Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	406598	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	A post processing software medical device intended to assist physicians in performing embolization of hypervascular tumors in the liver using interventional X-ray. It provides tools to help the user with the analysis of 3D rotational angiography images. Its output is intended as an adjunct means to help with the planning and guidance of the embolization procedure. It provides real time overlay of 3D rotational angiography images on live 2D X-ray images of the same anatomy to support device/catheter guidance.

Specific Conditions

No Specific Conditions included on Record

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