



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

**Summary for ARTG Entry:** 406599 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
<b>GMDN</b>	40868 X-ray system, diagnostic, fluoroscopic, angiographic, application program software		
<b>Intended Purpose</b>	A tool to assists the user with treatment of structural heart diseases using minimal invasive interventional techniques. In addition to the conventional live fluoroscopy it provides the user with tools to plan and guide the procedure using 3D image data.		

### Specific Conditions

No Specific Conditions included on Record

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