DEPARTMENT OF HEALTH

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MEDEX AFRICA IMPORT AND EXPORT
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Enquiries: X-Ray devices: Ms N.P. de Koker
Other devices: Mr J.F. Uys
Mr S. G. Diedericks

Reference 983/15428

Date: 04 September 2009

Attention: George Lenghel

- **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: MEDEX AFRICA IMPORT AND EXPORT

ADDRESS: 115 9th Street , Orange Grove , 2192

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

LICENCE NUMBER	BRAND	MODEL	LICENCE CONDITIONS
983/15429	DEXCO	DX3000	01, 03, 09
983/15430	DEXCO	ADX4000	01, 03, 09

Signed at Bellvile on **04 September 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 **04 September 2009**

for DIRECTOR-GENERAL: HEALTH

LICENCE CONDITION 03

a) Details of transaction

(i) Details of a transaction (form RC011-1(DIAGNOSTIC) OR form RC011-1(DENT) OR form RC011-1(rev 1) must be submitted by the licence holder to the Director: Radiation Control within 21 days after the transaction has been finalised.

(ii) If the licence holder makes use of a third party to perform the final transaction with the end-user, the licence holder must still take full responsibility to ensure that all the paragraphs under licence condition 01 and 03 are implemented.

b) Any X-ray unit as well as any therapeutic X-ray unit and electron accelerator.

(i) The licence holder must provide the purchaser with a copy of the application form RC001-1 (**EXCLUDING** dental X-ray equipment) or in the case of radiotherapy equipment form RC003-1.

(ii) Installation of any unit/component may commence only after the licence holder has received the form RC011-1 (DIAGNOSTIC) OR form RC011-1(rev 1) OR form RC011-1(DENT) OR form RC011-1(R) from the Department of Health with the following wording stamped on it - **MAY INSTALL.**

(iii) If this model is a mobile X-ray unit, the licence holder must inform the purchaser that the Department of Health will licence mobile X-ray units exclusively for mobile diagnostic radiography.

(iv) If this model is a diagnostic X-ray unit/component (**EXCLUDING** lithotripter, bone densitometer, and dental X-ray unit), the licence holder must ensure that the applicable acceptance tests as set out in the document **Diagnostic QC** are performed before the unit is put into clinical service. After **March 2009** all the acceptance tests prescribed in document **Diagnostic QC** must be performed by an **Inspection Body** approved by the Department of Health.
(http://www.doh/department/radiation/01.html->Licensing->Electronic Products ->Licence Conditions).

(v) If this model is licensed as a component, the licence holder must draw up a declaration in which the licence holder states that the compatibility of this component has been verified in accordance with the manufacturers' instructions and that the licence holder has carried out the installation in accordance with these instructions. The licence holder must provide the purchaser with a copy of this declaration.

(vi) If this model is a fixed fluoroscopic x-ray unit, the licence holder must ensure that each unit sold after January 2007 is equipped with a Dose Area Product (DAP) meter or a device that provides a dose readout during fluoroscopy.

c) Class 3b or Class 4 laser

(i) If this model is a Class 3b or Class 4 laser device, the licence holder must provide the purchaser with a copy of the application form SBLM-1.

(ii) Any unit of this model may only be supplied to the purchaser if the purchaser possess documentary prove that the required licence to use that unit, has been issued by the Department of Health.

d) MRI

(i) If this model is an MRI device, the licence holder must provide the purchaser with a copy of the application form SBMR-1.

(ii) Installation of any unit may commence only after the licence holder has received form RC011-1(rev 1) back from the Department of Health with the following wording stamped on it - **MAY INSTALL**.

Signed at Bellvile on 04 September 2009

for DIRECTOR-GENERAL: HEALTH

LICENCE CONDITION 09

ANNUAL SUBMISSION OF COMPLIANCE INFORMATION

The licence holder must submit the following information by 1 August 2010 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 04 September 2009

for DIRECTOR-GENERAL: HEALTH