the documents kept? 7. Detail any arrangement for electronic or microfilmed records.
F	**MEDICAL DEVICE COMPLAINTS AND FIELD SAFETY CORRECTIVE ACTION**	
I	**Arrangements for the handling of complaints**	Following points should be included: 1. Is there a written procedure for medical device complaints? 2. Who is responsible for:- a. Logging; b. Classifying; c. Investigating complaints. 3. Are written reports prepared? 4. Who reviews these reports? 5. For how long are complaint records kept?
II	**Arrangements for the handling of field safety corrective action**	Following points should be included: 1. Is there a written procedure which describes the sequence of actions to follow including:- a. Retrieval of distribution data; b. Notification to customers; c. Receipt/segregation/inspection of returned medical devices; d. Investigation/reporting of cause. e. Reporting corrective action. 2. Who is responsible for coordinating medical device field safety corrective actions? 3. Who notifies the Competent Authority of field safety corrective actions? 4. Can field safety corrective actions be effected below wholesale level? 5. Is there written procedure for destruction of defective/unsafe devices?
G	**SELF INSPECTION**	
I	**Short Description of the internal audit system**	Following points should be included: 1. Describe how the internal audit system verifies that those activities that have a bearing on medical device quality comply with the planned arrangement. 2. Are there documented procedures for the internal audit system and for the follow-up actions? 3. Are the results of the internal audit documented, brought to the attention of the personnel having responsibility for the area and activities inspected?

		4. Does the system ensure that those responsible for the area or activity take timely corrective action on the deficiencies found?
H	**CONTRACT ACTIVITIES**	
I	**Description of the way in which the compliance of the contract acceptor is assessed**	Describe briefly the details of the technical contract between the contract giver and acceptor and the way in which the QMS compliance, or compliance with other appropriate standards, is assessed. The selected standards should be assessed for the suitability of its application. The type of activities undertaken by the contract acceptor should be specified.

NOTE:

1. Any information which is not relevant may be stated as 'Not Applicable' in the relevant Sections/Columns of the above format, and reasons for non-applicability should be provided.
2. The above information should be submitted in bounded form (like spiral binding or hard binding).

ANNEXURE – V

SPECIFIC ENVIRONMENTAL REQUIREMENTS

1 – Moulding, Assembly and Packing area ;(HVAC)

1. The Plastic or Rubber based components May be moulded/extruded in positive pressurized, ventilated area complying to a Clean Zone as per ISO 14644-1 of at least Class 9 and subsequently assembled/processed and packed in Clean Room as per ISO 14644-1 of at least Class 7(Grade-C) (at rest condition).
2. Component of Orthopaedic Implants may be initially Prepared and Processed (cutting, lathing, etc.) in a well ventilated area. Polishing, cleaning and packing of Orthopaedic Implants (Non Sterile-to be sterilised in the Hospital) may be done in Clean Zone as per ISO 14644-1 of at least Class 8(Grade-D). While polishing and cleaning of Orthopaedic Implants (to be Sterilized in the premises) may be done in Clean Zone as per ISO 14644-1 of at least class 7 (at rest condition)(Grade-C) and primary packing should be carried out under Laminar Air Flow work station with Grade C background.
3. For high risk devices like cardiac stents, bone cements, Internal Prosthetic Replacements, Heart Valve and Intra Ocular Lenses, and packing should be done under class 5(Grade-A) with a background of class 7.

Name of Device	Type of Operation	Grade	ISO Class
Cardiac stent/Drug Eluting Stent	Packing, Coating, Crimping	A	5
	Washing, Ultrasonic cleaning, Annealing	C	7
	Tube laser cutting	D	8
Heart Valve	Valve Packing	A	5
	Ultrasonic cleaning, visual inspection	C	7
	Frame, Disc Processing	D	8
Intra Ocular Lenses	Packing and sealing	A	5
	Cleaning, Inspection, Power Checking	C	7
	Tumble polishing, Lathe Cutting	D	8
Bone Cements	Final product filling	A	5
	Sieving after calcinations	C	7
	Powder preparation, Granulation, Drying	D	8
Internal Prosthetic Replacement	Packing	A	5
	Product preparation	C	7
	Component Preparation	D	8
Catheters/IV Cannulae/Scalp vein Set	Assembling, Coating, Wrapping, Packing	C	7
	Component Preparation, Cleaning	D	8
	Moulding	Ventilated area	9

2. Testing Facilities;

1. The licensee shall provide testing facilities for requisite tests carrying out Chemical and Physico-Chemical testing of medical devices and of raw materials used in its own premises: Provided that the Licensing Authority may permit the licensee to carry out microbiological/sterility testing [wherever applicable] from an external approved public testing laboratory, at the initial stage.

