**Applications:** **nirmed.application@sahpra.org.za**

 **Enquiries:** **nirmed.enquiry@sahpra.org.za**

**Annual information compliance (ASOCI):** **radcon.asoci@sahpra.org.za**

**A: PRIMARY IMPORTER – APPLICANT**

|  |
| --- |
| **Name:**  |
| **Postal Address:** | **Street Address:** |
|  |  |
|  |  |
|  |  |
|  | **Postcode:** |  |
| **Website:** |

B: PRODUCT INFORMATION

|  |
| --- |
| **Brand:** |
| **Model:** |
| **Intended purpose of this device according to the manufacturer’s labeling and instructions for use:** |
|  |
|  |
|  |

#### C: MANUFACTURER

|  |
| --- |
| **Name:** |
| **Address:** |
|  |
|  |
| **Website:** |

#### D: AUTHORISED REPRESENTATIVE IN THE EUROPEAN UNION

|  |
| --- |
| **Name:** |
| **Address:** |
|  |
| **Website:** |
| **Email:** | **Fax:** |

E: COMPANY CONTACT PERSON (for all regulatory correspondence)

|  |
| --- |
| **I, ……………………………………………………………………… declare all the information supplied to be correct and true.** |
| **Signature:** | **Date:** |
| **Title (Mr, Ms, Mrs, Dr, etc.):** | **Designation:** |
| **Tel:** | **Cell:** |
| **Email:** | **Fax:** |

**REQUIREMENTS**

**re**

**APPLICATION FOR A LICENCE TO IMPORT
A NEW LISTED ELECTROMEDICAL DEVICE**

The applicant must supply the following documentation for **each** model to be imported:

(Please note: \* Faxed applications will not be acceptable;
\* The electronic version of any document will be acceptable only if it is in either MS Word or pdf format)

**🞏** Annexure **1**: Completed application form 41BM-1(IMP); ***and***

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

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

**🞏** Annexure **4**: **EC Certificate(s) issued by a Notified Body** in terms of MDD 93/42/EEC, MDD 90/385/EEC or MDR 2017/745/EU (whichever one is applicable); ***and***

**🞏** Annexure **5**: **EC Declaration of Conformity by the manufacturer** in terms of MDD 93/42/EEC, MDD 90/385/EEC or MDR 2017/745/EU (whichever one is applicable).