Declaration of Conformity

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

European Representative: ***KTR Europe GmbH***
Mergenthalerallee 77, 65760 Eschborn, Germany

Generic Device Term: ***Hydrocolloid Dressing***

Product Name: ***See attachment 1***

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: Annex II excluding (4)

Standard: See *Attachment 2*

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

Place: T&L *Co., Ltd., KOREA*
Date: June 06, 2022

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

TLF-DOC-100 2022.06.06(Rev.12)

Attachment 1

List of CE Marked Product

PRODUCT NAME: RenoCare Hydrocolloid Dressing(Suprasorb H)/Updated June 06, 2022
Lot No.: RT3070601
Technical File No. : TNL-TF-100, Control No.: TLF-DOC-100 2022.06.06(Rev.12)
EC Certificate No. : G1 067241 0005 Rev. 00, ISO 13485 Certificate No. : Q5 067241 0003 Rev. 01
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.	108830	10 x 10 (Standard)	10	IIb	4	Annex II	43186	MD 0301	October 9, 2008
2.	108831	15 x 15 (Standard)	5	IIb	4	Annex II	43186	MD 0301	October 9, 2008
3.	108832	20 x 20 (Standard)	5	IIb	4	Annex II	43186	MD 0301	October 9, 2008
4.	108860	5 x 5 (Thin)	10	IIb	4	Annex II	43186	MD 0301	October 9, 2008
5.	108861	5 x 10 (Thin)	10	IIb	4	Annex II	43186	MD 0301	October 9, 2008
6.	108862	5 x 20 (Thin)	10	IIb	4	Annex II	43186	MD 0301	October 9, 2008
7.	108863	10 x 10 (Thin)	10	IIb	4	Annex II	43186	MD 0301	October 9, 2008
8.	108864	15 x 15 (Thin)	5	IIb	4	Annex II	43186	MD 0301	October 9, 2008
9.	108865	20 x 20 (Thin)	5	IIb	4	Annex II	43186	MD 0301	October 9, 2008
10.	108866	14 x 14 (Border)	5	IIb	4	Annex II	43186	MD 0301	October 9, 2008
11.	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
ISO 13485:2016	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 13726-2:2002	Test methods for primary wound dressings Part 2: Moisture vapour transmission rate of permeable film dressings
BS EN 13726-3:2003	Test methods for primary wound dressings Part 3: Waterproofness
ISO 15223-1:2021	Medical devices-- Symbols to be used with medical device labels, labeling and information to be supplied-- Part1: General requirements
ISO 10993-1:2018	Biological evaluation of medical devices-Part 1: Evaluation and testing
ISO 10993-5:2009	Biological evaluation of medical devices-Part 5: Test for in vitro cytotoxicity
ISO 10993-10:2013	Biological evaluation of medical devices-Part10: Tests for irritation and skin sensitization
ISO 10993-12:2012	Biological evaluation of medical devices-Part12: Sample preparation and reference materials
ISO 10993-18:2020	Biological evaluation of medical devices-Part 18: Chemical characterization of medical device materials within a risk management process
BS EN 556-1:2001	Sterilization of medical devices-requirements for medical devices to be designated “STERILE”-Part1: Requirements for terminally sterilized medical devices
ISO 20417:2021	Information supplied by the manufacturer with medical devices
ISO 14971:2019	Medical devices-Application of risk management to medical devices
ISO/TR 24971:2020	Medical devices-Guidance on the application of ISO 14971
ISO 11607-1:2019	Packaging for terminally sterilized medical device-Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2019	Packaging for terminally sterilized medical device-Part 2: Validation requirements for forming, sealing and assembly processes
ASTM D 4169-16	Standard guide for Performance Testing of Shipping Containers and Systems
ASTM D3330 / D3330M - 04(2018)	Standard Test Method for Peel Adhesion of Pressure-Sensitive Tape
ISO 11137-1:2006/AMD2:2018	Sterilization of health care products-Radiation-Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11137-2:2013	Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose
ISO 11737-1:2018	Sterilization of health care products-Microbiological methods-Part 1: Determination of a population of microorganisms on products
ISO 11737-2:2019	Sterilization of health care products-Microbiological methods-Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
ASTM F 1980-16	Standard guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ISO 14644-1:2015	Cleanrooms and associated controlled environments-Part 1: Classification of air cleanliness by particle concentration
ISO 14644-2:2015	Cleanrooms and associated controlled environments-Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
ISO/TR 20416:2020	Medical devices-Post-market surveillance for manufacturers
MEDDEV 2.12/2 revision January 2012	Guidelines on medical devices-Post market clinical follow-up studies(A guide for manufactures and notified bodies)
IEC 62366-1:2015+AMD1:2020 CSV	Medical devices-Part 1: Application of usability engineering to medical devices

MEDDEV 2.7/1 revision 4 June 2016	Clinical Evaluation: A guide for manufactures 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 Hydrocolloid Dressing	

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