



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

**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**  
 Micromedics Inc

**Address**  
 Suite 120 / 1270 Eagan Industrial Road  
 Eagan, MN, 55121  
 United States Of America

**Products**

**1. Insufflator, middle ear**

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

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