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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 045286 0079 Rev. 04

Manufacturer:

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

SRN Manufacturer - DE-MF-000005052

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 045286 0079 Rev. 04

Report No.:	713239656 / 713312928
Preceding Certificate No.:	G10 045286 0079 Rev. 03
Valid from:	2024-08-15
Valid until:	2025-06-02
Date of Initial Issuance:	2020-06-03

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-08-15

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Classification:	Class IIb
Device Group:	M040414 - MULTI-LAYER ABSORBENT DRESSINGS
Intended Purpose:	Absorbent multilayer wound dressings are intended for exudate management of acute and chronic wounds.

Classification:	Class IIb
Device Group:	A0680 - DRAINAGE AND FLUID COLLECTION DEVICES - ACCESSORIES
Intended Purpose:	CNP endo Foam Drain is used in sterile condition in adults in combination with the Suprasorb CNP endo therapy unit, for the negative pressure therapy in the oesophagus and rectum to support defect- and wound healing.

Classification:	Class IIb
Device Group:	A0680 - DRAINAGE AND FLUID COLLECTION DEVICES - ACCESSORIES
Intended Purpose:	CNP endo Foam Drain (N) is used in sterile condition in adults in combination with the Suprasorb CNP endo therapy unit, for the negative pressure therapy in the oesophagus to support defect- and wound healing with simultaneously enteral feeding.

Classification:	Class IIa
Device Group:	M020199 - COTTON GAUZES - OTHER
Intended Purpose:	-

Classification:	Class IIa
Device Group:	M020102 - COTTON GAUZES, FOLDED
Intended Purpose:	-

Classification:	Class IIa
Device Group:	M020103 - LAPAROTOMY COTTON GAUZES
Intended Purpose:	-

Classification:	Class IIb
Device Group:	M020302 - IMPREGNATED GAUZES
Intended Purpose:	Impregnated wide-mesh tulle that protects superficial wounds from adhesion and promotes exudate drainage

Classification:	Class IIb
Device Group:	M040703 - WOUND DEBRIDEMENT PADS
Intended Purpose:	The monofilament fibre pad is used to absorb exudate, debris and skin keratoses during the debridement of superficial wounds.

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Classification:	Class IIb
Device Group:	M040703 - WOUND DEBRIDEMENT PADS
Intended Purpose:	The monofilament fibre stick is used for the absorption of exudate, debris and skin keratoses during the debridement of superficial and deep to surgically invasive wounds or wound cavities.

Classification:	Class IIb
Device Group:	M040406 - POLYURETHANE DRESSINGS
Intended Purpose:	The PU foam dressing is intended for absorption of wound exudate and mechanical protection of the wound. It is used to treat moderately exuding, superficial wounds.

Classification:	Class IIb
Device Group:	M040404 - CELLULOSE AND/OR MODIFIED CELLULOSE DRESSINGS, NON-COMBINED OR COMBINED WITH OTHER SUBSTANCES
Intended Purpose:	Hydrobalance bio-cellulose wound dressings/ packing ropes aid wound healing, by donating moisture to and absorbing exudate from lightly to moderately exuding, superficial or deep wounds.

Classification:	Class IIa
Device Group:	D0799 - ALCOHOLS FOR THE DISINFECTION OF MEDICAL DEVICES - OTHER
Intended Purpose:	-

Classification:	Class IIa
Device Group:	D0901 - AMMONIUM SALTS FOR THE DISINFECTION OF MEDICAL DEVICES
Intended Purpose:	-

Classification:	Class IIb
Device Group:	Z120190 - VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY
Intended Purpose:	The drainage tube is placed inside a wound filler during negative pressure therapy with the Suprasorb CNP P3 system to drain and transport exudate from the wound to the exudate pouch.

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Classification:	Class IIb
Device Group:	Z120190 - VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY
Intended Purpose:	The foam dressing is used as a wound filler as part of negative pressure therapy with the CNP-system and allows the negative pressure to be distributed in the wound and the exudate to be drained.

Classification:	Class IIb
Device Group:	Z120190 - VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY
Intended Purpose:	The film dressing is used to protect exposed organs, vessels, tissues and other body structures and to drain body fluids during negative pressure therapy.

Classification:	Class IIb
Device Group:	M040202 - ALUMINIUM NON-WOVEN ABSORBENT DRESSINGS
Intended Purpose:	The Dressings are coated with Aluminium and are used for absorbing exudate, reducing adhesion to wounds and covering wounds.

Classification:	Class IIa
Device Group:	M040302 - STICKS/LANCETS/STRIPS FOR OPHTHALMIC USE
Intended Purpose:	-

Classification:	Class IIa
Device Group:	M040406 - POLYURETHANE DRESSINGS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A060101 - VACUUM AND GRAVITY DRAINAGE SYSTEMS
Intended Purpose:	-

The validity of this certificate depends on conditions and/or is limited to the following:	./.

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Revision History:

Rev.	Dated	Report	Description
00	2020-06-03	713165532	-
01	2023-08-03	713210564	Supplemented: Device(s)/group of device(s) added
02	2024-05-24	713276815	Supplemented: Device(s)/group of device(s) added
03	2024-07-19	713265821/ 71332928_1/7 13306240	Supplemented: Device(s)/group of device(s) added
04	2024-08-15	713239656 / 713312928	Supplemented: Device(s)/group of device(s) added

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