ANNEXURE-VI

Device Master File

Note: The manufacturer shall submit the duly signed information pertaining to Medical Device in the following format. It is expected that the information submitted in the form of hard copy shall also be submitted in the form of soft copy.

The dossier shall have an index listing the details of the documents produced as requested hereunder and shall reflect the page numbers.

1.0 EXECUTIVE SUMMARY (Not more than three A4 size pages):

An executive summary shall be provided by the manufacturer and shall contain:

1.1 Introductory descriptive information on the medical device, the intended use and indication for use, Class of Device, novel features of the device (if any), Shelf Life of the Device and a synopsis on the content of the dossier (not more than 500 words).
1.2 Information regarding Sterilization of the Device (whether it is sterile or Non-sterile; if sterile, mode of sterilization)
1.3 Regulatory status of the similar device in India (Approved or New Device)
1.4 Domestic Price of the device
1.5 Marketing History of the device from the date of introducing the device in the market
1.6 Safety and performance related information on the device:
a. Summary of reportable events and field safety corrective action from the date of introduction

For Adverse event

Adverse Event	Frequency of Occurrence during the period(Number of Report/Total Units sold)

For Field Safety Corrective Action (FSCA)

Date of FSCA	Reason for FSCA	Countries where FSCA was conducted (If any)

b. If the device contains any of the following then descriptive information on the following need to be provided.
1. Animal or human cells tissues and/or derivatives thereof, rendered non-viable (e.g. Porcine Heart Valves)
2. Cells, tissues and/or derivatives of microbial recombinant origin (e.g. Dermal fillers based on Hyaluronic acid derived from bacterial fermentation process)
3. Irradiating components, ionising or non ionising

2.0 DEVICE DESCRIPTION AND PRODUCT SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES

2.1 Device Description

The dossier should contain t he following descriptive information for the device:

a) a general description including its generic name, Model name, intended use/purpose, Indications, Instructions for Use, Contraindications, Warnings, Precautions and Potential Adverse Effects;
b) the intended patient population and medical condition to be diagnosed and/or treated and other considerations such as patient selection criteria;
c) principles of operation or Mode of Action, accompanies by animation/videos (if available)
d) risk class and the applicable classification rule according to Principles of Medical Devices Classification as per GHTF guidelines
e) an explanation of any novel features;
f) A description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with it. It should also be clarifies whether these accessories/devices are supplied as a kit or separate components.
g) a description or complete list of the various configurations/variants of the device that will be made available;
h) A general description of the key functional elements, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality. Where appropriate, this will include: labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams.
i) a description of the materials incorporated into key functional elements and those making either direct contact with a human body or indirect contact with the body, e.g., during extracorporeal circulation of body fluids. Complete chemical, biological and physical characterization of the material (s) of the Medical Device.
j) For medical devices intended to emit ionising radiation, information on radiation source (e.g. radioisotopes) and the material used for shielding of unintended, stray or scattered radiation from patients, users and other persons shall be provided.

2.2 Product Specification

The dossier should contain a list of the features, dimensions and performance attributes of the medical device, its variants and accessories, that would typically appear in the product specification made available to the end user, e.g. in brochures, catalogues etc.

2.3 Reference to predicate and/or previous generations of the device

Where relevant to demonstrating conformity to the Essential Principles, and to the provision of general background information, the dossier should contain an overview of:

a) the manufacturer's previous generation(s) of the device, if such exist; and/or
b) Predicate devices available on the local and international markets.

3.0 LABELLING

The dossier should typically contain a complete set of labelling associated with the device as per the requirements of Labelling. Information on labelling should include the following:

- Original labels of the device, including accessories if any, and its packaging configuration;
- Instructions for use (Prescriber's manual)
- Product broacher; and
- Promotional material.

