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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICATE



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
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ZLG-BS-244.10.08



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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Productgroup	Classification	Rule
Procedure Packs/ Set Systems	Art. 12	---
Swabs and Balls	Is	4
Opthalmological 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