CHECKLIST FOR DOCUMENT ACCEPTING OF MEDICAL DEVICE FOREIGN MANUFACTURING SITE APPLICATION

National Medicines Regulatory Authority, Sri Lanka

Application No:

Name of the Legal Manufacturer:

Name/s of the Actual Manufacturer:

Name of the Local Agent:

	Document	Page Number	Availability	Remark
1.	E-mail Confirmation			
2.	Application form for registration of manufacturing site overseas manufacturer of medical devices			
3	Copy of Business Registration of authorized local agent			
4.	Copy of Board of Directors' registration of authorized local agent (If applicable)			
5.	Copy of company registration (Form 01)			
6.	Letter of Authorization (If the legal manufacturer appointed more than one local agent tabulated letter of authorization including the detail of all local agent, product range and actual sites should be submitted)			
7.	Declaration letter from manufacturer stating that there is no further local agents appointed at present			
8.	Declaration of the status of the manufacturer (Whether own site, contract site or any other specify)			
9.	Valid GMP/ Free Sale Certificate/ Hygienic Certificate issued by health authority			
10.	Valid ISO quality management certificate certificate			
11.	Site master file (SMF)			
12.	Declaration letter from manufacturer stating that information given in SMF and/or other documents submitted with same is correct			
13.	Consent letter from the local agent to withdraw the application when the NMRA noticed duplications			
14.	Declaration letter from regulatory officer of the local agent stating that information given in this application is correct			

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Signature

Name:

Designation of the applicant:

Date:

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Signature

Name:

Designation of the accepting officer:

Date: