Guidance Document

(Medical Devices Division)

Title	:	Guidance Document on Common Submission Format for Registration/ Re-Registration of Notified Medical Devices in India
Doc No.	:	CDSCO/MD/GD/RC/01/00
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CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
DIRECTORATE GENERAL OF HEALTH SERVICES
MINISTRY OF HEALTH & FAMILY WELFARE
GOVT. OF INDIA

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A. Preface:

In India import, manufacturing, 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.	Cardiac Stents.
5.	Drug Eluting Stents.
6.	Catheters.
7.	Intra Ocular Lenses.
8.	I.V. Cannulae.
9.	Bone Cements.
10.	Heart Valves.
11.	Scalp Vein Set.
12.	Orthopedic Implants.
13.	Internal Prosthetic Replacements.

Further the following products are regulated as "Drugs" under Drugs and Cosmetics Act and Rules there under which are considered as 'Medical Device' in the Country of Origin.

1. Blood Grouping Sera
2. Ligatures, Sutures, Staples
3. Intra Uterine Devices (Cu-T)
4. Condoms
5. Tubal Rings
6. Surgical Dressing
7. Umbilical Tapes
8. Blood / Blood Component Bags

This document may also be applicable for submission of application for the registration of above products.

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The proposed requirements for the regulatory control over notified medical devices are being uploaded for the information of all stakeholders.

The document is intended to provide guidance for use in the registration of notified medical devices (excluding notified IVD's) 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 Registration Certificate.

SCOPE:

For marketing of imported medical devices in India, Registration Certificate in Form-41 and Import License in Form-10 is required under Drugs and Cosmetics Rules. The Rule 24-A, 25-B, 27-A and 28-A of Drugs and Cosmetics Rules describe the information/data required for grant of registration certificate. This guidance documents has been prepared to specify the general requirements for grant of registration certificate in Form-41. 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 to review such application in systematic manner. It is apparent that this structured application with comprehensive and rational contents will help the CDSCO 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 at CDSCO

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B. Requirements for Common Submission Format for Registration of Medical Devices in India

The following documents are required to be submitted in the following manner and order for the registration of the medical devices for import into India: -

1. **Covering Letter** – The covering letter is an important part of the application and should clearly specify the intent of the application (whether the application for the registration of the manufacturing site is being submitted for the first time, whether the application is for re-registration or is for the endorsement of additional products to an existing Registration Certificate) the list of documents that are being submitted (Index with page no's) 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 alongwith the name and address of the firm.

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 (along with the name and address of the firm) legal documents such as Form 40, Power of Attorney etc. on behalf of the firm should be submitted at the time of submission of the application for registration. Duly self attested photocopies of the Authorization letter may be submitted at the time of submission of subsequent applications.

3. A duly filled **Form 40** as per the Performa prescribed in the Drugs & Cosmetics Rules, signed & stamped by the Indian Agent along with name & designation. The name and address of the Indian Agent should be as given in the Drug Sale Licence in Form 20B & 21B or its renewal in Form 21C. Form 40 Performa is enclosed at **Annexure - I**.

4. The **requisite fee** as prescribed in the Drugs & Cosmetics Act & Rules viz. 1500 USD for the registration of the manufacturing premises and 1000 USD for a single Device and an additional fee at the rate of 1000 USD for each additional device proposed to be imported may be submitted at notified branches of Bank of Baroda under the Head of Account "0210 - Medical and Public Health, 04 - Public Health, 104 - Fees and Fines" adjustable to Pay and Account Officer, DGHS, New Delhi in the form of a Treasury

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Challan. Performa for Treasury Challan (TR 6) is annexed at **Annexure - II**. The Receipt in original (TR 6) is required to be submitted along with the application for registration. Applicants are advised to make sure that the TR6 Challan clearly indicates the USD equivalence of the amount paid in Indian Rupees.

In case of any direct payment of fee by the manufacturer in the country of origin, the fee shall be paid through Electronic Clearance System (ECS) from any bank in the Country of Origin to the Bank of Baroda, Kasturba Gandhi Marg, New Delhi, through the electronic code of the bank in the head of Account stated above and the original receipt of the said transfer shall be treated as an equivalent to the Bank Challan, subject to the approval by the Bank of Baroda that they have received the payment.

