



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Product Category	Medical Device Included Class IIa
GMDN	60924
GMDN Term	General ultrasound imaging system, battery-powered
Intended Purpose	A battery-powered, hand-held device/device assembly designed to be placed over the external body surface for collection, display, and analysis of ultrasound information during a variety of ultrasound imaging procedures (i.e., non-dedicated); it may in addition be intended to be used with a sterile cover for intraoperative imaging. It consists of a flat- or concave-lensed ultrasound transducer and includes an integrated image processing system; it may include an integrated display or be intended to wirelessly transmit images to an off-the-shelf device (e.g., smartphone, tablet) with dedicated software installed.

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. General ultrasound imaging system, battery-powered

Product Specific Conditions

No specific conditions have been recorded against this entry.

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