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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Production Quality Assurance Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A

Certificate No. G26 011858 0077 Rev. 00

Manufacturer:

PAUL HARTMANN AG
Paul-Hartmann-Str. 12
89522 Heidenheim
GERMANY

SRN Manufacturer - DE-MF-000005861

The quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex XI Part A with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class I devices in sterile conditions, with measuring function, or reusable surgical instruments are covered by this certificate, the audit was limited to the respective aspects relating to
- establishing, securing, and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

If class IIa devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The devices conform to the technical documentation. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class IIb or class III devices are covered by this certificate, the quality management system ensures that devices conform to the type that has undergone a type examination. An EU Type-Examination Certificate in accordance with Annex X is required before placing them on the market.

All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G26 011858 0077 Rev. 00

Report No.: 713381129
Preceding Certificate No.: G21 011858 0069 Rev. 05

Valid from: 2025-11-30
Valid until: 2030-11-29

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-10-21

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EU Production Quality Assurance Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A

Certificate No. G26 011858 0077 Rev. 00

Classification:	Class I
Device Group:	T0399 - PROTECTION DEVICES (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT PPE) - OTHER
Device Properties:	MDS 1005 - Devices in sterile condition MDS 1010 - Devices with a measuring function
Classification:	Class I
Device Group:	M040101 - ADHESIVE DRESSINGS, WITH ABSORBENT PAD
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	M040102 - FIXING DRESSINGS
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	M040301 - EYE PADS, COTTON OR NON-WOVEN MATERIALS
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	T030102 - COVER SHEATHS, INSTRUMENTS AND EQUIPMENTS
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	T0202 - SURGICAL PROCEDURAL KITS (EXCLUDING SURGICAL INSTRUMENT KITS)
Device Properties:	MDS 1005 - Devices in sterile condition MDS 1010 - Devices with a measuring function
Classification:	Class I
Device Group:	T0299 - PROTECTION DRAPES AND GARMENTS - OTHER
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	Z129080 - VARIOUS INSTRUMENTS FOR FUNCTIONAL EXPLORATION AND THERAPEUTIC INTERVENTIONS - HARDWARE ACCESSORIES
Device Properties:	MDS 1005 - Devices in sterile condition

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EU Production Quality Assurance Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A

Certificate No. G26 011858 0077 Rev. 00

Classification:	Class I
Device Group:	Z120190 - VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	T010202 - SYNTHETIC EXAMINATION / TREATMENT GLOVES
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	M020102 - COTTON GAUZES, FOLDED
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	M020101 - COTTON GAUZES, CUT
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	M020107 - COTTON GAUZES IN ROLLS
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	M020201 - NON-WOVEN FOLDED GAUZES
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	M040201 - ABSORBENT DRESSINGS WITH CELLULOSE PAD AND NON-WOVEN WRAPS
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	M040299 - NON-ADHESIVE ABSORBENT DRESSINGS - OTHER
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	A0699 - DRAINAGE AND FLUID COLLECTION DEVICES - OTHER
Device Properties:	MDS 1005 - Devices in sterile condition

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EU Production Quality Assurance Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A

Certificate No. G26 011858 0077 Rev. 00

Classification:	Class I
Device Group:	H02010106 - METAL SURGICAL STAPLE REMOVERS, SINGLE-USE
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	T020401 - STANDARD SURGICAL GOWNS
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	T020402 - REINFORCED SURGICAL GOWNS
Device Properties:	MDS 1005 - Devices in sterile condition
The validity of this certificate depends on conditions and/or is limited to the following:	-

Revision History:

Rev.	Dated	Report	Description
00	2025-11-30	713381129	Renewal of certificate Administrative merge / transfer to new Certificate Type

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