



Australian Government

Department of Health and Aged Care  
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 Australia - Medical image management system application software**

<b>ARTG Identifier</b>	385183
<b>ARTG Start Date</b>	4/03/2022
<b>Product Category</b>	Medical Device Included Class IIa
<b>GMDN</b>	60724
<b>GMDN Term</b>	Medical image management system application software
<b>Intended Purpose</b>	The software is intended for use in the communication and storage of medical images. The software is also intended for use as a comprehensive solution to view, optimize, and post-process diagnostic medical images as an aid to physicians and other healthcare professionals in the evaluation of digital imaging examinations. Due to special customer requirements based on the imaging modality and clinical focus, the software can be configured with different combinations of clinical applications which are intended to assist the physician in diagnosis or treatment planning. This includes commercially available post-processing techniques such as multi-planar reconstruction (MPR). Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using cleared monitors intended for mammography display. MPR is not intended for mammography use. Not intended for diagnostic use on mobile devices. Rx Only

Manufacturer Details	Address	Certificate number(s)
Heart Imaging Technologies	305 Church at N Hills St Raleigh , North Carolina , 27609 United States Of America	DV-2022-MC-00577-1

## 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. Medical image management system application software

## Product Specific Conditions

No specific conditions have been recorded against this entry.

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