

Department of Health

Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Emergo Asia Pacific Pty Ltd T/a Emergo Australia

for approval to supply

Emergo Asia Pacific Pty Ltd T/a Emergo AustraliaPty Ltd - Picture archiving and communication system, radiology

 ARTG Identifier
 149923

 ARTG Start date
 6/02/2008

Product Category Medical Device Included Class IIa

GMDN 35719

GMDN Term Picture archiving and communication system, radiology

IntelePACS? is a device that receives digital images and data from

various sources (such as, CT scanners, MR scanners, ultrasound systems, R/F units, computer and direct radiographic devices, secondary capture devices, scanners, imaging gateways, or other imaging sources). Images and data can be communicated, processed, manipulated, enhanced, stored, and displayed within the system and/or across computer networks at distributed locations. Post-processing of the images can be performed using Multi Planar Reconstruction (MPR).

Manufacturer Details	Address	Certificate number(s)
Intelerad Medical Systems Incorporated	800 Boulevard de Maisonneuve East 12th Floor Montreal, Quebec, H2L 4L8 Canada	DV-20071219-MC-051346-11

ARTG Standard Conditions

The above Medical Device Included Class IIa 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. Picture archiving and communication system, radiology

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration PO Box 100, Woden ACT 2606 Australia

Phone: 1800 020 653 Email: info@tga.gov.au ARTG Identifier: 149923 ARTG Start Date: 6/02/2008