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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT



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Zentralstelle der Länder
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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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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 |
| Surfacedisinfekt | IIa | 15 |

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

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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

Surgical Instruments

IIa

6

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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

