



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

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. 01

Manufacturer:

**Lohmann & Rauscher
International GmbH & Co. KG**

Westerwaldstraße 4
56579 Rengsdorf
GERMANY

Product Category(ies): Gauze Dressings, Gauze Balls, Set-Systems,
Wound Dressings / Ropes, Ribbon Gauzes,
(Bed) Sheets, Tampons, Controlled Negative Pressure
Therapysystems and Accessories, Catheter Sets,
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.

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Valid from: 2018-11-12

Valid until: 2021-03-22

Date, 2018-11-12

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 International GmbH & Co. KG
Westerwaldstraße 4, 56579 Rengsdorf, GERMANY

Productgroup/Productname	Classification	Rule
Gauze Dressings:		
Gazin Gauze Dressings	IIa	7
OR swab	IIa	6
Gauze Balls:		
Gazin Gauze Balls	IIa	6
Vessel Swab, Xray detectable	IIa	6
Pro ophta Sticks	IIa	6
Debrisoft Lolly	IIa	6
Customer special Standard- and Individual Sets		
such as Raucoset, Setpack	IIa	6,7
Kitpack	IIa/IIb/III	6,7,8
	IIa/IIb	9
	IIa	11
	III	13
<i>for use in</i>		
e.g. General Surgery, Arthroscopy, Angiography, Dermatology, Gynaecology, Ophtalmology, Orthopaedy, Urology		
<i>with components such as</i>		
e.g. Surgical Drapes, Drainages, Needles, Suction Tubes, Scalpels, Syringes, OR-Clothes, Gauze Dressings, Wound Dressings		
Suprasorb CNP Kit	IIa/IIb	7,8

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

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TÜV SÜD
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Wound Dressings/Ropes:

Vliwaktiv Silver	IIb	4
Suprasorb X	IIb	4
Suprasorb A	IIb	4
Suprasorb C Collagen Wound Dressing	III	17
Suprasorb X + PHMB Polihexanide		
Antimicrobial HydroBalance Wound Dressing, -Rope	III	13
Lomatuell H	IIb	4
Lomatuell Pro	IIb	4
Raucosan Wound Dressing Hydro	IIa	4
Suprasorb A + AG		
Wound Dressing + Rope	III	13
Ribbon gauze with Vaseline	IIb	4
Suprasorb P	IIb	4
Suprasorb H, thin	IIa	4
Suprasorb H, standard, border, sacrum	IIb	4
Vliwasorb	IIb	4
Vliwasorb Pro	IIb	4
Suprasorb P silicone	IIb	4
Flivasorb	IIb	4
Suprasorb F	IIa	4
Suprasorb G Dressing	IIb	4
Suprasorb G Amorphous Gel	IIb	4
Suprasorb CNP Drainage film	IIb	8
Suprasorb CNP EasyDress	IIa	4
Suprasorb Liquacel	IIb	4
Rationline protect	IIa	4
Ribbon Gauze:		
Gazin Ribbon Gauzes	IIa	7
Metalline:		
(Bed) Sheet	IIb	4
Dressing	IIb	4
Wound Dressing	IIb	4
Controlled Negative Pressure Therapysystems and Accessories:		
Suprasorb CNP Controlled Negative Pressure Therapysystem	IIa	11
Suprasorb CNP P3 Accessories (Deep Drain)	IIb	8
Laparotomie Swabs:		
Compresses de Laparotomie	IIa	7
Champ bordant	IIa	7



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Surface disinfectants:

L+R Surfacedisinfekt universal	IIa	15
L+R Surfacedisinfekt alcohol	IIa	15

Gauze Balls:

Opracleen Gauze Dressing with Iodoform	III	13
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Surgical Instruments:

Surgical single use instruments, sterile	IIa	6
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