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TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 045286 0073 Rev. 02

Manufacturer:

Lohmann & Rauscher International GmbH & Co. KG
Westerwaldstraße 4
56579 Rengsdorf
GERMANY

Product Category(ies): **Swabs and balls, active medical devices for negative pressure wound therapy including accessories, wound dressings, surface disinfectants, surgical single use instruments**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713152842/713160691

Valid from: 2020-05-27
Valid until: 2024-05-26

Date, 2020-05-27

Christoph Dicks
Head of Certification Notified Body

Digitally signed by Ionascu Andrei
Date: 2021.11.09 11:48:10 EET
Reason: MoldSign Signature
Location: Moldova

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Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 045286 0073 Rev. 02

Productgroup/ Product name	Classification	Rule
Swabs and Balls	**IIa,**	**6, 7**
Active medical devices for negative pressure wound therapy incl. Accessories	**IIa, IIb**	**4, 11, 8**
Wound Dressings	**IIa, IIb, III**	**4, 13, 17**
Alginate Dressings	IIb, III	4, 13
Hydrocolloid Dressings	IIa, IIb	4
Hydroactive Fiber	IIb	4
Hydrobalance Wounddressings	IIb, III	4, 13
Film Dressings	IIa	4
Contact Net	IIb	4
Foam Dressings	IIb	4
Gel Dressings	IIb	4
Activated Charcoal Dressings	IIb	4
Vaseline Dressings	IIb	4
Superabsorbent Dressings	IIb	4
Aluminized Dressings	IIb	4
Collagen Wound Dressings	III	17
Dressing Material, impregnated with Iodoform	III	13
Surfacedisinfect	**IIa**	**15**

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No. G1 045286 0073 Rev. 02

Surgical Instruments	**IIa**	**6**

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TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 045286 0075 Rev. 01

Manufacturer

Lohmann & Rauscher International GmbH & Co. KG
Westerwaldstraße 4
56579 Rengsdorf
GERMANY

Product Category(ies):

Procedure Packs/ set systems, swabs and balls, ophthalmological devices, wound dressings, OR-materials, products for compression/ retention and support, material for padding, maternity pads, accessories to active medical devices for negative pressure wound therapy, ENT-devices

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: 713163955/713157373

Valid from: 2020-05-29
Valid until: 2024-05-26

Date, 2020-05-29

Christoph Dicks
Head of Certification/Notified Body

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EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 045286 0075 Rev. 01

Productgroup	Classification	Rule
Procedure Packs/ Set Systems	Art. 12	---
Swabs and Balls	Is	4
Ophtalmological Devices	Is	4, 1
Wound Dressings	Is	4, 1
OR-Materials	Is	1, 4
Products for compression, retention and support	Is	1
Material for padding	Is	1
Maternity Pads	Is	1
Accessories to active medical devices for negative pressure wound therapy	Is	2, 4, 1
ENT Devices	Is	5

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