**APPLICATION FOR REGISTRATION OF MANUFACTURING SITE**

**OVERSEAS MANUFACTURER OF MEDICAL DEVICE**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Have you already submit this application through e- NMRA?**  Yes No | | | | | | | | |
| If Yes, Reference **FMSA number** | | |  | | | Date of submission |  | |
| **Status of online application**  (please tick relevant box if you already submit applications through e- NMRA) | | | | | | | | |
| Screening level (pending payment ) |  | Review level  (after payment ) | |  | Invoice number of system generated payment receipt  (if available) | | |  |

|  |  |  |
| --- | --- | --- |
| **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)** | |
| Type of products to be inspected | Sterile ☐ Non sterile ☐ |
| Class of device as per NMRA classification | General Medical Devices (Class I, IIa, IIb, III) ☐  In vitro Diagnostic Devices ( IVD – Class A, B, C, D) ☐  Listed device ☐ |

|  |  |  |
| --- | --- | --- |
| **PART D: List of supporting documents** (compulsory to submit with this application ) | **Page number**  **(filled by the applicant)** | **NMRA use only( Assign pharmacist)** |
| 1. Copy of Business Registration of authorized local agent |  |  |
| 1. Copy of Board of Directors’ Registration of Authorized Local Agent ( If applicable) |  |  |
| 1. Site master file (SMF) (Only for Class IIb and Class III and IVD Class D devices)   Note: It is required to submit information as per annexure 4  (Refer NMRA web site for Requirement for site master file) |  |  |
| 1. 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 site should be submitted) |  |  |
| 1. Declaration letter from manufacturer stating that there is no further local agents appointed at present. |  |  |
| 1. Declaration of the status of the manufacturer (whether own site , contract site or any other specify) |  |  |
| 1. Valid GMP / Free Sale certificate/ hygienic certificate issued by health authority of country of origin (not mandatory for listed devices) |  |  |
| 1. Valid manufacturing license with product list (If applicable) |  |  |
| 1. Valid quality management system certificate issued by authorized notified body according to ISO (Particular site/s details and scope/s should be included in the certificate) |  |  |
| 1. Certification issued by chamber of commerce (If applicable) |  |  |
| 1. Details of other manufacturing sites belong to this legal manufacturer and which are not included in this application. |  |  |
| 1. Declaration letter from manufacturer stating that premises is ready to be inspected any time |  |  |
| 1. List of exporting countries |  |  |
| 1. Declaration letter from manufacturer stating that information given in SMF and/or other documents submitted with same is correct |  |  |
| 1. Consent letter from local agent to withdraw the application when the NMRA noticed duplications. |  |  |
| 1. Declaration letter from regulatory Pharmacist/ qualified person stating that submitted information/documents are same as already submitted application through online. |  |  |
| 1. Declaration letter from regulatory Pharmacist/ qualified person stating that information given in this application is correct |  |  |
| 1. Evidence for online submission (Please attached relevant email notifications, printout of online applications, payment receipts, and bank slips etc.) |  |  |

|  |
| --- |
| ……………………………………………  Signature of Regulatory Pharmacist/ Qualified person  Name :  Designation :    Date : |

|  |
| --- |
| NMRA use only    Comments of Assign pharmacist  .................................................................................................................................................................  ……………………………………….............................................................................................……  Signature / Date (Assign pharmacist) :    Signature / Date (Checking pharmacist/Focal point): |