Saimax Healthcare & Surgicals		
Doc. No.	**Rev.**	**Review**
SH/F-02	**00**	**31.12.2025**

Checklist for Import of medical devices

Sr. No.	Requirements	Comments
1.	Dully Apostilled Power of attorney (Original)	Will Be prepare sign and stamp by the manufacturer
2.	Dully Apostilled/Notarized copy of Free Sale Certificate/ Marketing Authorization of the Product from National Regulatory Authority of Country of Origin	From Manufacturer
3.	Dully Apostilled/Notarized copy of Free Sale Certificate/ Marketing Authorization of the Product from National Regulatory Authority of any of the following countries viz USA, EU, Canada, Japan and Australia	From Manufacturer
4.	Copy of latest Inspection or Audit Report carried out by Notified Bodies or National Regulatory Authority or Competent Authority within last 3 years.	From Manufacturer
5.	Duly Notarized Copy of Quality Certificates in respect of the legal and actual manufacturing site (wherever applicable)	
5.1	Notarized copy of ISO 13485	From Manufacturer
5.2	Notarized Full Quality Assurance Certificate/CE type examination Certificate/CE product quality assurance	From Manufacturer
5.3	Notarized copy of Overseas Manufacturing Site or Establishment or Plant Registration Certificate by whatever named called in the country of origin issued by competent authority	From Manufacturer
5.4	Notarized copy of Declaration of Conformity	From Manufacturer
6.	Plant Master file from the manufacturer	Manufacture (Find the attached dossier)
7.	Device Master File from the manufacturer	Manufacture (Find the attached dossier)
8.	Certificate of Analysis of three batches of each product	From Manufacturer

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