



Australian Government

Department of Health
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 - Stethoscope, electronic

| | |
|-------------------------|--|
| ARTG Identifier | 294431 |
| ARTG Start date | 28/09/2017 |
| Product Category | Medical Device Included Class IIa |
| GMDN | 13754 |
| GMDN Term | Stethoscope, electronic |
| Intended Purpose | The device is intended to be used as a part of a physical assessment of a patient by healthcare professionals for diagnostic decision support in clinical settings. Eko is intended for use on pediatric and adult patients. It can electronically amplify, filter, and transfer sounds to the accompanying mobile application for storage and sharing. It can be used to record heart sounds and cardiac murmurs, bruits, respiratory sounds and abdominal sounds during physical examination in normal patients or those with suspected diseases of the cardiac, vascular, pulmonary or abdominal organ systems. |

| Manufacturer Details | Address | Certificate number(s) |
|----------------------|--|-----------------------|
| Eko Devices, Inc | 2600 10th Street Suite #260 Berkeley, CA, 94710 United States Of America | DV-2017-MC-12575-1 |

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. Stethoscope, electronic

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Identifier: 294431
ARTG Start Date: 28/09/2017