



Medical Device Details

Sponsor: Clinical & Regulatory Services Limited
P O Box 766
Hastings
New Zealand

WAND Reference: 231207-WAND-72FFS9

Sponsors Own Reference: DICOM Grid dba Ambra Health_41670_Class IIa

GMDN: Radiology picture archiving and communication system application software [41670]

Class: IIa

Intended Purpose: Ambra PACS software is intended for use as a primary diagnostic and analysis tool for diagnostic images for hospitals, imaging centers, radiologists, reading practices and any user who requires and is granted access to Patient image, demographic and report information. Ambra Pro Viewer, a component of Ambra PACS, displays, modifies and manages diagnostic quality DICOM images including 3D visualization and reordering functionality. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary diagnosis or image interpretations. Mammographic images may only be viewed using cleared monitors intended for mammography Display. Not intended for diagnostic use on mobile devices.

Manufacturer: DICOM Grid dba Ambra Health 450 Park Ave S
New York
New York
United States

ARTG ID:

- > The device is supplied unsterilised.
- > The device is not intended to be invasive.
- > The device is not intended for single use.
- > The device is an active device.
- > The device does not contain material or ingredients of microbial origin.
- > The device does not contain material or ingredients of recombinant origin.
- > The device does not contain material or ingredients manufactured or formulated using a genetically modified organism.
- > The device does not contain material or ingredients of human origin.
- > The device does not contain human blood or its components.
- > The device consists of: Single product
- > The device does not contain material or ingredients of animal origin.
- > The device is not medicated.
- > The device is not formulated.
- > The product does not contain a medicine that has consent for marketing in New Zealand.
- > The product does not contain a medical device which incorporates a medicine as an integral part and that has an action ancillary to the device.

Status: Active