NOTE: **ALLOW 30 WORKING DAYS FOR ADMINISTRATION**

1. **PRIMARY IMPORTER - APPLICANT**

|  |  |
| --- | --- |
| Company Name:**(REGISTERED NAME ONLY)** |  |
| Postal Address: | Street Address: |
|  |  |
|  |  |
|  |  |
| Company Registration no (CICP): |
| New applicant | YES | NO | Existing File no: |

1. **PRODUCT INFORMATION**

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| --- |
| Brand: |
| Model:  |
| Technical File no.: |
| Intended purpose of this device according to the manufacturer’s labelling and instructions for use: |
|  |
|  |
|  |

1. **MANUFACTURER**

|  |
| --- |
| Name: |
| Address: |
|  |
|  |
| Contact Person: |
| Contact person email: |

1. **COMPANY CONTACT PERSON FOR ALL REGULATORY CORRESPONDENCE**

|  |
| --- |
| Name: |
| Designation: |
| Tel: | Cell no.: |
| Email: |

1. **DECLARATION BY APPLICANT**

|  |
| --- |
| **I\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_hereby declare that all** **information supplied is true and correct.****Signature: Date:**  |

**Requirements:**

The applicant must supply the following documentation in support of their application:

[ ] Annexure **A**: Completed application form 41BM-1(CLINIMP);

[ ] Annexure **B**: Colour brochure (including technical specifications);

[ ] Annexure C: Letter of appointment as authorised representative of the original manufacturer;

[ ] Annexure D: **EC Certificate(s) issued by a Notified Body** for the model concerned in terms of MDD 93/42/EEC, MDD MDR 2017/745/EU (whichever one is applicable)

[ ] Annexure E: **EC Declaration of Conformity by the manufacturer** in terms of MDD 93/42/EEC, or MDR 2017/745/EU (whichever one is applicable).

AND

[ ] Annexure **1**: Proof of registration of the clinical trial on the South African National Clinical Trials Register (www.sanctr.gov.za), i.e. the National Register Number;

[ ] Annexure **2**: List of the medical institutions where the clinical trial will be conducted;

[ ] Annexure 3: List of the medical practitioners who will supervise the clinical trial

[ ] Annexure **4**: Copy of the letter in which the Medical Ethics Committee of a medical institution gives approval for the clinical trial to be performed at that particular medical institution;

[ ] Annexure 5: Copy of the approved Research Protocol for the clinical trial;

[ ] Annexure 6: Copy of the “Informed Consent” form.

**Please note:**

* Please allow 4-6 weeks for processing of your import application; the 4-6 weeks’ timeline is on condition that all required documentation have been submitted.
* Completed applications in terms of guideline SAHPGL-RDN-XR-24\_v1 must be submitted to import.xrays@sahpra.org.za
* Once successful the applicant will also be required to complete an application for use to satisfy regulatory requirements in terms of the Hazardous Substances Act, Act 15 of 1973