APPLICATION FOR REGISTRATION OF MANUFACTURING SITE

OVERSEAS MANUFACTURER OF MEDICAL DEVICE

PART-A: General information on local agent (LA)	
Name of the company	
Business Registration No	
Contact details of registered office	
Address	
TP #	
Email address	
Fax #	
Contact details of warehouse	
Address	
TP #	
Email address	
Fax #	

PART-B: General information on manufacturer	
Status of the manufacturer Existing manufacturer ☐ New manufacturer ☐	
Name of the legal manufacturer	(Separate application shall submit for different legal entity)
Address of registered office	
TP #	
Email address	
Fax #	
Details of manufacturing sites (Separate application shall submit for manufacturing site/s which are located in different countries. Site/s which are located in a same country can be added in the same application)	
Site 1 :	
Name	
Address	
Country	
TP #	
Email address	
Fax #	

Site 2 (If applicable) :	
Name	
Address	
Country	
TP #	
Email address	
Fax #	
Site 3 (If applicable):	
Name	
Address	
Country	
TP #	
Email address	
Fax #	
Site 4 (If applicable):	
Name	
Address	
Country	
TP #	
Email address	
Fax #	
Site 5 (If applicable):	
Name	
Address	
Country	
TP #	
Email address	
Fax #	

PART C: Product information (Please tick the appropriate box)	
Category of the medical device	General Medical Devices ☐ In vitro Diagnostic Devices ☐

PART D: List of supporting documents (compulsory to submit with this application)	**Page number (To be filled by the applicant)**	**NMRA use only (Assigned Evaluator)**
1. Copy of Business Registration of authorized local agent		
2. Copy of Board of Directors' Registration of Authorized Local Agent (If applicable)		
3. Company registration (Form 01/15/40)		
4. Site master file (SMF) Note: It is required to submit information as per the NMRA requirements for site master file (Refer NMRA website)		
5. Declaration letters		
5.1 Declaration letter from manufacturer stating local representation, manufacturing site status, readiness for inspection, and accuracy of submitted documents.		
5.2 Declaration letter from regulatory Pharmacist/qualified person stating that information given in this application is correct.		
5.3 Declaration letter from legal manufacturer mentioning the details of other manufacturing sites belong to the legal manufacturer and which are not included in the application		
5.4 Consent Letter from local agent to withdraw the application when the NMRA noticed duplications		
6. List of exporting countries		

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Signature of Regulatory Pharmacist/ Qualified person

Name :

Designation :

Date :

NMRA use only

Comments of Assigned Evaluator:
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Signature / Date (Assigned Evaluator) :

Signature / Date (Checking Evaluator/ Head Of the Division):