



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 406623 Philips Electronics Australia Ltd - X-ray system, diagnostic, fluoroscopic, angiographic, application program software

ARTG entry for Medical Device Included Class IIb
Sponsor Philips Electronics Australia Ltd
Postal Address Locked Bag 30, NORTH RYDE BC, NSW, 1670
Australia
ARTG Start Date 22/03/2023
Product Category Medical Device Class IIb
Status Active
Approval Area Medical Devices

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.

Manufacturers

Name	Address
Philips Medical Systems Nederland BV	Veenpluis 6 , Best, 5684 PC Netherlands

Products

1 . X-ray system, diagnostic, fluoroscopic, angiographic, application program software

Product Type	Single Device Product	Effective Date	22/03/2023
GMDN	40868 X-ray system, diagnostic, fluoroscopic, angiographic, application program software		
Intended Purpose	Intended to provide navigation support for cardiovascular devices for heart rhythm disorders, such as catheters and guidewires, by superimposing 3D cardiac anatomical image data, such as CT, MRI, or 3D rotational scan over intra-procedural X-ray images of the same anatomy.		

Specific Conditions

No Specific Conditions included on Record

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