5. **Power of Attorney –** The authorization by a manufacturer to his agent in India shall be documented by a Power of Attorney executed and authenticated either in India before a First Class Magistrate, or in the country of origin before such an equivalent authority, the certificate of which is attested by the Indian Embassy of the said country, and the original of the same shall be furnished along with the application for Registration Certificate. Apostille Power of Attorney from Hague convention member countries is also acceptable. Performa for Power of Attorney is enclosed at **Annexure III.**

While submitting the Power of Attorney, the following points should be kept in mind: -

- It should be co-jointly signed and stamped by the manufacturer as well as the Indian Agent indicating the name & designation of the authorized signatories (along with the name and address of the firm).
- It should clearly list the names(generic and Model, if any) of all the proposed devices (including Model No's, if applicable) along with their specific Indication and/or intended use. Further, the names of the proposed devices should correlate with those mentioned in the Form 40 and Free Sale Certificate to be submitted.
- The names & addresses of the manufacturer as well as the Indian Agent stated in the Power of Attorney should correlate with the Form 40.
- It should be valid for the period of said Registration Certificate.

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6. A duly attested/notarized (in India) and valid copy of **Wholesale License** for sale or distribution of drugs under Drugs and Cosmetics Rules **in Form 20B & 21B** or its renewal in **Form 21C** issued by the State Licensing Authority.

7. Duly notarized/Apostilled/Attested (by Indian Embassy in the country of origin) and valid copy of **Free Sale Certificate/Certificate to Foreign Government/ Certificate of Marketability** for each device issued by any one of the countries viz. USA, Canada, Japan, Australia and European Union and from the National Drug Regulatory Authority of the country of origin. Free Sale Certificate should state that the proposed device is freely sold in Country of Origin and can be legally exported. It should also specify name and address of legal and actual manufacturing site along with applied product name(s) in generic and Model name, if any.

8. Duly notarized/Apostilled/Attested (by Indian Embassy in the country of origin) and valid copy of **ISO 13485 Certificate** in respect of the legal and actual manufacturing site (s).

9. Duly notarized/Apostilled/Attested (by Indian Embassy in the country of origin) and valid copy of **CE Full Quality Assurance Certificate/CE Production Quality Assurance Certificate/ CE Type Examination Certificate/ CE Product Quality Assurance** in respect of the legal and actual manufacturing site (s), depending upon path of conformity assessment.

10. Duly notarized/Apostilled/Attested (by Indian Embassy in the country of origin) and valid copy of **CE Design Certificate** in respect of the proposed Device (s) in generic and Model name, if applicable.

11. Duly notarized/Apostilled/Attested (by Indian Embassy in the country of origin) and valid copy of **Declaration of Conformity** in respect of the proposed Device (s), if any.

12. Copy of latest **Inspection/Audit Report** carried out by Notified bodies/National Regulatory Authority/Competent Authority.

13. A) A duly filled **Schedule D (I)** along with the undertaking as per the Performa prescribed in the Drugs & Cosmetics Act & Rules, signed & stamped by the manufacturer indicating the name and designation of the authorized signatory is required to be submitted Performa for **Schedule D (I)** is enclosed at **Annexure IV**.

B) The requirements for **Plant/ Site Master File** are enclosed at **Annexure V.**

14. A duly filled **Schedule D (II)/Device Master File** as enclosed at **Annexure VI**.

Note:

- Soft copy of the Plant/ Site Master File may also be submitted along with the application.
- All certificates submitted should be with in the validity period and should have at least six months valid period at the time of submission of application.
- All the regulatory and legal documents (S. No: 1-12 as given above) may be provided in one file and other documents like Plant/ Site Master File and Device Master File may be provided as separate file(s).
- In case of re-registration, a copy of registration certificate in form-41 should be submitted along with application.

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C. Annexures

Annexure I	Format for Form 40
Annexure II	Format for TR6 Challan
Annexure III	Format for Power of Attorney
Annexure IV	Format for Schedule DI
Annexure V	Plant/ Site Master File
Annexure VI	Schedule DII/ Device Master File

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ANNEXURE – I

FORM 40

(See rule 24-A)

Application for issue of Registration Certificate for import of drugs into India under the Drugs and Cosmetics Rules 1945

I/We*_____ (Name, full address, as per wholesale license, with telephone, fax and E-mail address) hereby apply for the grant of Registration Certificate for the manufacturer, M/s. _____ (full address with telephone, fax and E-mail address of the foreign manufacturer) for his premises M/s_____(full address with telephone, fax and E-mail address), and manufactured drugs meant for import into India.

