SOUTH AFRICAN HEALTH PRODUCT REGULATORY AUTHORITY

SAHPRA South African Health Products Regulatory Authority
Building A
Loftus Park
402 Kirkness Street
Arcadia
0083

Web: www.sahpra.org.za/radiation-control

FOLIVEX PTY LTD
Unit 2A Stanford Place
De-Havilland Street
Walmer Industrial
PORT ELIZABETH
6070

Enquiries:
X-Ray Devices: Import.xrays@sahpra.org.za
All Other Devices:
nirmed.enquiry@sahpra.org.za

Reference: 1656/30447
Date: 12 Julv 2023

Attention: Nombulelo Williams

- **This updated document contains the licences for electromedical devices as well as the licence conditions that are currently valid, and replaces the document dated 19 May 2021 and all previous documents.**
- Apart from the other licensing considerations, the 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

Digitally Signed by:
Boitumelo Semete-Makokotlela

53e72d92-3391-4cd7-8da3-b6116e65c520

Chief Executive Officer

SAHPRA
South African Health Products Regulatory Authority

SAHPRA

RADIATION CONTROL

LICENCE HOLDER: FOLIVEX PTY LTD

ADDRESS: Unit 2A Stanford Place , De-Havilland Street , Walmer Industrial

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

LICENCE NUMBER	BRAND	MODEL	LICENCE CONDITIONS
1656/30449	RUNYES	RAY68 (W)	01, 03, 09
1656/30874	TRIDENT	I-VIEW	01, 03, 09
1656/30875	TRIDENT	I-VIEW 2	01, 03, 09
1656/30876	TRIDENT	I-VIEW GOLD	01, 03, 09
1656/30877	TRIDENT	I-VIEW GOLD 2	01, 03, 09
1656/31029	TRIDENT	RIX-70-DC	01, 03, 09
1656/32432	TRIDENT	X-VIEW 2D PAN	01, 03, 09
1656/32433	TRIDENT	X-VIEW 2D PAN CEPH	01, 03, 09
1656/32434	TRIDENT	X-VIEW 3D PAN	01, 03, 09
1656/32435	TRIDENT	X-VIEW 3D PAN CEPH	01, 03, 09
1656/34899	RUNYES	RAY68(P)	01, 03, 09

The above model must be supplied with a full length lead apron. Source to Skin Distance (SSD) must be at least 200 mm.

Signed at Pretoria

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Chief Executive Officer

Date

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 SAHPRA.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 SAHPRA**. The device therefore complies with SAHPRA'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 SAHPRA 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 SAHPRA.

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 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 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 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 Pretoria

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Chief Executive Officer **Date**

LICENCE CONDITION 03

IF A THIRD PARTY IS USED TO PERFORM THE FINAL TRANSACTION WITH THE END-USER, THE LICENCE HOLDER IS RESPONSIBLE TO ENSURE THAT ALL PARAGRAPHS UNDER LICENCE CONDITIONS 01 AND 03 ARE ADHERED TO.

a) In the case of any diagnostic X-ray unit, therapeutic X-ray unit , electron accelerator, reporting monitor, CR reader or DDR detector:

(i) For installation and use, the licence holder must submit the appropriate **form** to SAHPRA:

RC-DEALER: Diagnostic X-ray device and related components
RC-DENT: Dental X-ray device and related components
RC003-1 and RC011-1 (rev 1): Therapy equipment

(ii) Delivery or installation of any unit/component may commence only after the licence holder has received approval ("**MAY INSTALL**") from SAHPRA:.

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

(iv) The licence holder must ensure that the applicable acceptance tests are performed before the unit is put into clinical service. All prescribed acceptance tests must be performed by an **Inspection Body** approved by SAHPRA:, for:

- **DIAGNOSTIC** X-ray unit, component, reporting monitor, CR reader / DDR detector (**EXCLUDING** lithotriptor, bone densitometer) as set out in the document **Diagnostic QC** (latest version),

- **DENTAL** X-ray unit and related components, as set out in the document **Diagnostic QC Dental** (latest version).

The above documents are available at (www.sahpra.org.za/radiation-control).

(v) If a reporting monitor is delivered to a client or installed by the licence holder, the licence holder must ensure that the reporting monitor complies with section V (Table 4) of the document **DIAGNOSTIC QC** (latest version) which is available at www.sahpra.org.za/radiation-control

(vi) 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.

(vii) 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.

b) In case of any Class 3b or Class 4 laser:

(i) The licence holder must provide the purchaser with a copy of the latest version of the application form SBLM-1.
(ii) This model may only be supplied to the purchaser once the purchaser possesses documentary proof that the required licence to use that particular unit has been issued by SAHPRA:.
(iii) Details of the transaction involving this model must be submitted by the licence holder on form RC011(MRI) to Radiation Control within 21 days after the transaction has been finalised.

c) In case of any MRI:

(i) The licence holder must provide the purchaser with a copy of the latest version of the application form SBMR-1.
(ii) This model may only be supplied to the purchaser once the purchaser possesses documentary proof that the required licence to use that particular unit has been issued by SAHPRA:.
(iii) Details of the transaction involving this model must be submitted by the licence holder on form RC011(MRI) to Radiation Control within 21 days after the transaction has been finalised.

Signed at Pretoria

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Chief Executive Officer

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LICENCE CONDITION 09

ANNUAL SUBMISSION OF COMPLIANCE INFORMATION

The licence holder must submit the following information by 1 May 2023 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 Pretoria

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