



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 216880 France Medical Pty Ltd - Intense pulsed light dry eye therapy unit

ARTG entry for Medical Device Included Class IIb
Sponsor France Medical Pty Ltd
Postal Address 15/35 Paringa Road, MURARRIE, QLD, 4172
 Australia
ARTG Start Date 4/11/2013
Product category Medical Device Class IIb
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
E-Swin	5 Rue De La Noue , Adainville, F-78113 France

Products

1. Intense pulsed light dry eye therapy unit

Product Type	Single Device Product	Effective date	4/11/2013
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GMDN 60386 Intense pulsed light dry eye therapy unit
Intended purpose to treat meibomian blepharitis (dry eye syndrome) by targeting the skin surrounding the meibomian glands (around the eyelid) with intense pulsed light (IPL)

Specific Conditions

No Specific Conditions included on Record

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