1. Names of drugs for registration.

S. No.	Name of Medical Devices (Including model No's, if applicable)		Components (if any)	Indication and/or Intended Use	Shelf Life
	Generic Name	Model Name, if any			

2. I/We enclose herewith the information and undertakings specified in Schedule D (I) and Schedule D(II) duly signed by the manufacturer for grant of Registration Certificate for the premises stated below.

3. A fee of_____ for registration of premises, the particulars of which are given below, of the manufacturer has been credited to the Government under the Head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines" under the Drugs and Cosmetics Rules, 1945-Central *vide* Challan No._____ dated_____(attached in original).

4. A fee of_____for registration of the drugs for import as specified at Serial No. 2 above has been credited to the Government under the Head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines" under the Drugs and Cosmetics Rules, 1945-Central vide Challan No._____, dated_____. (Attached in original).

5. Particulars of premises to be registered where manufacture is carried on:

Address _____
Telephone No. _____
Fax No. _____
E-mail _____

I/We* undertake to comply with all terms and conditions required to obtain Registration Certificate and to keep it valid during its validity period.

Place: _____
Date: _____

Signature
(Name & Designation)
Seal / Stamp of authorized agent in India

**Delete whichever is not applicable.*

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ANNEXURE – II

TR6 Challan

T.R. - 6.
(See Rule 92)
Challan No.

Please indicate whether	Civil
	Defence
	Railways
	Posts & Telegraphs

Challan of cash paid into Treasury/Sub-Treasury ……

Bank of Baroda, K.G. Marg, New Delhi

To be filled by the remitter					To be filled by the Department Officer or the Treasury		
By whom Tendered	Name (designation) and address of the person on whose behalf money is paid	Full particular of the remittance and/of authority (If any)	Amount		Head of Account	Accounts Officer by whom adjustable	Order to the Bank
Name			Rs.	P.			
		Name and address of the manufacturing site Name of Products			0210-Medical + Public Health, 04-Public Health, 104-Fee and Fines	Pay and Accounts Offices, DGHS,New Delhi	Date Correct, Receive and grant receipt (Signature and full Designation of the Officer ordering the money to be paid in).
Signature		Total					
(in words) Rupees_____equivalent to USD (In words)_____					To be used only in the case of remittance to the Bank through Departmental officer or the Treasury Officer.		
Received payment (in words) Rupees							
Treasurer	Accountant	Date			Treasury Officer Agent or Manager		

P.T.O.

Note:

1. In the case of payment at the Treasury, receipts for sums less than Rs. 50,000.00 do not require the Signature of the Treasure Officer but only of the Accountant and the Treasurer. Receipts for cash and cheques paid for service postage stamps should be given in form T.R. 5.

2. Particulars of money tendered should be given below.

3. In case where direct credit at the Bank are permissible the column, "Head of Account" will be filled in by the Treasury Officer or the Accountant General as the case may be on receipt of the Bank's Daily Sheet.

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Particulars	Amount	
	Rs.	P.
Coins Notes (with details) Cheque (with details)		
Total Rs.		

ANNEXURE – III

Power of Attorney

(Power of Attorney to accompany an application for issue of Registration Certificate for import of Medical Device (s) into India)

Whereas, _____ (Name of Authorized person) of M/s _____(Name of applicant, full address, as per wholesale/manufacturing license, with telephone, fax and E-mail address) herein after to be known as authorized agent for the M/s _____(Name of Manufacturer) intends to apply for a Registration Certificate under the *Drugs & Cosmetics Rules 1945*, for the import, use and marketing into India, of the Medical Devices, we M/s. _____ (Name and full address with telephone, fax and E-mail address of the foreign manufacturer) for his premises M/s_____(full address with telephone, fax and E-mail address), hereby delegate Power of Attorney that for the duration of the said registration period.

1. The said applicant shall be our Authorized agent for the Registration Certificate of Medical Devices imported into India, under Rule 27-A of the Drugs & Cosmetics Rules and shall act in the following respects:
    a. To act as the official representative for the product registration for and on behalf of (Manufacturer's Name) in India
    b. To submit all necessary documents in the name of (manufacturer's name) for the registration of medical devices manufactured by (Manufacturer's name) as defined in the schedule.

2. We shall comply with all the conditions imposed on the Registration Certificate, read with rules 78 of the *Drugs* and Cosmetics rules, 1945.

