



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 345834 Symbiotic Devices Pty Ltd - Gel, <specify>

ARTG entry for Medical Device Included Class 1
Sponsor Symbiotic Devices Pty Ltd
Postal Address Suite 138 / 245 Thomas Street, DANDENONG, VIC, 3175
Australia
ARTG Start Date 13/10/2020
Product Category Medical Device Class 1
Status Active
Approval Area Medical Devices

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.

Manufacturers

Name	Address
Weaver & Co	565 Nucla Way Unit B Aurora, CO, 80011 United States Of America

Products

1 . Gel, <specify>

Product Type	Single Device Product	Effective Date	13/10/2020
GMDN	15584 Gel, <specify>		
Intended Purpose	Gel-based skin prepping material that lowers skin impedance to improve tracings between the patient's skin and the electrode.		

Specific Conditions

No Specific Conditions included on Record

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