The label should comply with provisions of Drugs & Cosmetics Rules

4.0 Device Description and Product Specification, Including Variants and Accessories

4.1 Device Design

The dossier should contain information to allow a reviewer to obtain a general understanding of the design stages applied to the device. The information may take the form of a flow chart. Device design validation data should be submitted.

4.2 Manufacturing Processes

The dossier should contain information to allow a reviewer to obtain a general understanding of the manufacturing processes. The information may take the form of a process flow chart showing, an overview of production, manufacturing environment, facilities and controls used for manufacturing, assembly, any final product testing, labelling & packaging and storage of the finished medical device. If the manufacturing process is carried out at multiple sites, the manufacturing activities at each site should be clearly specified.

5.0 ESSENTIAL PRINCIPLES (EP) CHECKLIST

The dossier should contain an EP checklist that identifies:-

a) the Essential Principles;
b) whether each Essential Principle applies to the device and if not, why not;
c) the method(s) used to demonstrate conformity with each Essential Principle that applies;
d) a reference for the method(s) employed (e.g., standard), and
e) the precise identity of the controlled document(s) that offers evidence of conformity with each method used.

Methods used to demonstrate conformity may include one or more of the following:

a) conformity with recognised or other standards
b) conformity with a commonly accepted industry test method(s);
c) conformity with an in-house test method(s);
d) the evaluation of pre-clinical and clinical evidence
e) comparison to a similar device if already available on the market.

The EP checklist should incorporate a cross-reference to the location of such evidence both within the full technical documentation held by the manufacturer and within the dossier

A template for a checklist is shown in as under

Essential Principle	Identity of the Device	Relevant Yes/No	Specification/standard Sub-clause/reference	Complies Yes/No	Document Reference Justification and/or comments

6.0 RISK ANALYSIS AND CONTROL SUMMARY

The dossier should contain a summary of the risks identified during the risk analysis process and how these risks have been controlled to an acceptable level. This risk analysis should be based on recognized standards e.g. ISO 14971 and be part of the manufacturer's risk management plan based on complexity and risk class of the device. The technique used to analyse the risk must be specified, to ensure that it is appropriate for the medical device and risk involved. The risks and benefits associated with the use of the medical device should be described. The risk analysis submitted shall have periodic updation of the risks identified as per risk management plan.

7.0 PRODUCT VERIFICATION AND VALIDATION

7.1 General

The dossier should contain product verification and validation documentation.

As a general rule, the dossier should summarise the results of verification and validation studies undertaken to demonstrate conformity of the device with the Essential Principles that apply to it. Such information would typically cover wherever applicable:

a) engineering tests;
b) laboratory tests;
c) simulated use testing;
d) any animal tests for demonstrating feasibility or proof of concept of the finished device;
e) any published literature regarding the device or substantially similar devices.Such summary information may include:
    i. declaration/certificate of conformity to a recognised standard(s) and summary of the data if no acceptance criteria are specified in the standard;
    ii. declaration/certificate of conformity to a published standard(s) that has not been recognised, supported by a rationale for its use, and summary of the data if no acceptance criteria are specified in the standard;

iii. declaration/certificate of conformity to a professional guideline(s), industry method(s), or in-house test method(s), supported by a rationale for its use, a description of the method used, and summary of the data in sufficient detail to allow assessment of its adequacy;
iv. a review of published literature regarding the device or substantially similar devices.

In addition, where applicable to the device, the dossier should contain detailed information on:

a) biocompatibility studies data as per recognized standards e.g. ISO 10993 requirements
b) medicinal substances incorporated into the device, including compatibility of the device with the medicinal substance;
c) biological safety of devices incorporating animal or human cells, tissues or their derivatives;
d) sterilisation;
e) software verification and validation;
f) animal studies that provide direct evidence of safety and performance of the device, especially when no clinical investigation of the device was conducted;
g) clinical evidence.

Detailed information will describe test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions. Where no new testing has been undertaken, the dossier should incorporate a rationale for that decision, e.g. biocompatibility testing on the identical materials was conducted when these were incorporated in a previous, legally marketed version of the device. The rationale may be incorporated into the Essential Principle checklist.

7.2 Biocompatibility

The dossier should contain a list of all materials in direct or indirect contact with the patient or user.

