

## EU Declaration of Conformity

Heidenheim, 2025-11-18

|                             |                                                                          |
|-----------------------------|--------------------------------------------------------------------------|
| <b>Product Group Number</b> | 3561                                                                     |
| <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 legislation. The conformity assessment procedure has been performed and the Technical Documentation is kept available.

### Applied legislative act

Medical Device Regulation (EU) 2017/745

|                                 |                                                                                                                                                                                                                                                          |                                        |
|---------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
| High Level Intended Purpose     | Single-use, non-active, non-implantable devices for wound and skin care                                                                                                                                                                                  |                                        |
| Classification                  | <b>Risk Class</b>                                                                                                                                                                                                                                        | <b>Rule</b>                            |
|                                 | Class Is                                                                                                                                                                                                                                                 | Rule 4   main paragraph + 1st indent   |
| Conformity Assessment Procedure | Article 52 (7) and Annex XI part A with respect to sterility (a)                                                                                                                                                                                         |                                        |
| Notified Body                   | TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123                                                                                                                                                                         |                                        |
| EU Certificates                 | EU Production Quality Assurance Certificate (MDR) No. G26 011858 0077 Rev. 00, Device Group: M040101 - ADHESIVE DRESSINGS, WITH ABSORBENT PAD, Device Properties: MDS 1005.1 - Ethylene Oxide sterilization<br>MDS 1005.2 - Sterilisation by irradiation |                                        |
| Single Registration Number      | Manufacturer: DE-MF-000005861                                                                                                                                                                                                                            |                                        |
| Basic UDI-DI                    | 40495003561L2                                                                                                                                                                                                                                            |                                        |
| EMDN<br>GMDN<br>UMDNS           | <b>Code</b>                                                                                                                                                                                                                                              | <b>Term</b>                            |
|                                 | M040101                                                                                                                                                                                                                                                  | ADHESIVE DRESSINGS, WITH ABSORBENT PAD |
|                                 | 34864                                                                                                                                                                                                                                                    | Adhesive bandage                       |
|                                 | 10-288                                                                                                                                                                                                                                                   | Bandages, Self-Adherent                |

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  
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**Jochen Bauer**

Vice President R&D Wound Care & Consumer  
Health

ppa.

**Stefan Fischer**

Senior Vice President Regulatory Affairs

Valid from: 2025-11-30

Valid until: 2030-11-29

List of products falling under the respective Product Group Number:

| REF    | Name - Description                                                          |
|--------|-----------------------------------------------------------------------------|
| 901095 | Cosmopor Entry PPay 7,2x5 P10 ES, PT<br>Cosmopor Entry 7,2x5cm st P10 ES,PT |
| 901096 | Cosmopor Entry PPay 10x6 P10 ES, PT<br>Cosmopor Entry 10x6cm st P10 ES,PT   |
| 901097 | Cosmopor Entry PPay 10x8 P10 ES, PT<br>Cosmopor Entry 10x8cm st P10 ES,PT   |
| 901098 | Cosmopor Entry PPay 15x8 P10 ES, PT<br>Cosmopor Entry 15x8cm st P10 ES,PT   |
| 901099 | Cosmopor Entry PPay 20x10 P10 ES, PT                                        |

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