



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 409894 AA-Med Pty Ltd - Sternal fixation system

ARTG entry for Medical Device Included Class IIb
Sponsor AA-Med Pty Ltd
Postal Address Suite 4 Level 10 1 Chandos Street, St Leonards, NSW, 2065
Australia
ARTG Start Date 1/06/2023
Product Category Medical Device Class IIb
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
Jeil Medical Corporation	702 703 704 705 706 804 805 807 812 815-ho 55 Digital-ro 34-gil Gurogu, Seoul, 08378 Korea - Republic of

Products

1 . Sternal fixation system

Product Type	Single Device Product	Effective Date	1/06/2023
GMDN	34017 Sternal fixation system		
Intended Purpose	The device is intended for use in the stabilization and fixation of fractures of the anterior chest wall including sternal fixation following sternotomy and sternal reconstructive surgical procedures, to promote fusion.		

Specific Conditions

No Specific Conditions included on Record

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