Declaration of Conformity

Manufacturer: ***T&L Co., Ltd.***
70-17, Wonam-ro, Wongok-myeon, Anseong-si, Gyeonggi-do, Korea
Zip Code: 17554

European Representative: ***Obelis S.A.***
Bd. Général Wahis 53 1030
Brussels, Belgium

Name of device: ***Hydrocolloid Dressing***

Model: ***See Attachment 1***

Start date/ Lot of CE Marking: See Attachment 1

CE 0123

Classification (MDD, Annex IX): ***Class IIb***

We here with declare exclusively under sole responsibility that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices. All Supporting documentation is retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives: EC DIRECTIVE: *Medical Devices Directive*
(Medical Device Directive 93/42/EEC amended by 2007/47/EC)

Conformity Assessment Route: MDD Annex II.3. Full QA System

Standard: See *Attachment 2*

Notified Body: **TÜV SÜD Product Service GmbH (Identification no.:0123)**
Ridlerstraβe 65
80339 MÜNCHEN, Germany

Place: T&L *Co., Ltd., KOREA*
Date: Jan 22, 2019

Signature: Y. S. Choi
Full Name: *Choi, Yoon-So*
Position: *President*

TLF-DOC-100 2019.01.22(Rev.7)

Attachment 1

List of CE Marked Product

PRODUCT NAME: RenoCare Hydrocolloid Dressing(Sprasorb H)/Updated Jan 22, 2019
Lot No.: RT3070601
Technical File No. : TNL-TF-100, Control No.: TLF-DOC-100 2019.01.22(Rev.07)
EC Certificate No. : G1 067241 0002 Rev.00, ISO 13485 Certificate No. : Q5 067241 0001 Rev.00
Document Owner : T&L Co., Ltd

No.	Model	Dimension (cm)	Packing unit (pcs)	Classification	Rule to be applied	Conformity Assessment route	GMDN Code	MD Code	Start of CE Marking
1.	109833	10 x 10 (Standard)	8	IIb	4	Annex II	43186	MD 0301	October 9, 2008
2.	108830	10 x 10 (Standard)	10	IIb	4	Annex II	43186	MD 0301	October 9, 2008
3.	108831	15 x 15 (Standard)	5	IIb	4	Annex II	43186	MD 0301	October 9, 2008
4.	108832	20 x 20 (Standard)	5	IIb	4	Annex II	43186	MD 0301	October 9, 2008
5.	109866	5 x 10 (Thin)	8	IIb	4	Annex II	43186	MD 0301	October 9, 2008
6.	109867	10 x 10 (Thin)	8	IIb	4	Annex II	43186	MD 0301	October 9, 2008
7.	108860	5 x 5 (Thin)	10	IIb	4	Annex II	43186	MD 0301	October 9, 2008
8.	108861	5 x 10 (Thin)	10	IIb	4	Annex II	43186	MD 0301	October 9, 2008
9.	108862	5 x 20 (Thin)	10	IIb	4	Annex II	43186	MD 0301	October 9, 2008
10.	108863	10 x 10 (Thin)	10	IIb	4	Annex II	43186	MD 0301	October 9, 2008
11.	108864	15 x 15 (Thin)	5	IIb	4	Annex II	43186	MD 0301	October 9, 2008
12.	108865	20 x 20 (Thin)	5	IIb	4	Annex II	43186	MD 0301	October 9, 2008
13.	108866	14 x 14 (Border)	5	IIb	4	Annex II	43186	MD 0301	October 9, 2008
14.	108867	14 x 16 (Sacrum)	5	IIb	4	Annex II	43186	MD 0301	October 9, 2008

Prepared by _____ Approved by _____

cf. Notified Body is TÜV SÜD Product Service GmbH, identification no. 0123

Attachment 2

European Harmonized Standards supporting Technical Files;

Document Number	Title of Document
BS EN ISO 13485:2012	Medical devices-Quality management systems-Requirements for regulatory purposes
BS EN 13726-1:2002	Test methods for primary wound dressings Part 1: Aspects of absorbency
BS EN 13726-3:2003	Test methods for primary wound dressings Part 3: Waterproofness
ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
BS EN ISO 10993-1:2009	Biological evaluation of medical devices-Part 1 Evaluation and testing
BS EN ISO 10993-5:2009	Biological evaluation of medical devices-Part 5 Test for in vitro cytotoxicity
BS EN ISO 10993-10:2013	Biological evaluation of medical devices-Part10 Tests for irritation and skin sensitization
BS EN ISO 10993-12:2012	Biological evaluation of medical devices-Part 12 Sample preparation and reference materials
BS EN 556-1:2001	Sterilization of medical devices- requirements for medical devices to be designated "STERILE"-part1: Requirements for terminally sterilized medical devices
BS EN1041:2008+A1:2013	Information supplied by the manufacturer with medical devices
BS EN ISO 14971:2012	Medical devices-Application of risk management to medical devices
BS EN ISO 11607-1:2009 +A:2014	Packaging for terminally sterilized medical device- Part1 Requirements for materials, sterile barrier systems and packaging systems
BS EN ISO 11607-2:2006	Packaging for terminally sterilized medical device-Part2 Validation requirements for forming, sealing and assembly processes
ISO 11137-1:2006	Sterilization of health care products-Radiation-Part1:Requirements for development, validation and routine control of a sterilization process for medical devices
ANSI/AAMI/ISO 11737-1:2006/(R)2011	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
ISO 11737-2:2009	Sterilization of medical devices-Microbiological methods-Part2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
ASTM F 1980-07(Reapproved 2011)	Standard guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ISO 14644-1:2015	Cleanrooms and associated controlled environments-Part1: Classification of air cleanliness by particle concentration
ISO 14644-2:2015	Cleanrooms and associated controlled environments-Part2: Monitoring to Provide evidence of cleanroom performance related to air cleanliness by particle concentration
MEDDEV 2.7/1 revision 4 June 2016	Clinical Evaluation: A guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC
MDD 93/42 EEC	Council Directive 1993/42/EEC of 14 June 1993 concerning medical devices
Standard of T&L Co., Ltd. related RenoCare Hydrocolloid Dressing	