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

1. **MANUFACTURER /REFURBISHER IN SOUTH AFRICA - APPLICANT**

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

1. **PRODUCT INFORMATION**

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

1. **AUTHORISED REPRESENTATIVE IN THE EUROPEAN UNION IF SELLING WITHIN THE EUROPEAN UNION**

|  |
| --- |
| Name: |
| Address: |
|  |
|  |
| Contact no.: |
| Email: |

1. **COMPANY CONTACT PERSON (for all regulatory correspondence)**

|  |  |
| --- | --- |
| Name: | |
| Designation: | |
| Tel: | Cell: |
| 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 for **each** model to be imported:

Annexure 1: Completed application form 41BM-1(MAN);

Annexure 2: Colour brochure (including technical specifications);

Annexure 3: **EC Certificate(s) issued by a Notified Body to the manufacturer/refurbisher in South Africa** in terms of MDD 93/42/EEC or MDR 2017/745/EU (whichever one is applicable);

Annexure 4: **EC Declaration of Conformity by the manufacturer/refurbisher** **in South Africa** in terms of MDD 93/42/EEC, or MDR 2017/745/EU (whichever one is applicable).

**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](mailto:import.xrays@sahpra.org.za)