Where biocompatibility testing has been undertaken (as per recognized standards e.g. ISO 10993) to characterize the physical, chemical, toxicological and biological response of a material, detailed information should be included on the tests conducted, standards applied, test protocols, the analysis of data and the summary of results. At a minimum, tests should be conducted on samples from the finished, sterilised (when supplied sterile) device.

7.3 Medicinal Substances

Where the medical device incorporates a medicinal substance(s), the dossier should provide detailed information concerning that medicinal substance, its identity and source, the intended reason for its presence, and its safety and performance in the intended application.

7.4 Biological Safety

The dossier should contain a list of all materials of animal or human origin used in the device. For these materials, detailed information should be provided concerning the selection of sources/donors; the harvesting, processing, preservation, testing and handling of tissues, cells and substances of such origin should also be provided Process validation results should be included to substantiate that manufacturing procedures are in place to minimize biological risks, in particular, with regard to viruses and other transmissible agents. TSE/BSE Certificates should also be submitted.

The system for record-keeping to allow traceability from sources to the finished device should be fully described.

7.5 Sterilisation

Where the device is supplied sterile, the dossier should contain the detailed information of the initial sterilisation validation including sterilizer qualification, bioburden testing, pyrogen testing, testing for sterilant residues (if applicable) and packaging validation as per recognized standards e.g. ISO 11607.

Typically, the detailed validation information should include the method used, sterility assurance level attained, standards applied, the sterilisation protocol developed in accordance with recognized standards e.g ISO 11137, and a summary of results.

Evidence of the ongoing revalidation of the process should also be provided. Typically this would consist of arrangements for, or evidence of, revalidation of the packaging and sterilisation processes.

7.6 Software Verification and Validation

The dossier should contain information on the software design and development process and evidence of the validation of the software, as used in the finished device. This information should typically include the summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release. It should also address all of the different hardware configurations and, where applicable, operating systems identified in the labelling.

7.7 Animal Studies

Where studies in an animal model have been undertaken to provide evidence of conformity with the Essential Principles related to functional safety and performance, detailed information should be contained in the dossier.

The dossier should describe the study objectives, methodology, results, analysis and conclusions and document conformity with Good Laboratory Practices. The rationale (and limitations) of selecting the particular animal model should be discussed.

7.8 Shelf Life/Stability Data

The dossier should contain both Accelerated Stability Data as well as Real time Stability data to ensure the quality and effectiveness of the device during assigned shelf life period. The protocol to carry out stability studies should be submitted.

7.9 Clinical Evidence

The dossier should contain the clinical evidence that demonstrates conformity of the device with the Essential Principles that apply to it. It needs to address the elements contained in the Clinical Evaluation Requirements as per national/International guidelines e.g GHTF/SG5/N2, Schedule Y. If a predicate device (Gold Standard) is available nationally, the manufacturer needs to submit the substantial equivalence evaluation along with relevant published literature.

7.10 Post Marketing Surveillance Data (Vigilance Reporting)

The dossier should contain the Post Marketing Surveillance/ Vigilance Reporting procedures and Data collected by the manufacturing encompassing the details of the complaints received and corrective and Preventive actions taken for the same.

NOTE:

1. All reports submitted as a part of the dossier should be signed and dated by the responsible person.
2. Batch Release Certificates and Certificate of Analysis of finished product for minimum 3 batches should be submitted.
3. All certificates submitted must be with in the validity period.
4. Any information which is not relevant for the subject device may be stated as 'Not Applicable' in the relevant Sections/Columns of the above format, and reasons for non-applicability should be provided.
5. The above information should be submitted in the form of one or more bounded form (like spiral binding or hard binding).

Annexure VII

The list shall bear name and address of manufacturer, license number, validity period and undertaking.

Heart Valve

Name of firm & address of firm as per Form 28 in each & every page and Page Number.

Lic No. Validity period in each & every page

1	2	3	4	5	6	7	8	9	10	11	12	13	14
S.no	Model name	Generic name	MRI Compliant viz. Yes or No	Adult / Paediatric	Material of Construction	Sizes in mm	Annulus Diameter	Internal orifice Diameter	Other Attributes (Interference compensation) viz. Rotatable valve; x-ray visibility	Intended Use	Sterile /Non Sterile	Self-life	Export/ Domestic

Cardiac Stent System & Drug Eluting Stent

Name of firm & address of firm as per Form 28 in each & every page and Page Number.

