



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 15 12 45286 058

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

Westerwaldstraße 4
 56579 Rengsdorf
 GERMANY



Facility(ies):

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

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

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

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

**Product
 Category(ies):**

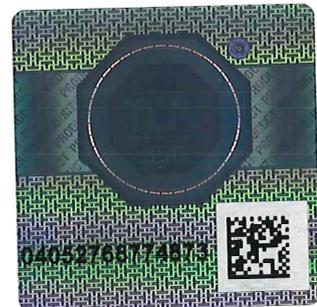
**Gauze Dressings, Gauze Balls, Wound Dressings,
 OR-Set-Systems, Surgical Clothes, Bandages,
 Undercast Paddings, Dressing Gauze, Sanitary
 Pads, Spatula, ENT-, and Ophthalmology products
 (see Attachment)**

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.: 713071390

Valid from: 2016-03-23

Valid until: 2021-03-22



Date, 2016-03-07

Stefan Preiß

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

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



Attachment for Certificate no G2S 15 12 45286 058 dated 2016-03-07

Raucosan First aid dressing	l s	4 Product Service
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	1
OR-Set-Systems and customer special Standard- and Individual Sets:		
such as Raucodrape, PEG-Dressing Change Sets, Dressing Kit <i>for use in</i>	l s	1,4
e.g. General Surgery, Arthroscopy, Angiography, Dermatology, Gynaecology, Ophthalmology, Orthopaedy, Gastrostomy consisting of		
e.g. Surgical Drapes, Clothes		
Surgical Clothes:		
Sentinex Surgical Gown	l s	1
Sentina Gown	l s	1
Bandages:		
Ideal Bandages DIN	l s	1
Mollelast Bandages	l s	1
Lenkelast Bandages	l s	1
Rosidal K	l s	1
Rosidal haft	l s	1
Lenkideal	l s	1
Bande de crêpe cotton	l s	1
Crimpelast	l s	1
Perfekta fine	l s	1
Stella Crepe	l s	1
Wadding:		
Cellona Undercast Paddings	l s	1
Eye Wadding	l s	4
Raucoset surgical cotton rolls	l s	4



Product Service

Dressing Gauze:

Gauze Rolls	l s	4
Dressing Gauze	l s	4

Gauze Dressings:

Perm Cath Gazin Gauze Dressings	l s	4
Dynaphar Gauze Dressings	l s	4

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 Drainage Pad	l s	2
Suprasorb CNP Gel Stripe	l s	4

Munich, CRT-2, 2016-03-07


Stefan Preiß

