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| **Application Number** | | **Rwanda FDA use only** |
| **Date of submission of dossier** | | **Rwanda FDA use only** |
| 1.0 PARTICULARS OF THE DEVICE or IVD | | |
| 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 device or IVD | |
| 1.3 | Classification of the device or IVD | |
| 1.4 | Intended use of the device or IVD | |
| 1.5 | Name and address (physical and postal) of Applicant  Address:  Country:  Telephone:  Telefax:  E-Mail | |

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| 1.6 | Name and address ( physical and postal) of manufacturer  Address:  Country:  Telephone:  Telefax:  E-Mail |
| 1.7 | Visual description of the device or IVD |
| 1.8 | Proposed shelf life (in months) (where applicable): |
| 1.9 | Proposed storage conditions (where applicable): |
| 1.10 | Other sister medical device (s) or IVD (s) registered or applied for registration |
| 1.11 | Do you hold Marketing Authorization(s) of other medical device(s) or in vitro diagnostics (IVDs) in any of the East African Community (EAC)?   Yes   No  If yes state Device or IVD name:  Regulatory Authority(ies) where product is authorized:  Marketing authorization number(s):  Indication(s): |
| 1.12 | Have you applied for Marketing Authorization(s) of medical device(s) or in vitro diagnostics (IVDs) in any of the country of East African Community (EAC)?   Yes   No  If yes state  Device name or IVD:  Regulatory Authority(ies) where you have applied for registration:  Indication(s): |
| 1.13 | Country of origin |
| 1.14 | Device Marketing Authorization in the country of origin (Attach Marketing Authorization of the device or IVD from the National Regulatory Authority). If not registered, state reasons   |  |  | | --- | --- | |  Authorized Country:  Date of authorization:  Authorization number:   Refused Country:  Date of refusal:  Reason of refusal: |  Withdrawn (by the applicant after authorization) Country:  Date of withdrawal:  Reason of withdrawal:   Suspended/revoked (by competent authority) Country:  Date of suspension/revocation:  Reason for suspension/revocation: | |
| 1.15 | Name(s) and physical address (es) of the manufacturing site (s) of the device or IVD. 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 |
| 1.16 | Name and address (physical and postal) of the Agent/Local Technical Representative (LTR)  Address:  Country:  Telephone:  Telefax:  E-Mail |
| 1.17 | Name and address (physical and postal) of the person or company responsible for Pharmacovigilance and Post Marketing Surveillance  Address:  Country:  Telephone:  Telefax:  E-Mail |
| 1.18 | State declaration of Conformity such as ISO Certificate(s) used for manufacturing of device or IVD |
| 1.19 | Qualitative and Quantitative composition of the device or IVD (If applicable) |
| 1.20 | Name and address (physical and postal) of the Contract Research Organisation(s) where the clinical studies of the device or IVD were conducted. (If applicable)  Address:  Country:  Telephone:  Telefax:  E-Mail |
| 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 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 Legislations and Regulations, which are applicable to IVDs and Medical Devices. 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 | |