

## COMMUNICATION TO STAKEHOLDERS

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### **Importing and operating unlicensed dental X-ray equipment is illegal and a health hazard**

It has come to the attention of SAHPRA, that dental X-ray equipment can easily be purchased online by unlicensed retailers and are being imported to South Africa without any authorization. In terms of Hazardous Substances Act, 15 of 1973 and the Regulations thereto, SAHPRA regulates the use of electronic products emitting ionizing radiation (e.g., dental X-Ray devices) classified as Group III. The Hazardous Substances Act prohibits anyone to import, sell, let use, operate, or apply any Group III hazardous substances without a licence issued by the regulator.

SAHPRA has noted an alarming increase of anonymous tip-offs of some dental practices and clinics using illegally imported X-ray equipment. Because the Dental X-ray equipment generates ionizing radiation, they therefore fall under group III hazardous substances. Accordingly, importing, selling and or using the unlicensed or unregistered equipment contravenes section 3 of the Hazardous Substances Act, and if caught the person shall be guilty of an offence that may carry a penalty or criminal offence as provided for in sections 18 and 19 of the Hazardous Substances Act.

SAHPRA, as the Regulator issues import licence to dealers who apply to import dental X-ray equipment that are supplied by manufacturers who meet the regulatory requirements. Part of the requirements includes *inter alia* the submission of an Encumbrance Certificate (EC) issued by a recognized notified body in terms of the EC Directive 93/42/EEC and or 90/385/EEC. *"A notified body is an organisation designated by an EU country to assess the conformity of certain products before being placed on the market"*<sup>1</sup>. Dealers are issued with an import licence with a list of licence number(s) for individual model(s) intended to be imported. The licence to import is issued with certain conditions applicable to different models and considering the intended use of the devices.

Part of the conditions of a licence to import is that dealers are required to report each sale of the device to the Regulator by submitting the appropriate application form. This allows the Regulator to

assess and authorise the applicant by issuing a licence to USE if the applicant meets the regulatory requirements. The dealer licence conditions also prohibit the delivery or installation of any unit/component unless a “May Install” approval has been issued by the Regulator. Another condition for dealers is the annual submission of compliance information (ASOCI) for each model listed under their licence.

Each licence to use or operate a dental x-ray device is issued to appropriately qualified and accredited professionals as per their scope of practice and scope of profession from the Health Professional Council of South Africa (HPCSA). A licence holder may nominate such qualified and accredited persons as the responsible persons as per regulation III.3 d. 2 of the Regulation. In addition, the licence to use is issued with certain conditions that the licence holder must adhere to in addition to the Act and Regulations. An example of such condition includes the acceptance tests and quality control tests to be performed by an approved inspection body <sup>2</sup> on the stipulated period as determined by the Regulator.

Any devices under group III hazardous substances in South Africa must be imported by licenced dealers and must be used by licenced holders. *“Unlicensed devices that are in possession of practitioners or dealers must immediately be reported to SAHPRA in order to verify whether these units can be licensed or whether it must be disposed of in a legal manner”*. Any contravention or suspected illegal activities can be reported via [www.sahpra.org.za/whistleblower](http://www.sahpra.org.za/whistleblower) and enquires may be directed to radiation control via [radcon.enquiries@sahpra.org.za](mailto:radcon.enquiries@sahpra.org.za). Guidelines and application forms are available to assist licence holders and the public and they can be downloaded from <https://www.sahpra.org.za/radiation-control-guidelines-and-codes-of-practice/>

1. [https://ec.europa.eu/info/index\\_en](https://ec.europa.eu/info/index_en)
2. <https://www.sahpra.org.za/radiation-control-inspection-bodies/>
3. <https://www.sahpra.org.za/radiation-control-acts-and-regulations/>
4. <https://www.sahpra.org.za/radiation-control-guidelines-and-codes-of-practice/>

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