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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G21 011858 0069 Rev. 03

Manufacturer:

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

SRN Manufacturer - DE-MF-000005861

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex XI Part A of this regulation with a positive result.
As applicable the involvement of the notified body is limited to the 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.

The certified quality assurance system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. 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:G21 011858 0069 Rev. 03

Report No.:	713334121
Preceding Certificate No.:	G21 011858 0069 Rev. 02
Valid from:	2024-06-18
Valid until:	2025-11-29
Date of Initial Issuance:	2020-11-30

Issue date: 2024-06-18

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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No. G21 011858 0069 Rev. 03

Classification:	Class I
Device Group:	T0399 - PROTECTION DEVICES (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT PPE) - OTHER
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1010 - Devices with a measuring function
Classification:	Class I
Device Group:	M040101 - ADHESIVE DRESSINGS, WITH ABSORBENT PAD
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	M040102 - FIXING DRESSINGS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1005.2 - Sterilisation by irradiation
Classification:	Class I
Device Group:	M040301 - EYE PADS, COTTON OR NON-WOVEN MATERIALS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	T030102 - COVER SHEATHS, INSTRUMENTS AND EQUIPMENTS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	T0202 - SURGICAL PROCEDURAL KITS (EXCLUDING SURGICAL INSTRUMENT KITS)
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1010 - Devices with a measuring function
Classification:	Class I
Device Group:	T0299 - PROTECTION DRAPES AND GARMENTS - OTHER
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	Z129080 - VARIOUS INSTRUMENTS FOR FUNCTIONAL EXPLORATION AND THERAPEUTIC INTERVENTIONS - HARDWARE ACCESSORIES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

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Classification:	Class I
Device Group:	Z120190 - VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	T010202 - SYNTHETIC EXAMINATION / TREATMENT GLOVES
Device Properties:	MDS 1005.2 - Sterilisation by irradiation

Classification:	Class I
Device Group:	M020102 - COTTON GAUZES, FOLDED
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	M020101 - COTTON GAUZES, CUT
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1005.3 - Sterilization by moist heat

Classification:	Class I
Device Group:	M020107 - COTTON GAUZES IN ROLLS
Device Properties:	MDS 1005.3 - Sterilization by moist heat

Classification:	Class I
Device Group:	M020201 - NON-WOVEN FOLDED GAUZES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1005.3 - Sterilization by moist heat

Classification:	Class I
Device Group:	M040201 - ABSORBENT DRESSINGS WITH CELLULOSE PAD AND NON-WOVEN WRAPS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1005.3 - Sterilization by moist heat

Classification:	Class I
Device Group:	M040299 - NON-ADHESIVE ABSORBENT DRESSINGS - OTHER
Device Properties:	MDS 1005.3 - Sterilization by moist heat

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Classification:	Class I
Device Group:	A0699 - DRAINAGE AND FLUID COLLECTION DEVICES - OTHER
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	H02010106 - METAL SURGICAL STAPLE REMOVERS, SINGLE-USE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

The validity of this certificate depends on conditions and/or is limited to the following: ./.

Revision History:

Rev.	Dated	Report	Description
00	2020-11-30	713191741	-
01	2021-12-08	713213658	-
02	2022-07-20	713214126	-
03	2024-06-18	713334121	Supplemented: Device(s)/group of device(s) added

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