



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 356849 ACRA Regulatory Services Pty Ltd - Electromyographic endotracheal tube electrode

ARTG entry for Medical Device Included Class IIa
Sponsor ACRA Regulatory Services Pty Ltd
Postal Address 7/84 Poinciana Avenue, Tewantin, QLD, 4565
Australia
ARTG Start Date 16/03/2021
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
Technomed Europe	Amerikalaan 71 Maastricht Airport, , 6199 AE Netherlands

Products

1 . Electromyographic endotracheal tube electrode

Product Type	Single Device Product	Effective Date	16/03/2021
GMDN	62208 Electromyographic endotracheal tube electrode		
Intended Purpose	Single use sterile laryngeal lantern electrodes are intended to be attached to an endotracheal tube and positioned for continuous EMG monitoring of the larynx during surgical procedures with recording and monitoring equipment		

Specific Conditions

No Specific Conditions included on Record

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