

## EU Declaration of Conformity

Heidenheim, 2025-11-20

|                             |                                                                          |
|-----------------------------|--------------------------------------------------------------------------|
| <b>Product Group Number</b> | <b>2144</b>                                                              |
| <b>Manufacturer</b>         | PAUL HARTMANN AG<br>Paul-Hartmann-Str. 12<br>89522 Heidenheim<br>GERMANY |

We herewith declare under our sole responsibility that the product listed above, first placed on the market by PAUL HARTMANN AG, satisfies the applicable provisions of the following listed legislations. The conformity assessment procedures have been performed and the Technical Documentation is kept available.

### Applied legislative acts

#### Medical Device Regulation (EU) 2017/745

|                                 |                                                                                                |             |
|---------------------------------|------------------------------------------------------------------------------------------------|-------------|
| High Level Intended Purpose     | General single-use, non-active, non-implantable devices used in health care                    |             |
| Classification                  | <b>Risk Class</b>                                                                              | <b>Rule</b> |
|                                 | I s                                                                                            | Rule 1      |
| Conformity Assessment Procedure | Article 52 (7) and Annex XI part A with respect to sterility                                   |             |
| Notified Body                   | TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123               |             |
| EU Certificates                 | EU Production Quality Assurance Certificate<br>No. G26 011858 0077 Rev. 00,                    |             |
|                                 | Device Group: T0399 - PROTECTION DEVICES (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT PPE) - OTHER |             |
| Single Registration Number      | Manufacturer: DE-MF-000005861                                                                  |             |
| Basic UDI-DI                    | 40495002144K7                                                                                  |             |

GLN 404 9500 00000 0

Vorstand/Management Board: Britta Fünfstück  
(Vorsitzende des Vorstands/CEO), François Georgelin,  
Stefan Grote, Oliver Neubrand  
Aufsichtsratsvorsitzender/Chairman of the Supervisory Board:  
Fritz-Jürgen Heckmann

Sitz Heidenheim  
Amtsgericht Ulm HRB 661090  
Registered Office Heidenheim  
Commercial Register of the District Court of Ulm file no. HRB 661090

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| Product Group Number | 2144   |                                                                          |
|----------------------|--------|--------------------------------------------------------------------------|
|                      | Code   | Term                                                                     |
| EMDN                 | T0399  | PROTECTION DEVICES (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT PPE) - OTHER |
| GMDN                 | 47783  | Patient surgical drape, single-use, sterile                              |
| UMDNS                | 15-646 | Drapes, Surgical, Disposable                                             |

PAUL HARTMANN AG

ppa.

**Martin Walther**  
Senior Vice President  
Risk Prevention

i.V

**Christiana Hofmann**  
Head of Regulatory Affairs, PRRC  
Risk Prevention

**Valid from:** 2025-11-30

**Valid until:** 2030-11-29

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Helps. Cares. Protects.

List of products falling under the respective Product Group Number:

**2144**

| REF    | Name - Description                              |
|--------|-------------------------------------------------|
| 936225 | Foliodrape Protect Split sheet, adhesive        |
| 938813 | Foliodrape Protect Adhesive split sheet         |
| 938815 | Foliodrape Protect Split sheet, adhesive, crepe |
| 938817 | Foliodrape Protect Split sheet, adhesive, crepe |

GLN 404 9500 00000 0

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