Australian Government

Department of Health

Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

ConMed Linvatec Australia Pty Ltd

for approval to supply

Skin - ConMed Linvatec Australia Pty Ltd

ARTG Identifier 299299

ARTG Start date 2/02/2018

Product Category Biological Included Class 2

Intended Use 1. Replacement of damaged or inadequate integumental tissue, or reinforcement of soft tissue defects
2. Replacement of damaged or inadequate integumental tissue, or reinforcement of soft tissue defects

Manufacturer Details	Address	Manufacturing Steps
Musculoskeletal Transplant Foundation	1232 Mid Valley Drive Jessup, Pennsylvania, 18434-1823 United States Of America	Testing - Analytical/Biological
Musculoskeletal Transplant Foundation	1175 Mid Valley Drive Olyphant, Pennsylvania, 18447 United States Of America	Testing - Analytical/Biological
Musculoskeletal Transplant Foundation * Principal Manufacturer	Suite 300 / 125 May Street Edison, NJ, 08837 United States Of America	Processing Storage on site Testing - Analytical Packaging and labelling Release for supply
Nelson Laboratories LLC	6280 South Redwood Road Salt Lake City, UT, 84104 United States Of America	Testing microbial
VRL Eurofins	6665 S Kenton Street Suite 205 Centennial, Colorado, 80111 United States Of America	Virology Screening and Syphilis Testing NAT Testing for HIV, HCV and HBV

ARTG Standard Conditions

The above Biological Included Class 2 has been entered on the Register subject to the following conditions:

No conditions have been recorded against this entry.

Products Covered by This Entry

1. Dermis, Freeze dried - L - AlloPatchHD

Container Type	Container Material	Container Condition	Container Closure	Shelf Life Time	Shelf Life Temperature	Shelf Life Conditions
Pouch	Other plastic laminate/Al	Not recorded	Not recorded	3 Years	Room temperature	Store at room temperature Do not Freeze Do not Refrigerate

Product Specific Conditions

· If a good that is distributed overseas is the same as a good that is included in the Register and supplied

in Australia, any product recall or similar regulatory action taken in relation to the good outside Australia that concerns, or is related to, the quality, safety or efficacy of the good, must be notified to the Secretary by the sponsor of the good as soon as the sponsor becomes aware of the action. For this purpose, the Secretary is taken to have been notified when the information is forwarded to the Post-market Surveillance Branch at the TGA either by email at adr.reports@tga.gov.au or via online report forms provided on the TGA website.

- The actual date of commencement of supply of the good after inclusion under Part 3-2A of the Act must be notified to the Director, Biological Sciences Section of the TGA. Please note the definition of 'supply' in subsection 3(1) of the Act for this purpose.
- The sponsor must keep records of the supply and distribution of the good for a period of ten (10) years after the distribution of the good.
- Any variations or changes to the good cannot be implemented without either the approval of the Secretary under section 9D of the Act to vary the product's entry in the ARTG or through a change to a condition.

2. Dermis - L - AlloPatchHD

Container Type	Container Material	Container Condition	Container Closure	Shelf Life Time	Shelf Life Temperature	Shelf Life Conditions
Pouch	Other plastic laminate/Al	Not recorded	Not recorded	3 Years	Room temperature	Store at room temperature

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