3. We declare that we are carrying on the manufacture of the Medical Device (s) mentioned in this Schedule, at the premises specified above, and we shall from time to time report any change of premises on which manufacture will be carried on and in cases where manufacture is carried on in more than one factory any change in the distribution of functions between the factories.

4. We shall comply with the provisions of Part IX of the Drugs and Cosmetics Rules, 1945.

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5. Every drug manufactured by us for import under the Registration Certificate into India shall be as regard strength, quality and purity where ever applicable conforms with the provisions of Chapter III of Drugs and Cosmetics Act, 1940 and Part IV of the Drugs and Cosmetics Rules 1945, and their amendments from time to time.

6. We shall from time to time report for any change or manufacturing process, or in packaging, or in labeling, or in testing, or in documentation of any of the Medical Device (s), pertaining to the Registration Certificate, to be granted to us. Where any change in respect of any of the Medical Device (s) under the Registration Certificate has taken place, in respect of any of the above matters, we shall inform the same to the licensing authority in writing within 30 days from the date of such changes. In such cases, where there will be any major change/modification in manufacturing or in processing or in testing, or in documentation, as the case may be, at the discretion of the licensing authority, we shall obtain necessary approval within 30 days by submitting a separate application, alongwith the registration fee as specified in clause (ii) of sub rule (3) of rule 24-A.

7. We shall from time to time report for any administrative action taken due to adverse reaction, viz. market withdrawal regulatory restriction, or cancellation of authorization and/or "not of standard quality report" of any Medical Device pertaining to the Registration Certificate declared by any Regulatory Authority of any country where the Medical Device is marketed/sold or distributed. The dispatch and marketing of the Medical Device in such cases shall be stopped immediately and the licensing authority shall be informed immediately. Further action in respect of stop marketing of Medical Device shall be taken as per the directions of the licensing authority. In such cases, action equivalent to that taken with reference to the concerned Medical Device (s) in the country of origin or in the country of marketing will be followed in India also, in consultation with the licensing authority. The licensing authority may direct any further modification to this course of action, including the withdrawal of the Medical Device from Indian market within 48 hours time period.

8. We shall comply with such further requirements, if any, as may be specified, by the Government of India, under the Act and the rules made there under.

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9. We shall allow the licensing authority and/or any person authorized by him in that behalf to enter and inspect the manufacturing premises and to examine the process/procedure and documents in respect of any Medical Device manufactured by us for which the application for Registration Certificate has been made.

10. We shall allow the licensing authority or any person authorized by him in that behalf to take samples of the Medical Device (s) concerned for test, analysis or examination, if considered necessary by the licensing authority.

11. We do hereby state and declare that all the photocopies in the application are true copies of the original documents.

12. We do hereby state and declare that all the documents submitted by the undersigned are true and correct.

List of Medical Device (s)

S. No.	Name of Medical Devices (Including model No's, if applicable)		Indication and/or Intended Use	Shelf Life
	Generic Name	Model Name, if any		

Place:
Date:

Signature of the manufacturer
(Name & Designation)
Seal / Stamp

Place:
Date:

Signature of the Indian Agent
(Name & Designation)
Seal / Stamp

ANNEXURE – IV

SCHEDULE D(I)

(*See* rule 21 (d) and rule 24 A)

Information and undertaking required to be submitted by the manufacturer or his authorized agent with the Application Form for a Registration Certificate. The format shall be properly filled in for each application in Form 40.

1. *Particulars of the manufacturer and manufacturing premises*

1.1 Name and address of the manufacturing premises (Telephone No., Fax No., E-mail address) to be registered.

1.2 Name(s) and address(es) of the Proprietor /Partners / Directors.

1.3 Name and address of the authorized Agent in India, responsible for the business of the manufacturer.

1.4 A brief profile of the manufacturer's business activity, in domestic as well as global market.

1.5 A copy of Plant/ Site Master File (duly notarized)

1.6 A copy of Plant Registration / approval Certificate issued by the Ministry of Health/National Regulatory Authority of the foreign country concerned (duly notarised)

1.7 A brief profile of the manufacturer's research activity.

2. *Particulars of the manufactured Medical Devices to be registered under Registration Certificate.*

2.1 Names of Medical Devices to be registered meant for import into and use in India.

2.2 A copy of the approved list showing the Medical Devices mentioned in 2.1 above are permitted for manufacturing / marketing in the country of origin (duly notarized).

