

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 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 74 and 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*.
5. Every drug manufactured by us for import under the Registration Certificate into India shall be as regard strength, quality and purity

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.
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 Device (s) (Including model No's, if applicable)	Indication and/or Intended Use

Place:

Date:

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

Place:

Date:

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