



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 303310 Suretest - Autologous blood collection tube

ARTG entry for Medical Device Included Class IIa
Sponsor Suretest
Postal Address 1291 Malvern Road, Malvern, Melbourne, VIC, 3144
Australia
ARTG Start Date 22/05/2018
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
Beijing Hanbaihan Medical Devices Co Ltd	Building 18 Campus 6 8th Hengye Street Tongzhou Beijing, China, 101149 China

Products

1 . Autologous blood collection tube

Product Type	Single Device Product	Effective Date	22/05/2018
GMDN	61377 Autologous blood collection tube		
Intended Purpose	A sterile vacuum tube intended to be used for the collection of venous blood and production of autologous Platelet-rich plasma. It is used in the treatment of burns, bone injuries and other biological, oral, maxillofacial surgery, plastic surgery and other fields.		

Specific Conditions

No Specific Conditions included on Record

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