



Australian Government

Department of Health and Aged Care
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 - Patient data recorder, long-term, sphygmomanometer

ARTG Identifier 375199
ARTG Start Date 23/09/2021
Product Category Medical Device Included Class IIa
GMDN 36888
GMDN Term Patient data recorder, long-term, sphygmomanometer
Intended Purpose Non-invasive blood pressure (BP) monitor(s) intended to measure optical Photoplethysmography (PPG) signals on the user's wrist or fingertip and to calculate blood pressure and heart rate using a Pulse Wave Analysis (PWA) technique.

Manufacturer Details	Address	Certificate number(s)
Aktiia SA	Rue du Bassin 8a , Neuchatel , 2000 Switzerland	DV-2021-MC-15849-1

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. Patient data recorder, long-term, sphygmomanometer

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

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