



## EU Declaration of Conformity

Heidenheim, 2025-11-18

|                             |  |
|-----------------------------|--|
| <b>Product Group Number</b> | 1401   |
| <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

|  |  |  |
|--|--|--|
| <b>High Level Intended Purpose</b>     | Single-use, non-active, non-implantable devices for wound and skin care  |  |
| <b>Classification</b>                  | <b>Risk Class</b>  | <b>Rule</b>  |
|  | Class Is   | Rule 4   main paragraph + 1st indent                           |
| <b>Conformity Assessment Procedure</b> | Article 52 (7) and Annex XI part A with respect to sterility (a)   |  |
| <b>Notified Body</b>                   | TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123   |  |
| <b>EU Certificates</b>                 | EU Production Quality Assurance Certificate (MDR) No. G26 011858 0077 Rev. 00, Device Group: M040201 - ABSORBENT DRESSINGS WITH CELLULOSE PAD AND NON-WOVEN WRAPS, Device Properties: MDS 1005.3 - Sterilization by moist heat |  |
| <b>Single Registration Number</b>      | Manufacturer: DE-MF-000005861  |  |
| <b>Basic UDI-DI</b>                    | 40495001401JV  |  |
| <b>EMDN</b>                            | <b>Code</b>  | <b>Term</b>  |
|  | M040201  | ABSORBENT DRESSINGS WITH CELLULOSE PAD AND NON-WOVEN WRAPS     |
| <b>GMDN</b>                            | 44970  | Exudate-absorbent dressing, hydrophilic-gel, non-antimicrobial |
| <b>UMDNS</b>                           | 15-216   | Dressings, other   |

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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PAUL HARTMANN AG

ppa.

**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               |
|--------|----------------------------------|
| 413651 | Zetuvit steril 10x10 cm LPPR P10 |
| 413652 | Zetuvit steril 10x20 cm LPPR P10 |
| 413653 | Zetuvit steril 15x20 cm LPPR P10 |
| 413654 | Zetuvit steril 20x25 cm LPPR P10 |
| 413701 | Zetuvit st 10x10cm P25           |
| 413702 | Zetuvit st 10x20cm P25           |
| 413703 | Zetuvit st 20x20cm P15           |
| 413704 | Zetuvit sterile, 20x40 cm P5     |
| 413708 | Zetuvit steril 10x10 cm DE P25   |
| 413709 | Zetuvit steril 10x20 cm DE P25   |

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