

Australian Government

Department of Health and Aged Care Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Herbresearch Pty Ltd

for approval to supply

Herbresearch Pty Ltd - Red/infrared light phototherapy unit

ARTG Identifier	424530
ARTG Start Date	9/10/2023
Product Category	Medical Device Included Class Ila
GMDN	65723
GMDN Term	Red/infrared light phototherapy unit
Intended Purpose	Hydrosun models 575, 750 and PhytoDyn are intended to provide water-filtered, infrared-A light and superficial hyperthermia therapy, or to provide the light source for photodynamic therapy. The devices are typically used in dermatology, rheumatology, physiotherapy, ENT (Ear, Nose and Throat) and oncology.

Manufacturer Details	Address	Certificate number(s)
Hydrosun Medizintechnik GmbH	Mauchener Strasse 14 , Mullheim , 79379 Germany	DV-2022-MC-27814-1

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. Red/infrared light phototherapy unit

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: 424530 ARTG Start Date: 9/10/2023