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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



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



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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
Surfacedisinfekt	IIa	15

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT

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Surgical Instruments

IIa

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