

Public Summary

Summary for ARTG Entry: 142722 Rymed Pty Ltd - Insufflator, middle ear

ARTG entry for Medical Device Included Class IIa
Sponsor Rymed Pty Ltd
Postal Address PO Box 1020, BLACKTOWN, NSW, 2148
 Australia
ARTG Start Date 1/08/2007
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
Micromedics Inc	Suite 120 / 1270 Eagan Industrial Road Eagen, MN, 55121 United States Of America

Products

1. Insufflator, middle ear

Product Type	Single Device Product	Effective date	1/08/2007
--------------	-----------------------	----------------	-----------

GMDN 36745 Insufflator, middle ear

Intended purpose The EarPopper? is a non-invasive device for treating conditions such as otitis media with effusion, middle ear effusion, rotitis/barotitis and eustachian tube dysfunction, without the need for surgery or antibiotics.
 The EarPopper? delivers a constant, regulated stream of air pressure and flow into the nasal cavity through the nostril with a plastic tip.

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>.