

Declaration of Conformity

Declaration Number: DOC-TOR-003

Manufacturer/Supplier: Derma Sciences, Inc.
 104 Shorting Road Toronto, Ontario, Canada M1S 3S4
(A wholly owned division of Integra LifeSciences Corporation)

| Product Name | Class (MDD, Annex IX) | Conformity Assessment Route | Sterile/ Non Sterile |
|------------------------------------------|-----------------------|-------------------------------|----------------------|
| Medihoney Antibacterial Wound Gel | Class IIb; Rule 4 | Annex II, Excluding Section 4 | Sterile |
| Medihoney Antibacterial Medical Honey | | | |
| Medihoney Hydrogel Colloidal Sheet | | | |
| Medihoney Antibacterial Apinate Dressing | | | |
| Medihoney Antibacterial Tulle Dressing | | | |
| Medihoney Antibacterial Honey Gel Sheet | | | |

Catalog No/Effective Lot No/Date CE Mark Affixed: See page 2

Notified Body

SGS Belgium N.V.,
 Noorderlaan 87, BE-2030
 Antwerpen, Belgium

Authorized EC Representative

Integra LifeSciences Services (France)
 Immeuble Séquoia 2
 97 Allée Alexandre Borodine
 Parc Technologique de la Porte des Alpes
 69800 Saint Priest – France

Notified Body Number: 1639

This Declaration is supported by;

Certificate

US19/819943523

Issued by

SGS

Date Issued

16DEC2019

Declaration of Conformity

Catalog No/ Product Description /Date CE Mark Affixed:

Medihoney Antibacterial Wound Gel

| Catalog Number | Part Description | Date CE Marked Affixed |
|----------------|------------------|------------------------|
| 391 | 10g tube | July 2010 |
| 395 | 20g tube | July 2010 |

Medihoney Antibacterial Medical Honey

| Catalog Number | Part Description | Date CE Marked Affixed |
|----------------|------------------|------------------------|
| 398 | 20g tube | July 2010 |
| 405 | 50g tube | July 2010 |

Medihoney Hydrogel Colloidal Sheet

| Catalog Number | Part Description | Date CE Marked Affixed |
|----------------|-----------------------------------------------|------------------------|
| 780 | Non-adhesive 2.4 x 2.4" (6 x 6cm) | September 2010 |
| 781 | Non-adhesive 4.3 x 4.3" (11 x11 cm) | September 2010 |
| 782 | Adhesive 2.8 x 2.8" (7.2 x7.2 cm) | September 2010 |
| 783 | Adhesive 4.5 x 4.5" (11.5 x 11.5 cm) | September 2010 |
| 784 | Non-adhesive 8 x 8" (20 x 20 cm) | September 2010 |
| 785 | Non-adhesive 8 x 12" (20 x 30 cm) | September 2010 |
| 787 | Adhesive Surgical 1.75 x 6.5" (4.5 x 16.5 cm) | September 2010 |

Medihoney Antibacterial Apinate Dressing

| Catalog Number | Part Description | Date CE Marked Affixed |
|----------------|----------------------------------|------------------------|
| 793 | Rope 1.9cm x 30cm (3/4in x 12in) | July 2010 |
| 794 | 5cm x 5cm (2in x 2in) | July 2010 |
| 795 | 10cm x 10cm (4in x 4in) | July 2010 |

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Medihoney Antibacterial Tulle Dressing

| Catalog Number | Part Description | Date CE Marked Affixed |
|----------------|-------------------------|------------------------|
| 796 | 5cm x 5cm (2in x 2in) | August 2010 |
| 797 | 10cm x 10cm (4in x 4in) | August 2010 |

MediHoney Antibacterial Honey Gel Sheet

| Catalog Number | Part Description | Date CE Marked Affixed |
|----------------|-------------------------|------------------------|
| 798 | 5cm x 5cm (2in x 2in) | August 2010 |
| 799 | 10cm x 10cm (4in x 4in) | August 2010 |

I, the undersigned hereby ensure that the medical devices specified in the above/attachment is in conformity with;

93/42/EEC Medical Device Directive and all applicable amendments

ISO 13485:2016 & EN ISO 13485:2016 Medical Devices-Quality Management Systems- Requirements for Regulatory Purposes

Harmonized Standards listed as per Essential Requirement checklist- current version

Place of Issue: Plainsboro, New Jersey, USA

Date of Issue: 12MAR2020



Kathryn Coressel
Sr. Manager, Regulatory Affairs

** Integra LifeSciences Corporation is exclusively responsible for the Declaration of Conformity**