DEPARTMENT OF HEALTH
Directorate: Radiation Control

APPLICATION FOR A LICENCE TO CONDUCT CLINICAL TRIALS ON A LOCALLY MANUFACTURED LISTED ELECTROMEDICAL PRODUCT

HAZARDOUS SUBSTANCES ACT, 1973 (ACT 15 OF 1973)

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A: APPLICANT (MANUFACTURER)

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 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 CONDUCT CLINICAL TRIALS ON A NEW LISTED ELECTROMEDICAL PRODUCT

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

- ☐ Annexure **A**: Completed application form 41BM-1(CLIN); ***and***
- ☐ Annexure **B**: Technical specifications;

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