



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Pro Medicus Ltd

for approval to supply

Pro Medicus Ltd - Radiology picture archiving and communication system application software

ARTG Identifier	338810
ARTG Start Date	2/07/2020
Product Category	Medical Device Included Class IIa
GMDN	41670
GMDN Term	Radiology picture archiving and communication system application software
Intended Purpose	Visage Breast Density is a software application intended for use with digital mammography systems. It assesses breast density from a mammography study and provides a density category to aid radiologists in the assessment of breast tissue composition

Manufacturer Details	Address	Certificate number(s)
Visage Imaging GmbH	Lepsiusstrasse 70 , Berlin , 12163 Germany	DV-2020-MC-18338-1

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. Radiology picture archiving and communication system application software

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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