

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 310748 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 25/10/2018

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 (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 25/10/2018

GMDN 61377 Autologous blood collection tube

Intended Purpose Mainly used in the treatment of burns, bone injuries and other biological, oral, maxillofacial surgery, plastic surgery and other fields.

In recent years, the field of medical cosmetology is also gradually applied PRP technology for tissue and cell regeneration, and

other purposes.

Specific Conditions

No Specific Conditions included on Record

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