



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 351149 Antidote Biomedical - Protection equipment, radiation, shielding material, ionizing

ARTG entry for Medical Device Included Class 1
Sponsor Antidote Biomedical
Postal Address 2/17 South Crescent, Heidelberg West, VIC, 3081
Australia
ARTG Start Date 8/12/2020
Product Category Medical Device Class 1
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
Antidote Biomedical	10/1 Bell Street Preston, VIC, 3072 Australia

Products

1 . Protection equipment, radiation, shielding material, ionizing

Product Type	Single Device Product	Effective Date	8/12/2020
GMDN	38369 Protection equipment, radiation, shielding material, ionizing		
Intended Purpose	A dense solid device used to shield specific parts of the patient's anatomy from ionising radiation during a course of radiation therapy. This is a reusable device.		

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