



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 315072 Siemens Healthcare Pty Ltd - Coagulation calibrator/control IVDs

ARTG entry for Medical Device Included - IVD Class 2
Sponsor Siemens Healthcare Pty Ltd
Postal Address Level 3, 141 Camberwell Rd, Hawthorn East, VIC, 3123
Australia
ARTG Start Date 4/03/2019
Product Category Medical Device Class 2
Status Active
Approval Area IVD

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
HYPHEN BioMed SAS	155 rue d'Eragny , Neuville Sur Oise, 9500 France

Products

1 . Coagulation calibrator/control IVDs

Product Type	IVD	Effective Date	4/03/2019
GMDN	CT872 Coagulation calibrator/control IVDs		
Intended Purpose	For in vitro diagnostic use in establishing known points of reference and/or to verify the performance of coagulations assays.		

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