

## *Declaration of Conformity*

**Declaration Number:** DOC-TOR-011

**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 ® Barrier Cream	Class I	Annex II	Non-Sterile

**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 Séquoïa 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;

<b>Certificate</b>	<b>Issued by</b>	<b>Date Issued</b>
US19/819943523	SGS	16DEC2019

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**Catalog No/ Product Description /Date CE Mark Affixed:**

Catalog Number	Part Description	Date CE Marked Affixed
582	50g tube	21-Mar-2011
800	2g tube	21-Mar-2011

**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:** Princeton, New Jersey, USA

**Date of Issue:** 7-Aug-2020

  
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**Cecile Cualing**  
**Manager, Regulatory Affairs**

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