



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Lovell Surgical Supplies International Pty Ltd

for approval to supply

**Lovell Surgical Supplies International Pty Ltd - Medical device
disinfectant**

ARTG Identifier 302115
ARTG Start date 20/04/2018
Product Category Medical Device Included Class IIb
GMDN 47631
GMDN Term Medical device disinfectant
Intended Purpose Amity HP 75 is a Hydrogen Peroxide based disinfectant suitable for the disinfection of the Chalice Medical ParaTherm 540016 Heater Cooler Unit and the Medos ME DPHC 0001 Deltastream HC Heater Cooler Unit. Amity HP 75 should be used undiluted for this application and should only be used in accordance with the Chalice Medical and Medos cleaning instructions accompanying the heater cooler unit.

Manufacturer Details	Address	Certificate number(s)
Amity Group trading as Amity Ltd and Amity International	Libra House West Street Worsbrough Dale, Barnsley, S70 5PG United Kingdom	DV-2017-MC-04803-1

ARTG Standard Conditions

The above Medical Device Included Class IIb 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. Medical device disinfectant

Product Specific Conditions

- * The person in relation to whom the kind of medical device is included in the ARTG (the sponsor) must not import, supply or export the medical devices of the kind in Australia if the information provided with the device (including labelling, instructions for use and any other technical and/or promotional material) contains any statements that the device is intended to be used for any purpose other than for cleaning and decontamination of water circuits for the Chalice Medical ParaTherm 540016 Heater Cooler Unit manufactured by Chalice Medical Ltd or the ME DPHC 0001 Deltastream HC Heater Cooler Unit manufactured by MEDOS Medizintechnik AG.
- * The intended purpose of the kind of device cannot be changed until and unless information to support additional claims is provided, assessed and approved by the TGA in relation to the kind of device.
- * If a sponsor requires a variation to the ARTG entry to include details for the medical device that is to be imported, supplied or exported, the sponsor will need to submit a variation request to the TGA.

Therapeutic Goods Administration
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