



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

## Public Summary

**Summary for ARTG Entry:** 326840 Bella Derm Pty Ltd - Nitrogen plasma skin surface treatment system

**ARTG entry for** Medical Device Included Class IIb  
**Sponsor** Bella Derm Pty Ltd  
**Postal Address** 111/45 Gilby Road, Mount Waverley, VIC, 3149  
Australia  
**ARTG Start Date** 28/11/2019  
**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
GCS Co Ltd	1008 (1009 1003) 555 Dunchon-daero Jungwon-gu Seongnam-si Gyeonggi-do , Republic of Korea, Korea - Republic of

### Products

#### 1 . Nitrogen plasma skin surface treatment system

<b>Product Type</b>	Single Device Product	<b>Effective Date</b>	28/11/2019
<b>GMDN</b>	60761 Nitrogen plasma skin surface treatment system		
<b>Intended Purpose</b>	restoring a variety of skin conditions such as scars and blemishes caused by, for example, diseases and accidents		

### Specific Conditions

No Specific Conditions included on Record

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