Lic No. Validity period in each & every page

S.no	Model name	Generic name	Name of the coated Drug (in case of DES)	Stent length in mm	Stent diameter in mm	Material of Construction	Intended Use	Sterile /Non Sterile	Self-life	Export/ Domestic

Central License Approving Authority Licensing Authority

IOL (Intra Ocular lens)

Name of firm & address of firm as per Form 28 in each & every page and Page Number.

Lic No. Validity period in each & every page

S.no	Model name	Generic name	Overall length	Overall Diameter	Power range	Optic Resolution	Optic Design	Dialing Whole	Material of Construction	Multi Piece / single piece	Intended Use	Sterile/ Non Sterile	Export/ Domestic

Note:- Product Description like as foldable hydrophilic acrylic intraocular lens, hydrophobic acrylic foldable intra ocular lens, PMMA intra ocular lens, single /multi piece acrylic foldable intraocular lens, hydrophilic foldable poly hydroxyl ethyl methacrylate intraocular lens with dual haptic & square edge, single piece PMMA intraocular lens, natural yellow hydrophilic acrylic foldable aspheric square edge intraocular lens etc. needs to be mentioned on the List.

Central License Approving Authority Licensing Authority

Orthopedic Implant

Name of firm & address of firm as per Form 28 in each & every page and Page Number.

Lic No. Validity period in each & every page

S.no	Model name	Generic name	Length in mm	Diameter in mm	Other information Like Hole etc.	Material of Construction	Intended Use	Sterile /Non Sterile	Self-life	Export/ Domestic

Note:- In case the orthopaedic Implants are Coated then details of Coating Material along with specifications needs to be mentioned on the list

Central License Approving Authority Licensing Authority

Catheters

Name of firm & address of firm as per Form 28 in each & every page and Page Number.

Lic No. Validity period in each & every page

S.no	Model name	Generic name	Length in mm	Diameter in mm	Material of Construction	Intended Use	Sterile /Non Sterile	Self-life	Export/ Domestic

Note:- In case the Catheters are Coated then details of Coating Material along with specifications needs to be mentioned on the list

Central License Approving Authority Licensing Authority

Scalp Vein Set

Name of firm & address of firm as per Form 28 in each & every page and Page Number.

Lic No. Validity period in each & every page

S.no	Model name	Generic name	Length in mm	Diameter in mm	Material of Construction	Needle Size (Gauze)	Intended Use	Sterile /Non Sterile	Self-life	Export/ Domestic

Central License Approving Authority Licensing Authority

I.V cannula

Name of firm & address of firm as per Form 28 in each & every page and Page Number.

Lic No. Validity period in each & every page

S.no	Model name	Generic name	Length in mm	Diameter in mm	Material of Construction	Needle Size (Gauze)	Intended Use	Sterile /Non Sterile	Self-life	Export/ Domestic

Central License Approving Authority Licensing Authority

Bone Cement

Name of firm & address of firm as per Form 28 in each & every page and Page Number.

Lic No. Validity period in each & every page

S.no	Model name	Generic name	Composition	Size (Dia x leng in case of granule, Block, Button, Rod, etc) Dia x leng x hole Dia in case of Spacer etc)	Intended Use	Sterile/Non Sterile	Self-life	Export/ Domestic

Note:- In case the antibiotics are used then details of antibiotic along with specifications needs to be mentioned on the list

Central License Approving Authority Licensing Authority

Internal Prosthetic Replacement

Name of firm & address of firm as per Form 28 in each & every page and Page Number.

Lic No. Validity period in each & every page

S.no	Model name	Generic name	Dimension In mm	Bulk Density	Material of Construction	Surface Texture	Pore Size	Hardness	Intended Use	Sterile /Non Sterile	Self-life	Export/ Domestic

Central License Approving Authority Licensing Authority

Undertaking at the end of list of Medical Devices.

1. **The above are the only Medical Devices intended for manufacture at present and we undertake that any addition thereto or any deletion therefrom will not be carried out without the permission of the Licensing Authority/Central License Approving Authority.**

2. **We undertake to comply with all the provision of the acts in force and the directions issued from time to time by Licensing Authority/Central License Approving Authority and not to manufacture any product under a name belonging to another manufacturer.**

(Sd/-)

Proprieter/Partner/Director.

Note:- The undertaking is common for the all category of the product list of Medical Devices