DEPARTMENT OF HEALTH

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Reference 933/14744

Date: 15 January 2009

Attention: DR WOUTER DE WET

- **This document contains the licences for electromedical devices as well as the licence conditions that are currently valid.**
- Apart from the other licensing considerations, the import licence for each individual model is issued on the strength of the fact that the intended purpose, as stated in the application form, is considered to be in agreement with the intended purpose of the device as reflected in the manufacturer's labelling and instructions for use (i.e. documentation required in terms of the certification process according to EC Directive 93/42/EEC or 90/385/EEC, whichever is applicable).
- The licence for each model remains valid only while the EC compliance documentation is valid.
- The safety and performance of all the licensed models remain the responsibility of the licence holder.
- Inspections may be performed to ascertain whether the licence conditions are being adhered to.

Yours faithfully

for DIRECTOR-GENERAL: HEALTH

DEPARTMENT OF HEALTH

DIRECTORATE: RADIATION CONTROL

LICENCE HOLDER: DR WJ DE WET

ADDRESS: DE WET MEDICAL CENTER , CNR.PRESIDENT AND KRAALKOP STREETS , FOCHV

LIST OF LICENCES TO IMPORT NEW ELECTROMEDICAL DEVICES HAZARDOUS SUBSTANCES ACT (ACT 15 OF 1973)

LICENCE NUMBER	BRAND	MODEL	LICENCE CONDITIONS
933/14745	ONDAMED	ONDAMED MA8 SYSTEM	01, 09

Signed at Bellvile on **15 January 2009**

for DIRECTOR-GENERAL: HEALTH

LICENCE CONDITION 01

a) The licence holder must keep a record of every transaction of this model, and such record must include the following information:

(i) Name and address of the purchaser.
(ii) Brand, model and serial number.
(iii) Date of transaction.

b) Any advertisement or other kind of promotional material may only contain the information about the **intended purpose** of this particular model that was supplied in the application form initially.

c) If the Department of Health is associated with this model in any advertisement or in other way, the following disclaimer must be clearly displayed, along with the licence number issued to this particular model:

"This device has been licensed by the Department of Health. The device therefore complies with the Department's minimum safety requirements, but its clinical efficacy has not been evaluated."

d) If this model is used in a medical application, the fact that it has been licensed by the Department of Health may not be used in any way by the licence holder as the basis for any claim regarding the clinical efficacy of this model.

e) This model may not be promoted or represented in any way as having been approved by the Department of Health.

f) If it comes to the notice of the licence holder or if the licence holder has reason to suspect that units of this model has a defect or a fault, the licence holder must immediately notify the Directorate: Radiation Control of the relevant facts. This written notification must contain the following information:

(i) Licence No, Brand and Model (as on licence)
(ii) Date on which and circumstances under which such defect or fault was discovered or first suspected
(iii) Description of the defect or fault
(iv) Evaluation of the risk of injury resulting from such defect or fault
(v) Number of units of this model that have been distributed in South Africa
(vi) Proposed plan for rectifying such defect or fault - for approval by the Directorate: Radiation Control
(vii) Date when execution of such plan is expected to be completed
(viii) Proposed instructions regarding the use of this model pending the rectification the defect or fault - for approval by the Directorate: Radiation Control

g) This licence is also subject to the provisions of the Regulations relating to Group III Hazardous Substances (Regulation R690, 14 April 1989).

Signed at Bellvile on 15 January 2009

for DIRECTOR-GENERAL: HEALTH

LICENCE CONDITION 09

ANNUAL SUBMISSION OF COMPLIANCE INFORMATION

The licence holder must submit the following information by 1 May 2009 with respect to this model, using form 41BM-2:

(i) Classification according to Annex IX of EC Directive 93/42/EEC
(ii) Annex(es) employed for conformity assessment
(iii) EC Certificate No(s)
(iv) Date(s) of EC Certificate(s)
(v) Expiry Date(s) of EC Certificate(s)
(vi) Notified Body Identification No
(vii) Date of EC Declaration of Conformity by the manufacturer

Signed at Bellvile on 15 January 2009

for DIRECTOR-GENERAL: HEALTH