2.3 A copy of Good Manufacturing Practice (GMP) certificate, as per WHO-GMP guidelines, or Certificate of Pharmaceutical Products (CPP), or Free Sale Certificate issued by the National Regulatory Authority of the foreign country concerned, in relation to the bulk Medical Devices or formulations or special products, meant for import into India, if applicable.

2.4 The domestic prices of the Medical Devices to be registered in India, in the currency of the country of origin.

2.5 The name(s) of the Medical Device(s) which are original research products of the manufacturer.

3. *Undertaking to declare that: -*

3.1. We shall comply with all the conditions imposed on the Registration Certificate, read with rules 74 and 78 of the Drugs and Cosmetics rules, 1945.

3.2 We declare that we are carrying on the manufacture of the Medical Devices mentioned in this Schedule, at the premises specified above, and we shall from time to time report any change of premises on which manufacture will be carried on and in cases where manufacture is carried on in more than one factory any change in the distribution of functions between the factories.

3.3 We shall comply with the provisions of Part IX of the Drugs and Cosmetics Rules, 1945.

3.4 Every Medical Device manufactured by us for import under the Registration Certificate into India shall be as regard strength, quality and purity, where ever applicable, conforms with the provisions of Chapter III of Drugs and Cosmetics Act, 1940 and Part IV of the Drugs and Cosmetics Rules 1945, and their amendments from time to time.

3.5 We shall from time to time report for any change or manufacturing process, or in packaging, or in labelling, or in testing, or in documentation of any of the Medical Devices, pertaining to the Registration Certificate, to be granted to us. Where any change in respect of any of the Medical Devices under the Registration Certificate has taken place, in respect of any of the above matters, we shall inform the same to the licensing authority in writing within 30 days from the date of such changes. In such cases, where there will be any major change/modification in manufacturing or in processing or in testing, or in documentation, as the case may be, at the discretion of the licensing authority, we shall obtain necessary approval within 30 days by submitting a separate application, alongwith the registration fee as specified in clause (ii) of sub rule (3) of rule 24-A.

3.6 We shall from time to time report for any administrative action taken due to adverse reaction, viz. market withdrawal regulatory restriction, or cancellation of authorization and/or “not of standard quality report” of any Medical Device pertaining to the Registration Certificate declared by any Regulatory Authority of any country where the Medical Device is marketed/sold or distributed. The despatch and marketing of the Medical Device in such cases, shall be stopped

immediately and the licensing authority shall be informed immediately. Further action in respect of stop marketing of Medical Device shall be taken as per the directions of the licensing authority. In such cases, action equivalent to that taken with reference to the concerned Medical Device(s) in the country of origin or in the country of marketing will be followed in India also, in consultation with the licensing authority. The licensing authority may direct any further modification to this course of action, including the withdrawal of the Medical Device from Indian market within 48 hours time period.

3.7 We shall comply with such further requirements, if any, as may be specified, by the Government of India, under the Act and the rules made there under.

3.8 We shall allow the licensing authority and/or any person authorized by him in that behalf to enter and inspect the manufacturing premises and to examine the process/procedure and documents in respect of any Medical Device manufactured by us for which the application for Registration Certificate has been made.

3.9 We shall allow the licensing authority or any person authorized by him in that behalf to take samples of the Medical Devices concerned for test, analysis or examination, if considered necessary by the licensing authority.

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Place:
Date:

Signature of the manufacturer
(Name & Designation)
Seal / Stamp

ANNEXURE – V

Plant/ Site Master File

NOTE: The manufacturer shall submit the duly signed and notarized information pertaining to Manufacturing premises in the following format. All information/reports/data should be in English only. 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 "Plant/Site Master File" containing specific and factual information about the production and/or control of manufacturing process carried out at actual 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), in addition to the site that is the subject of registration.
II	**Manufacturing activities as licensed by the Competent Authorities**	1. Indicate whether the site has been approved by national authority, or any foreign Competent Authority (if the latter, name the authority and state if approval granted is for the manufacture of Medical Device of the same or different description from that in the application). 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. Submit valid copy of manufacturing/establishment license/plant registration certificate.
III	**Any other operations carried out on the site**	This covers both medical device related and non-medical device (including medicinal products) related activities.

