



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Siemens Healthcare Pty Ltd

for approval to supply

Siemens Healthcare Pty Ltd - Patient audiovisual communication/entertainment system

ARTG Identifier	383550
ARTG Start Date	7/02/2022
Product Category	Medical Device Included Class 1
GMDN	64404
GMDN Term	Patient audiovisual communication/entertainment system
Intended Purpose	The IMROC-IR system is intended for use by trained personnel in functional, interventional and clinical MRI environments to facilitate audio communications during a scanning session.

Manufacturer Details	Address	Certificate number(s)
Optoacoustics Ltd	17 Hanotea , St Mazar , 7316000 Israel	

ARTG Standard Conditions

The above Medical Device Included Class 1 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. Patient audiovisual communication/entertainment system

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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