



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	427014	Actis Medical Pty Ltd - Orthopaedic bone screw (non-sliding)
ARTG entry for	Medical Device Included Class IIb	
Sponsor	Actis Medical Pty Ltd	
Postal Address	1/18 Dequetteville Terrace, Kent Town, SA, 5067 Australia	
ARTG Start Date	27/10/2023	
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
mahe medical gmbh	Friedrich-Wohler-Strasse 10 Emmingen-Liptingen, , 78576 Germany

Products

1 . Orthopaedic bone screw (non-sliding)

Product Type	Single Device Product	Effective Date	27/10/2023
GMDN	66947 Orthopaedic bone screw (non-sliding)		
Intended Purpose	A small, threaded, non-bioabsorbable screw manufactured from titanium alloy. Intended to be used for internal orthopaedic fixation by being screwed into bone to hold a plate prosthesis to the bone, or to provide direct interfragmentary stabilization of a fractured bone.		

Specific Conditions

No Specific Conditions included on Record

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary