DEPARTMENT OF HEALTH
Directorate: Radiation Control

APPLICATION FOR A LICENCE TO MANUFACTURE OR FULLY REFURBISH A LISTED ELECTROMEDICAL DEVICE IN SOUTH AFRICA

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: MANUFACTURER/REFURBISHER - 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:	
Manufacture in SA?	**Fully refurbish in SA?**

C: 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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The applicant must supply the following documentation for **each** model to be manufactured or fully refurbished in South Africa:

(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(MAN); ***and***
- ☐ Annexure **2**: Colour brochure (including technical specifications); ***and***
- ☐ Annexure **3**: **EC Certificate(s) issued by a recognised Notified Body to the manufacturer/ refurbisher in South Africa** in terms of EC Directive 93/42/EEC or 90/385/EEC (whichever one is applicable); ***and***
- ☐ Annexure **4**: **EC Declaration of Conformity issued by the manufacturer/refurbisher in South Africa** in terms of EC Directive 93/42/EEC or 90/385/EEC (whichever one is applicable).