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. **MANUFACTURER**

|  |
| --- |
| Name: |
| Address: |
|  |
|  |
| Contact Person Name for manufacturer: |
| Contact Person Email for manufacturer: |

1. **PRODUCT INFORMATION**

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

1. **AUTHORISED REPRESENTATIVE IN THE EUROPEAN UNION**

|  |
| --- |
| Name: |
| Address: |
|  |
|  |
| Contact no.: |
| Email: |
| 1. **COMPANY CONTACT PERSON IN SOUTH AFRICA (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(IMP);

Annexure **2**: Colour brochure (including technical specifications);

Annexure **3**: Letter of appointment as the authorised agent/representative of the original manufacturer in South Africa;

Annexure **4**: **EC Certificate(s) issued by a Notified Body** in terms of MDD 93/42/EEC, MDD MDR 2017/745/EU (whichever one is applicable);

Annexure **5**: **EC Declaration of Conformity by the manufacturer** 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)