

TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD
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Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
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. 00

Manufacturer

Lohmann & Rauscher

International GmbH & Co. KG

Westerwaldstraße 4

56579 Rengsdorf

GERMANY

Product

Category(ies):

**Gauze Dressings, Gauze Balls, Wound Dressings,
OR-Set-Systems, Surgical Clothes, Bandages,
Undercast Paddings, Dressing Gauze, Sanitary
Pads, Spatula, ENT-, and Ophthalmology Products**

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.: 713136894

Valid from: 2018-09-03

Valid until: 2021-03-22

Date, 2018-09-03

Stefan Preiß



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Facility(ies):

Lohmann & Rauscher GmbH & Co. KG
Irlicher Strasse 55, 56567 Neuwied, GERMANY

Lohmann & Rauscher s.r.o.
Bucovická ul. 256, 68401 Slavkov u Brna, CZECH REPUBLIC

Lohmann & Rauscher GmbH
Kirchengasse 17, 2525 Schönau a.d. Triesting, AUSTRIA

Lohmann & Rauscher s.r.o.
ul. Legií 265, 50901 Nová Paka, CZECH REPUBLIC

Product group/Product name	Classification	Rule
Gauze Dressings:		
Gazin Gauze Dressings, sterile	I s	4
Ratioline Non Woven Dressings	I s	4
Stella Gauze Dressings	I s	4
Vliwazell Absorbent Dressings	I s	4
Vliwasoft Nonwoven Wound Dressing	I s	4
Vliwin Universal Absorbent Dressing	I s	4
Cotopad	I s	4
Metalline Tracheo Dressing	I s	4
Metalline Drain Dressing	I s	4
Solvaline N	I s	4
Rondelle oculaire	I s	4
Raucosan Wound Dressing Soft	I s	4
Raucosan Wound Dressing Classic	I s	4
Stepcel	I s	4
Vliwaktiv Absorbent Activated Charcoal Dressing	I s	4
Vliwafix	I s	4
Debrisoft	I s	4
Zemuko	I s	4
Hydroband	I s	4
Mercurochrome Compress	I s	4

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Stellaline	l s	4
Pansement chirurgicaux	l s	4
Gauze Balls:		
Gazin Gauze Balls, sterile	l s	4
Raucotupf Cotton tipped Applicator	l s	5
Raucosan Wound Swabs Soft	l s	4
Dialysis-swabs	l s	4
FLAWA Zellstofftupfer	l s	4
Wound Dressings:		
Ratioline Wound Dressings	l s	4
Curapor sterile	l s	4
Curapor sterile transparent	l s	4
Curapont	l s	4
Curapor i.v.	l s	4
Porofix i.v.	l s	1
Curafix i.v.	l s	1
FLAWA M.I.C. Compress	l s	4
Raucosan First aid dressing	l s	4
Curagard	l s	4
Dressing Kit	l s	4
Ophthalmology:		
Pro-optha Products	l s	1
Gloves:		
Sentina CP	l s	1
ENT:		
Raucocel	l s	5

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OR-Set-Systems and customer special Standard- and Individual Sets: | s 1,4
 such as Raucodrape, PEG-Dressing Change Sets, Dressing Kit

for use in
 e.g. General Surgery, Arthroscopy, Angiography,
 Dermatology, Gynaecology, Ophthalmology,
 Orthopaedy, Gastrostomy
 consisting of
 e.g. Surgical Drapes, Clothes

Surgical Clothes:
 Sentinex Surgical Gown | s 1
 Sentina Gown | s 1

Bandages:
 Ideal Bandages DIN | s 1
 Mollelast Bandages | s 1
 Lenkelast Bandages | s 1
 Rosidal K | s 1
 Rosidal haft | s 1
 Lenkideal | s 1
 Bande de crêpe cotton | s 1
 Crimpelast | s 1
 Perfekta fine | s 1
 Stella Crepe | s 1

Wadding:
 Cellona Undercast Paddings | s 1
 Eye Wadding | s 4
 Raucoset surgical cotton rolls | s 4

Dressing Gauze:
 Gauze Rolls | s 4
 Dressing Gauze | s 4

Gauze Dressings:
 Perm Cath Gazin Gauze Dressings | s 4
 Dynaphar Gauze Dressings | s 4



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Sanitary Pads:

Sentina Sanitary Pads	l s	1
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Surgical Drapes:

Raucodrape	l s	1
Raucodrape Surgical Incise Drape	l s	4

Dressing Cloth:

Dressing Cloth aluminized	l s	4
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Spatula:

Wooden Tongue Depressor	l s	5
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Accessories:

Suprasorb CNP P3 Accessories (Drainage Pad, Exudate Pouch, Y Connector)	l s	1
Suprasorb CNP Drainage Pad	l s	2
Suprasorb CNP Gel Stripe	l s	4

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