ANNEXURE 2

Sr. No	Document	Manufacturer	Importer
1.	Details of Applicant	Name and address of entity manufacturing the medical device and the name and address of the manufacturing site.	Name of the entity importing the medical device and specification and standards of that medical device,
2.	Details of Medical Device	- Generic Name - Model Number - Intended Use - Class of Medical Device - Material of Construction - Dimension (if any) - Shelf Life - Sterile or Non-Sterile - Brand Name (Registered under the Trademarks Act, 1999)	- Generic Name - Model Number - Intended Use - Class of Medical Device - Material of Construction - Dimension (if any) - Shelf Life - Sterile or Non-Sterile - Brand Name (Registered under the Trademarks Act, 1999)
3.	Certificate of Compliance	Certificate of compliance with respect to ISO 13485 standard accredited by National Accreditation Board for Certification Bodies or International Accreditation Forum in respect of such medical device	Certificate of compliance with respect to ISO 13485 standard accredited by National Accreditation Board for Certification Bodies or International Accreditation Forum in respect of such medical device
4.	Undertaking	Undertaking duly signed by the manufacturer stating that the information furnished by the applicant is true and authentic.	Undertaking duly signed by the importer stating that the information furnished by the applicant is true and authentic.