

Declaration of Conformity

Declaration Number: DOC-TOR-012

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 ® Derma 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 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	Issued by	Date Issued
US19/819943523	SGS	16DEC2019

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Catalog No/ Product Description /Date CE Mark Affixed:

Catalog Number	Part Description	Date CE Marked Affixed
597	50g tube	21-Mar-2011

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

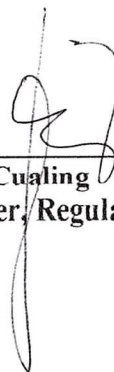
93/42/EEC Medical Device Directive and all applicable amendments

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



Cecile Cualing
Manager, Regulatory Affairs

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