



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/tomographic dental x-ray system, digital**

<b>ARTG Identifier</b>	340331
<b>ARTG Start Date</b>	28/07/2020
<b>Product Category</b>	Medical Device Included Class IIb
<b>GMDN</b>	44245
<b>GMDN Term</b>	Stationary panoramic/tomographic dental x-ray system, digital
<b>Intended Purpose</b>	Three dimensional Cone Beam Computer Tomography (CBCT) x-ray system intended to produce three-dimensional images of the human teeth, jaw and skull. The device uses cone shaped x-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations.

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/tomographic dental x-ray system, digital**

### **Product Specific Conditions**

No specific conditions have been recorded against this entry.

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