



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 342733 BBHA GROUP PTY LTD - Actigraft - Wound therapy autologous blood clot preparation kit

ARTG entry for Medical Device Included Class IIa
Sponsor BBHA GROUP PTY LTD
Postal Address PO BOX 331, Double Bay, NSW, 1360
Australia
ARTG Start Date 1/09/2020
Product Category Medical Device Class IIa
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
RedDress Ltd	Shkedim 11 Pardes, Hana, 3701142 Israel

Products

1 . Actigraft - Wound therapy autologous blood clot preparation kit

Product Type	Medical device system	Effective Date	1/09/2020
GMDN	64707 Wound therapy autologous blood clot preparation kit		
Intended Purpose	to draw blood from a patient and produce an autologous whole blood clot tissue mass (gel-like)		

Specific Conditions

No Specific Conditions included on Record

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