DEPARTMENT OF HEALTH
Directorate: Radiation Control

APPLICATION FOR A LICENCE TO IMPORT A NEW LISTED ELECTROMEDICAL DEVICE

HAZARDOUS SUBSTANCES ACT, 1973 (ACT 15 OF 1973)

Postal Address: Directorate: Radiation Control, Private Bag X62, Bellville, 7535
Street Address: 2nd Floor, Louwville Place, cor. Vrede & Kort St., Bellville, 7530
Enquiries: Tel: 021 - 948 6162 Fax: 021 - 946 1589

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 labelling 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

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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 Acrobat format)

- ☐ Annexure **1**: Completed application form 41BM-1(IMP); ***and***
- ☐ Annexure **2**: Colour brochure (including technical specifications); ***and***
- ☐ Annexure **3**: Letter of appointment as authorised representative of the original manufacturer; ***and***
- ☐ Annexure **4**: **EC Certificate(s) issued by a Notified Body** in terms of EC Directive 93/42/EEC or 90/385/EEC (whichever one is applicable); ***and***
- ☐ Annexure **5**: **EC Declaration of Conformity by the manufacturer** in terms of EC Directive 93/42/EEC or 90/385/EEC (whichever one is applicable).