



Certificate

No. Q5 045286 0078 Rev. 02

Holder of Certificate: **Lohmann & Rauscher
International GmbH & Co. KG**
Westerwaldstraße 4
56579 Rengsdorf
GERMANY

Certification Mark:



Scope of Certificate: **Design and development, production, purchasing control, marketing and distribution of Products for compression, fixation and support, Wound Dressings, Material for padding, OR-Materials, Surgical single use instruments, Active medical devices for negative pressure wound therapy incl. Accessories, Surface disinfection of Medical Devices, Procedure Packs/Set Systems, Ophthalmological Devices, Maternity Pads, ENT Devices, Swabs and Balls, Products for Immobilization, Orthoses as well as provision of service and maintenance of active medical devices for negative pressure wound therapy**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 045286 0078 Rev. 02

Report No.: 713318890

Valid from: 2024-04-15
Valid until: 2026-06-02

Date, 2024-04-15

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 045286 0078 Rev. 02

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Lohmann & Rauscher GmbH & Co. KG**
Irlicher Strasse 55, 56567 Neuwied, GERMANY

Central function of the quality management system, purchasing control, design and development as well as production of Products for compression, fixation and support, Wound Dressings, material for padding, OR-Materials, surgical single use instruments, Surface disinfection of Medical Devices, Ophthalmological Devices and Products for Immobilization

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

Production and distribution of Products for compression, fixation and support, Wound Dressings, material for padding, OR Materials, Procedure Packs/Set Systems, Ophthalmological Devices, Accessories for active medical devices for negative pressure wound therapy, ENT Devices, Maternity Pads, Swabs and Balls and Orthoses

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

Design, development and production of Products for compression, retention and support, Wound Dressings, material for padding, OR-Materials, active medical devices for negative pressure wound therapy incl. Accessories, Swabs and Balls as well as service and maintenance of active medical devices for negative pressure wound therapy

Lohmann & Rauscher GmbH
Johann-Schorsch-Gasse 4, 1141 Wien, AUSTRIA

Marketing and distribution of Products for compression, fixation and support, Wound Dressings, material for padding and OR-Materials

Certificate

No. Q5 045286 0078 Rev. 02

Lohmann & Rauscher International GmbH & Co. KG

Westerwaldstraße 4, 56579 Rengsdorf, GERMANY

Senior management, marketing and distribution of Products for compression, fixation and support, Wound Dressings, Material for padding, OR-Materials, Surgical single use instruments, Active medical devices for negative pressure wound therapy incl. Accessories, Surface disinfection of Medical Devices, Procedure Packs/Set Systems, Ophthalmological Devices, Maternity Pads, ENT Devices, Swabs and Balls, Products for Immobilization and Orthoses

Laboratoires Lohmann & Rauscher S.A.S

Z.A. de Choisy, 88200 Remiremont, FRANCE

Marketing and distribution of Products for compression, fixation and support, Wound Dressings, material for padding and OR-Materials

Lohmann & Rauscher s.r.l.

Via Edoardo Plinio Masini 2, 35131 Padova, ITALY

Distribution of Products for compression, fixation and support, Wound Dressings, material for padding and OR-Materials

Lohmann & Rauscher s.r.o.

ul. Legií 265, 50901 Nová Paka, CZECH REPUBLIC

Production of Products for compression, fixation and support, Wound Dressings, Material for padding, Ophthalmological Devices, Procedure Packs/Set Systems, Swabs and Balls and Consumer Products

Rauscher Consumer Products GmbH

Johann-Schorsch-Gasse 4, 1141 Wien, AUSTRIA

Marketing and distribution of consumer products, medical devices and Maternity Pads

Lohmann & Rauscher Medical Products France S.A.S.U.

Z.I. du Puits du Crêt, 42530 Saint-Genest Lerpt, FRANCE

Design and development, production and distribution of Products for compression and contention, fixation and support, Products for Immobilization and Orthoses

Certificate

No. Q5 045286 0078 Rev. 02

Lohmann & Rauscher AG

Oberstrasse 222, 9014 St. Gallen, SWITZERLAND

Marketing and distribution of Products for compression, fixation and support, Wound Dressings, material for padding and OR-Materials

Lohmann & Rauscher, s.r.o.

Revolucní 160, 507 91 Stará Paka, CZECH REPUBLIC

Production of Products for compression, fixation and support, Wound Dressings, Material for padding, Procedure Packs/Set Systems, Swabs and Balls and Products for Immobilization

Rauscher Consumer Products GmbH

Kirchengasse 17, 2525 Schönau a.d. Triesting, AUSTRIA

Design and development, production, and distribution of consumer products, medical devices and Maternity Pads

./.