Public Summary

Summary for ARTG Entry: 137213 Gunz Dental Pty Ltd - X-ray generator, diagnostic, mobile

ARTG entry for	Medical Device Included Class IIb
Sponsor	Gunz Dental Pty Ltd
Postal Address	Locked Bag 5000, ALEXANDRIA, NSW, 2015 Australia
ARTG Start Date	04/04/2007

Conditions

The automatic conditions applicable to the inclusion of all kinds of medical devices in the Register are as specified in section 41FN of the Therapeutic Goods Act 1989.

The standard conditions that are imposed under section 41FO of the Therapeutic Goods Act 1989 when kinds of medical devices are included in the Register are as set out in the following paragraphs.

For a medical device included in the Register under Chapter 4 and imported into Australia, the Sponsor must ensure that information about the Sponsor is provided in such a way as to allow the sponsor to be identified.

Each sponsor shall retain records of the distribution of all of the sponsor's medical devices included in the Register under Chapter 4. In the case of records relating to a Class AIMD medical device, Class III medical device, or Class IIb medical device that is an implantable medical device, the distribution records shall be retained for a minimum period of 10 years. In the case of records relating to any other device, the distribution records shall be retained for a minimum period of 5 years.

The sponsor of a medical device included in the Register under Chapter 4 shall keep an up to date log of information of the kind specified in Regulation 5.8.

The sponsor shall provide to the Director, Office of Devices, Blood and Tissues, Therapeutic Goods Administration, three consecutive reports which include information of a kind specified in Regulation 5.8 that arises during the reporting period, concerning Class III, Class AIMD or implantable Class IIb medical devices. The reporting period for the first report commences on the date of inclusion and is to be at least a period of six months but not more than 18 months ending on 1 October. For subsequent reports the reporting period is 12 months ending on 1 October.

Where a medical device included in the Register, contains a substance which is included in the Fourth Schedule to the Customs (Prohibited Imports) Regulations or the Eighth Schedule to the Customs (Prohibited Exports) Regulations the Sponsor shall, at the time of importation or exportation of the medical device, be in possession of a licence and a permission for importation or exportation of each consignment of the goods as required by those regulations.

A sponsor shall ensure that a medical device within their control is stored and transported in accordance with the instructions and information provided by the manufacturer.

Manufacturers

Name	Address	Steps
Dexcoin Co Ltd - 48863	1102 3rd E&C Venture Dream Tower 197-33 Guro-dong Guro-gu Seoul, ,	Manufacturing steps not recorded.

Products

1. X-ray generator, diagnostic, mobile

Product Type	Single Device Product	**Effective date**	04/04/2007

GMDN	37605 X-ray generator, diagnostic, mobile
Functional description	Not included on record
Intended purpose	An irradiating device to facilitate dental diagnostic X-ray images
Variant information	

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