# SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

South African Health Products Regulatory Authority

Enquiries: X-Ray devices: natalie.dekoker@sahpr



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

ADVANCED MACHINERY (PTY)LTD P.O. Box 2312 Edenvale 1610 Enquiries:

X-Ray Devices: Import.xrays@sahpra.org.za All Other Devices: nirmed.enquiry@sahpra.org.za Reference 1360/23331 Date: 02 April 2024

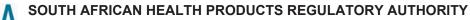
## Attention: Mr Eric Yin

- This updated document contains the licences for devices as well as the licence conditions that are currently valid, and replaces the document dated 2 March 2015 and all previous documents.
  - inspections may be performed to ensure that the licence requirements are adhered to.

Yours faithfully

Boijundo Sente Makokoffeta

**Chief Executive Officer (CEO)** 





**RADIATION CONTROL** 



LICENCE HOLDER: ADVANCED MACHINERY (PTY)LTD

ADDRESS: 2 Makro Place, Sunnyrock, 1401

## LIST OF LICENCES FOR NON MEDICAL DEVICES HAZARDOUS SUBSTANCES ACT (ACT 15 OF 1973)

LICENCE NUMBER	BRAND	MODEL	LICENCE CONDITIONS
1360/23332	ADVANCED MACHINERY	TRUCUT	04
1360/35654	ADVANCED MACHINERY	RAYCUT	04
1360/35655	ADVANCED MACHINERY	LABELMARK	04
1360/35656	ADVANCED MACHINERY	LASERMASTER	04
Signed at Pretoria			

Baifunelo Senrefe Makokotteta

Chief Executive Officer (CEO)

05 April 2024

Date

## **LICENCE CONDITION 04**

- 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) X-ray unit used for industrial, research, educational, security or any other purposes, electron or heavy particle accelerator and a neutron generator

- (i) The licence holder must submit form RC-DEALER to the SAHPRA.
- (ii) Delivery or installation of any unit/component on a premises may commence only after the licence holder has received approval (**RC-DEALER** stamped "**MAY INSTALL**") from SAHPRA.

#### c) Class 3b or Class 4 laser device

- (i) Details of a transaction (form RC011-1(rev 1)) must be submitted by the licence holder to Radiation Control within 21 days after the transaction has been finalised.
- (ii) 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 SBLN-1.
- (iii) Any unit of this model may only be supplied to the purchaser if the purchaser possess documentary proof that the required licence to use that unit, has been issued by SAHPRA.

#### d) MRI

- (i) Details of a transaction (form RC011-1(MRI)) must be submitted by the licence holder to Radiation Control within 21 days after the transaction has been finalised.
- (ii) If this model is an MRI device, the licence holder must provide the purchaser with a copy of the application form SBVETMR-1.
- (iii) Installation of any unit may commence only after the licence holder has received form RC011-1(MRI) back from SAPRA with the following wording stamped on it **MAY INSTALL.**

## e) Sunbed

- (i) If this model is a sunbed, the licence holder must ensure that the sunbed complies with the requirements as outlined in the document "Requirements for sunbeds intended for normal household use and for use in tanning salons, beauty parlours and similar premises".
- (ii) The licence holder must provide the purchaser with a copy of the document "Guidelines for the safe use of sunbeds". https://www.sahpra.org.za/radiation-control/

Signed at Pretoria

Boitumelo Semete Makokotteta

Chief Executive Officer (CEO)

05 April 2024 Date