|  |  |  |
| --- | --- | --- |
| Format: QMS/FMT/002Revision No: 1Effective Date: 20 June 2022 | Department/Division/Office/Unit | DFAR Department/HMDAR Division |
| Document Type: **Form** | Doc. No | :DFAR/HMDAR/FOM/023 |
|  | Title:**Application Form for Medical Devices and In Vitro Diagnostics Devices (IVDDs) notification** | Revision Number | : 0 |
| Revision Date:  | : 17/10/2022 |
| Effective Date | : 31/10/2022 |
| Review Due Date | : 30/10/2025 |
| Ref Doc.  | : |
| **Application Number** | **Rwanda FDA use only** |
| **Date of submission of dossier** | **Rwanda FDA use only** |
| 1.0 PARTICULARS OF THE MEDICAL DEVICE or IVDD (**Bold or Tick** the right type of application) |
| 1.1 | Type of application New  Renewal  Variation\*\* If variation has been made, information supporting the changes should be submitted.  |
| 1.2 | Name of the Medical Device or IVDD  |
| 1.3 | Classification of the Medical Device or IVDD  |
| 1.4 | Intended use of the Medical Device or IVDD Intended user:* Professional
* self user
 |
| 1.5 | Name and address (physical and postal) of ApplicantAddress: Country: Telephone: Telefax: E-Mail:  |
| 1.6 | Name and address ( physical and postal) of manufacturerAddress: Country: Telephone: Telefax: E-Mail  |
| 1.7 | Visual description of the Medical Device or IVDD  |
| 1.8 | Proposed shelf life (in months) (where applicable):  |
| 1.9 | Proposed storage conditions (where applicable):  |
| 1.10 | Other regulatory authority(ies) approval(s) (i.e. European conformity (CE) mark, United States Food and Drug Administration (USFDA) approval, etc)  |
| 1.11 | Country of origin (where the device was manufactured)  |
| 1.12 | Name(s) and physical address(es) of the manufacturing site(s) of the Medical Device or IVDD. Alternative sites should be also declared here.All manufacturing sites involved in the manufacturing process of the device, stating the role of each including quality control / in-process testing sites should be listed.Address: Country: Telephone: Telefax: E-Mail:  |
| 1.13 | Name and address (physical and postal) of the Agent/Local Technical Representative (LTR) (Attach a valid appointment letter notarized from the country of origin): Address: Country: Telephone: Telefax: E-Mail:  |
| 1.14 | Declaration of Conformity specifying all standards used in the manufacturing of the Medical Device or IVDD  |
| 1.15 |

|  |  |
| --- | --- |
| Global Medical Device Nomenclature (GMDN) Name |  |
| GMDN Code |  |

 |
| 1.16 | Version of the product insert (attach a copy of relevant labeling including the Instruction For Use (IFU)) |
| 2.0 DECLARATION BY THE APPLICANT |
| I, , the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge. I further confirm that the information referred to in my application dossier is available for verification during the Quality audit inspection. I also agree that I shall carry out pharmacovigilance and Post-marketing Surveillance to monitor the safety, quality and performance of the device on the market and provide safety, quality and performance update reports to Rwanda FDA.I further agree that I am obliged to follow the requirements of Rwanda's Legislations and Regulations, which are applicable to Medical Devices and IVDDs. I also consent to the processing of information provided to Rwanda FDA. It is hereby confirmed that fees will be paid/have been paid according to the authority’s rules\* Signature:Date: \* **Note**: If fees have been paid, attach proof of payment |