



## 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. 01**

**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 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:G21 011858 0069 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:G21_011858_0069_Rev.01)

**Report No.:** 713213658  
**Preceding Certificate No.:** G21 011858 0069 Rev. 00  
**Valid from:** 2021-12-08  
**Valid until:** 2025-11-29  
**Date of Initial Issuance:** 2020-11-30

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2022-02-09



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<b>Classification:</b>	I
<b>Device Group:</b>	T0399 - PROTECTION DEVICES (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT PPE) - OTHER
<b>Device Properties:</b>	MDS 1005.1 - Ethylene Oxide sterilization
<b>Classification:</b>	I
<b>Device Group:</b>	M04010101 - NON-WOVEN ADHESIVE DRESSINGS, WITH ABSORBENT PAD
<b>Device Properties:</b>	MDS 1005.1 - Ethylene Oxide sterilization
<b>Classification:</b>	I
<b>Device Group:</b>	M04010201 - NON-WOVEN FIXING DRESSINGS
<b>Device Properties:</b>	MDS 1005.1 - Ethylene Oxide sterilization
<b>Classification:</b>	I
<b>Device Group:</b>	M04010202 - POLYURETHANE FIXING DRESSINGS
<b>Device Properties:</b>	MDS 1005.1 - Ethylene Oxide sterilization
<b>Classification:</b>	I
<b>Device Group:</b>	M040301 - EYE PADS, COTTON OR NON-WOVEN MATERIALS
<b>Device Properties:</b>	MDS 1005.1 - Ethylene Oxide sterilization
<b>Classification:</b>	I
<b>Device Group:</b>	T030102 - COVER SHEATHS, INSTRUMENTS AND EQUIPMENTS
<b>Device Properties:</b>	MDS 1005.1 - Ethylene Oxide sterilization
<b>Classification:</b>	I
<b>Device Group:</b>	T0202 - SURGICAL PROCEDURAL KITS (EXCLUDING SURGICAL INSTRUMENT KITS)
<b>Device Properties:</b>	MDS 1005.1 - Ethylene Oxide sterilization
<b>Classification:</b>	I
<b>Device Group:</b>	T0299 - PROTECTION DRAPES AND GARMENTS - OTHER
<b>Device Properties:</b>	MDS 1005.1 - Ethylene Oxide sterilization
<b>Classification:</b>	I
<b>Device Group:</b>	Z129080 - VARIOUS INSTRUMENTS FOR FUNCTIONAL EXPLORATION AND THERAPEUTIC INTERVENTIONS - HARDWARE ACCESSORIES



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**Device Properties:** MDS 1005.1 - Ethylene Oxide sterilization

**Classification:** I  
**Device Group:** Z12019080 - VARIOUS INSTRUMENTS FOR GENERAL AND  
 MULTIDISCIPLINARY SURGERY - HARDWARE ACCESSORIES

**Device Properties:** MDS 1005.1 - Ethylene Oxide sterilization

**Classification:** I  
**Device Group:** T01020204 - NITRILE EXAMINATION / TREATMENT GLOVES  
**Device Properties:** MDS 1005.2 - Sterilisation by irradiation

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

<b>Revision History:</b>	Rev.	Dated	Report
	00	2020-11-30	713191741