# APPENDIX VI: APPLICATION SUBMISSION CHECKLIST

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **HAVE YOU INCLUDED THE FOLLOWING ITEMS IN YOUR APPLICATION? (INDICATE WITH A TICK)** | **Particulars to be filled by applicant** | **Yes** | **No** | **Remarks by assessor** |
|  | * + 1. **Details of the applicant**

Name Physical addressTelephone Email |  |  |  |  |
| **ALL APPLICATIONS** | 1. Soft copies of application
 |  |  |  |  |
| 1. Cover letter
 |  |  |  |  |
| 1. Correct application fees
 |  |  |  |  |
| * + 1. **Product details:**
 |  |  |  |  |
| 1. Proprietary/brand name
 |  |  |  |  |
| 1. Brief description of the appliance
 |  |  |  |  |
| 1. Class/Category of the appliance
 |  |  |  |  |
| 1. Intended use and method of use
 |  |  |  |  |
| 1. Medical specialty in which appliance is used
 |  |  |  |  |
| 1. Contraindications, warnings, precautions, potential adverse effects
 |  |  |  |  |
| 1. List of accessories and other appliances or equipment to be used in combination with the appliance
 |  |  |  |  |
| 1. Variations in shape, style or size of the appliance, if applicable
 |  |  |  |  |
| 1. Labelling details
 |  |  |  |  |
| 1. Packaging description including pack sizes.
 |  |  |  |  |
| 1. Recommended storage condition
 |  |  |  |  |
| 1. Two samples where practicable
 |  |  |  |  |
| 1. Certificate of analysis
 |  |  |  |  |
| 1. **Manufacturer details**
 |  |  |  |  |
| 1. Site name, physical address, telephone, fax and e-mail
 |  |  |  |  |
| 1. Particulars of other sites, if applicable
 |  |  |  |  |
| 1. Copy of manufacturing license(s)
 |  |  |  |  |
| 1. Evidence of repeat sales in country of manufacture
 |  |  |  |  |
| 1. Manufacturer's declarations to essential principles of safety and performance
 |  |  |  |  |
| 1. **LTR/Authorised agent in Uganda:** Name, physical address, telephone, fax and e-mail
 |  |  |  |  |
| 1. NOTARIZED POWERS OF ATTORNEY in country of origin for the LTR/Authorised agent
 |  |  |  |  |
| **TRACK 1** | 1. If the appliance is licensed in one of the IMDRF founding member countries
 |  |  |  |  |
| 1. Notarized copy of a license in a IMDRF member country
 |  |  |  |  |
| **TRACK 2** | 1. *If the appliance is NOT licensed in one of the IMDRF founding member countries*
 |  |  |  |  |
| 1. Evidence of conformity to standards from a certification body accredited by a regulatory authority in one of the IMDRF founding member countries or a recognized international organization
 |  |  |  |  |
| **TRACK 3** | 1. If the appliance does NOT have certification for any of the international quality system standards
 |  |  |  |  |
| 1. Manufacturer’s Declaration of Conformity (DOC) to IMDRF Essential Principles of Safety and Performance or as in appendix II of NDA guidelines
 |  |  |  |  |
| 1. Summary information on pre-clinical design verification and validation
 |  |  |  |  |
| 1. Summaries or reports of tests and evaluations based on other standards, manufacturer rules and tests, or alternative ways of demonstrating compliance. The data may cover:
2. engineering tests
3. laboratory tests (e.g.: sterility tests, metrology tests, etc)
4. biocompatibility tests where applicable
 |  |  |  |  |
| **Confirmation:** I confirm that all the relevant information for my application has been submitted as filled out in this checklist**Name and designation of signatory: ...................................................................****Signature and date: ............................................................................................****Tel: ..........................................................Email: .................................................****Name and designation of full-time contact person** **(if different from signatory): ..............................................................................****Tel: ...........................................................Email: ................................................*****Note: In case there is a change in the contact person, NDA should be notified immediately.*** |

Provide PDF OCR readable softcopy, a Microsoft word document along with application in USB/CD

Decision: Accept or Refuse to Accept

**Reviewed by:**

Name signature Date

**Approved by:**

Name signature Date