



## 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](http://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



## EU Production Quality Assurance Certificate

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

**Certificate No. G26 011858 0077 Rev. 00**

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



## EU Production Quality Assurance Certificate

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

**Certificate No. G26 011858 0077 Rev. 00**

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



## 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<br>Administrative merge / transfer to new Certificate Type |