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



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
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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