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<table>
<tr><td>IV</td><td>Name and exact address of the site, including telephone, fax numbers, web site URL and e-mail address</td><td colspan="3">1. Name of company, site address and mailing address (if different from site address)
2. Telephone, fax nos. and email address of contact person</td></tr>
<tr><td>V</td><td>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</td><td colspan="3">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)</td></tr>
<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>
</table>

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IX	**Short description of the quality management system of the company**	(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 - 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
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

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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. State the form of training e.g. in-house, external, and how practical experience is gained and which staff are involved. 3. Explain training evaluation procedures. 4. Explain how retraining needs are identified. 5. 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 2. Clean room classification where relevent (e.g.as per ISO 14644-1). 3. Describe the controls available to prevent unauthorized access. 4. Provide a simple plan of each area with indication of scale. Label areas and annotate plan with names. 5. Plans should be legible

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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 desirable) including sanitation**	Brief description of water system, including sanitation should include following: 1. The schematic drawing must go back to the city supply system 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

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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. Is the machinery constructed of appropriate material (e.g. AISI grade 316 stainless steel for product contact equipment)? 2. Have other materials been suitably validated e.g. polypropylene, chrome-plated brass, PVC, non-reactive plastic materials? 3. Is the equipment designed with ease of cleaning in mind? 4. A brief general description is required. If the equipment has additional devices, these should be recorded. 5. 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?

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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.

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II	**Arrangements for the handling of starting materials, packaging materials, bulk and finished products, including sampling, quarantine, release and storage.**	The following points should be addressed: 1. Control of manufacturing • Checks on key parameters during manufacture • Records of key parameters • In-process checks • 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 provided for disposal of rejected materials and products. 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**

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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 the form of one or more bounded form (like spiral binding or hard binding).

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ANNEXURE - VI

Schedule DII (Device Master File)

Note: The manufacturer shall submit the duly signed and notarized information pertaining to Medical Device in the following format. All information/reports/data should be in English only. 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 Not Approved in India)

1.4 Domestic Price of the device in the currency followed in the Country of origin

1.5 Marketing History of the device from the date of introducing the device in the market

1.6 List of regulatory approvals or marketing clearance obtained (Submit respective copies of Approval Certificates)

Country	Approved Indication	Approved Shelf life	Composition and/or Material of Construction	Class of Device	Date of First Approval
USA					
Australia					
Japan					
Canada					
European Union					
Others*					

Others* - Optional

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Status of pending request for market clearance

Regulatory Agency of the country	Intended use	Indication for use	Registration status and date	Reason for rejection/withdrawal, if any

1.7 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

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 the following descriptive information for the device:

a) a general description including its generic name, Model name, Model No., Materials of Construction, intended use/purpose, Indications, Instructions for Use, Contraindications, Warnings, Precautions and Potential Adverse Effects;

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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.

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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 Drugs and Cosmetics Act and Rules thereunder. 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 bear name of the product, batch/Lot number, date of expiry or use before date, storage conditions, name and address of the actual and Legal manufacturer(if any), and Name and address of Importer, Import license number etc

4.0 DESIGN AND MANUFACTURING INFORMATION

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

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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 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	Relevant Yes/No	Specification/standard Sub-clause/reference	Complies Yes/No	Document Reference Justification and/or comments

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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.

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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.

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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.

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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 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 manufacturer encompassing the details of the complaints received and corrective and Preventive actions taken for the same.

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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).

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D Rules Related to Registration of Medical Devices in India under Drugs and Cosmetics Act and Rules (For Information Only)

Rule-24-A. *Form and manner of application for Registration Certificate.—*

(1) An application for issue of a Registration Certificate shall be made to the licensing authority in Form 40, either by the manufacturer himself, having a valid wholesale licence for sale or distribution of drugs under these rules, or by his authorised agent in India, either having a valid licence under the rules to manufacture for sale of a drug or having a valid wholesale licence for sale or distribution of drugs under these rules, and shall be accompanied by the fee specified in sub-rule *(3)* and the information's and undertakings specified in Schedules D-I and D-II duly signed by or on behalf of the manufacturer.

(2) The authorisation by a manufacturer to his agent in India shall be documented by a power of attorney executed and authenticated either in India before a First Class Magistrate, or in the country of origin before such an equivalent authority, the certificate of which is attested by the Indian Embassy of the said country, and the original of the same shall be furnished along with the application for Registration Certificate.

