

## Public Summary

**Summary for ARTG Entry:** 299807 Emergo Asia Pacific Pty Ltd T/a Emergo Australia - Surgical procedure kit, dental, implant/prosthesis

**ARTG entry for** Medical Device Included Class IIa  
**Sponsor** Emergo Asia Pacific Pty Ltd T/a Emergo Australia  
**Postal Address** Level 20 Tower II Darling Park 201 Sussex Street, SYDNEY, NSW, 2000 Australia  
**ARTG Start Date** 20/02/2018  
**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   |
|-------------|---|
| CeraRoot SL | Joseph Umbert 128 Granollers<br>, Barcelona, 08402<br>Spain |

### Products

#### 1. Surgical procedure kit, dental, implant/prosthesis

| Product Type | Procedure Pack | Effective date | 20/02/2018 |
|--------------|----------------|----------------|------------|
|--------------|----------------|----------------|------------|

**GMDN** 44883 Surgical procedure kit, dental, implant/prosthesis

**Intended purpose** Reusable instruments are intended to be used as part of treatments with dental implants and restorative components.

### Specific Conditions

No Specific Conditions included on Record

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