DEPARTMENT OF HEALTH
Directorate: Radiation Control

APPLICATION FOR A LICENCE TO IMPORT A LISTED ELECTROMEDICAL PRODUCT FOR CLINICAL TRIALS

HAZARDOUS SUBSTANCES ACT, 1973 (ACT 15 OF 1973)

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A: APPLICANT (PRIMARY IMPORTER)

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

B: PRODUCT INFORMATION

Brand:
Model:
Intended purpose of this device according to the data supplied by the manufacturer on the labelling, and in the instructions and promotional materials:
Manufacturer Name:
Manufacturer Address:
Manufacturer Website:

C: COMPANY CONTACT PERSON (for all regulatory correspondence)

Name:	**Title:**
Designation:	
Tel:	**Cell:**
Fax:	**E-mail:**
I declare the information supplied above to be correct and true to the best of my knowledge.	
Signature:	**Date:**

REQUIREMENTS

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APPLICATION FOR A LICENCE TO IMPORT A NEW LISTED ELECTROMEDICAL PRODUCT FOR CLINICAL TRIALS

If the intention is to conduct clinical trials on a listed electromedical product, before it has been licensed to be imported into South Africa for commercial distribution, the importer must supply, for each model to be imported, the documentation indicated in Annexures A - C and 1 – 6 (below):

- ☐ Annexure **A**: Completed application form 41BM-1(CLIN); ***and***
- ☐ Annexure **B**: Technical specifications; ***and***
- ☐ Annexure **C**: Letter of appointment as authorised representative of the original manufacturer (if the original manufacturer is not directly represented in South Africa)

AND

- ☐ Annexure **1**: Proof of registration of the clinical trial on the South African National Clinical Trials Register (www.sanctr.gov.za), i.e. the National Register Number; ***and***
- ☐ Annexure **2**: List of the medical institutions where the clinical trial will be conducted; ***and***
- ☐ Annexure **3**: List of the medical practitioners who will supervise the clinical trial; ***and***
- ☐ Annexure **4**: Copy of the letter in which the Medical Ethics Committee of a medical institution gives approval for the clinical trial to be performed **at that particular medical institution**; ***and***
- ☐ Annexure **5**: Copy of the approved Research Protocol for the clinical trial; ***and***
- ☐ Annexure **6**: Copy of the "Informed Consent" form.

Please note that the electronic version of any document will be acceptable only if it is in either MS Word or Acrobat format