(3) (i) A fee of one thousand and five hundred US dollars [or its equivalent in Indian rupees] shall be paid along with the application in Form 40 as registration fee for his premises meant for manufacturing of drugs intended for import into and use in India

(ii) A fee of one thousand US dollars [or its equivalent in Indian rupees] shall be paid along with the application in Form 40 for the registration of a single drug meant for import into and use in India and an additional fee at the rate of one thousand US dollars for each additional drug:

Provided that in the case of any subsequent application for registration of additional drugs by the same manufacturer, the fee to accompany shall be one thousand US dollars [or its equivalent in Indian rupees] for each drug.

(4) The fees shall be paid through a Challan in the Bank of Baroda, Kasturba Gandhi Marg, New Delhi-110001 or any other branch or branches of Bank of Baroda, or any other bank, as notified, from time to time, by the Central Government, to be credited under the Head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines":

Provided that in the case of any direct payment of fees by a manufacturer in the country of origin, the fees shall be paid through Electronic Clearance System (ECS) from any bank in the country of origin to the Bank of Baroda, Kasturba Gandhi Marg, New Delhi, through the Electronic Code of the bank in the Head of Account "0210-Medical and Public Health, 04- Public Health, 104-Fee and Fines", and the original receipt of the said transfer shall be treated as an

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equivalent to the bank challan, subject to the approval by the Bank of Baroda that they have received the payment.

(5) The applicant shall be liable for the payment of a fee of five thousand US dollars [or its equivalent in Indian rupees] for expenditure as may be required for inspection or visit of the manufacturing premises or drugs, by the licensing authority or by any other persons to whom powers have been delegated in this behalf by the licensing authority under Rule 22.

(6) The applicant shall be liable for the payment of testing fees directly to a testing laboratory approved by the Central Government in India or abroad, as may be required for examination, tests and analysis of drug.

(7) A fee of three hundred US dollars [or its equivalent in Indian rupees] shall be paid for a duplicate copy of the Registration Certificate, if the original is defaced, damaged or lost.

(8) No Registration Certificate shall be required under these Rules in respect of an inactive bulk substance to be used for a drug formulation, with or without pharmacopoeial conformity.

Rule 25B. *Registration Certificate for import of drugs manufactured by one manufacturer.—*

(1) A single application may be made, and a single Registration *Drugs and Cosmetics Rules, 1945*

Certificate in Form 41 may be issued in respect of the import of more than one drug or class of drugs, manufactured by the same manufacturer:

Provided that the drug or classes of drugs, are manufactured at one factory or more than one factory functioning conjointly as a single manufacturing unit:
Provided further that if a single manufacturer has two or more factories situated in different places manufacturing the same or different drugs, separate Registration Certificates shall be required in respect of the drugs manufactured by each such factory.

Rule 27-A *Grant of Registration Certificate.*—

(*1)* On receipt of an application for Registration Certificate in the Form and manner specified in Rule 24-A, the licensing authority shall, on being satisfied, that, if granted, the conditions of the Registration Certificate will be observed, issue a Registration Certificate in Form 41:

Provided further that if the application is complete in all respects and informations specified in Schedules D-I and D-II are in order, the licensing

authority shall, within nine months from the date of receipt of an application, issue such Registration Certificate, and in exceptional circumstances and for reasons to be recorded in writing, the Registration Certificate may be issued within such extended period, not exceeding three months, as the licensing authority may deem fit.

(2) If the applicant does not receive the Registration Certificate within the period as specified in the proviso to sub-rule (1), he may appeal to the Central Government and the Central Government may after such enquiry into the matter, as it considers necessary, may pass such orders in relation thereto as it thinks fit.]

Rule 28-A. *Duration of Registration Certificate.*— A Registration Certificate, unless, it is sooner suspended or cancelled, shall be valid for a period of three years from the date of its issue:

Provided that if the application for a fresh Registration Certificate is made nine months before the expiry of the existing certificate, the current Registration Certificate shall be deemed to continue in force until orders are passed on the application.

Rule 29A. *Suspension and cancellation of Registration Certificate.* —If the manufacturer fails to comply with any of the conditions of the Registration Certificate, the licensing authority may after giving him an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefore, suspend or cancel the Registration Certificate for such period as it thinks fit either wholly or in respect of some of the substances to which it relates:

Provided that a person, who is aggrieved by the order passed by the licensing authority under this rule may, within thirty days of the receipt of the order, appeal to the Central Government, and the Central Government may, after such enquiry into the matter as it considers necessary and after giving the appellant an opportunity for representing his views in the matter, pass such orders in relation thereto as it thinks fit.

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