



Australian Government
Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

AA-Med Pty Ltd

for approval to supply

AA-Med Pty Ltd - Stationary panoramic dental x-ray system, digital

ARTG Identifier	339859
ARTG Start Date	20/07/2020
Product Category	Medical Device Included Class IIb
GMDN	43369
GMDN Term	Stationary panoramic dental x-ray system, digital
Intended Purpose	X-ray panoramic system, which are intended to produce two-dimensional overview images of maxilloface. The devices use x-ray beam to generate a series of projected image from the flat panel detector, and then a panoramic image is reconstructed by stitching method. This image can be used for diagnostic analysis of maxilloface.

Manufacturer Details	Address	Certificate number(s)
Hefei Meyer Optoelectronic Technology Inc	No 668 Wanjiang West Road High and New Tech Industry Development Zone , Hefei , 230088 China	DV-2020-MC-18446-1

ARTG Standard Conditions

The above Medical Device Included Class IIb has been entered on the Register subject to the following conditions:

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. Stationary panoramic dental x-ray system, digital

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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