



Australian Register of Therapeutic Goods Certificate

Issued to

Life Systems Medical Pty Ltd

for approval to supply

Life Systems Medical Pty Ltd - - Patient monitor, electrocardiograph

ARTG Identifier	328153
ARTG Start date	2/01/2020
Product Category	Medical Device Included Class IIa
GMDN	35195
GMDN Term	Patient monitor, electrocardiograph
Intended Purpose	An ambulatory ECG recorder, intended for recording three-channel ECG for up to 7 days continuously, storing ECG signals and motion data directly in the internal memory for analysis by other processing software to provide reports.

Manufacturer Details	Address	Certificate number(s)
Cortrium ApS	Erik Husfeldts Vej 7 Traastrup, Denmark, 2630 Denmark	DV-2019-MC-18862-1

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 monitor, electrocardiograph

Product Specific Conditions

No specific conditions have been recorded against this entry.