

## EU Declaration of Conformity

Heidenheim, 2025-04-09

|                             |                                                                          |
|-----------------------------|--------------------------------------------------------------------------|
| <b>Product Group Number</b> | 2852                                                                     |
| <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     | Sterile, non-medicated, products for negative pressure wound therapy                                                                                                                                                                            |                                                     |
| Classification                  | Risk Class                                                                                                                                                                                                                                      | Rule                                                |
|                                 | Class IIb                                                                                                                                                                                                                                       | Rule 4   main paragraph + 2nd indent                |
| Conformity Assessment Procedure | Article 52 (4) and Annex IX                                                                                                                                                                                                                     |                                                     |
| Notified Body                   | TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123                                                                                                                                                                |                                                     |
| EU Certificates                 | EU Quality Management System Certificate (MDR) No. G10 011858 0065 Rev. 04, Device Group: M040499 - DRESSINGS FOR WOUNDS, SORES AND ULCERATIONS - OTHER, Intended Purpose: Sterile, non-medicated, products for negative pressure wound therapy |                                                     |
| Single Registration Number      | Manufacturer: DE-MF-000005861                                                                                                                                                                                                                   |                                                     |
| Basic UDI-DI                    | 40495002852L9                                                                                                                                                                                                                                   |                                                     |
| EMDN                            | Code                                                                                                                                                                                                                                            | Term                                                |
|                                 | M040499                                                                                                                                                                                                                                         | DRESSINGS FOR WOUNDS, SORES AND ULCERATIONS - OTHER |
| GMDN                            | 47956                                                                                                                                                                                                                                           | Negative-pressure wound therapy system dressing set |
| UMDNS                           | 11-314                                                                                                                                                                                                                                          | Dressing kits                                       |

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  
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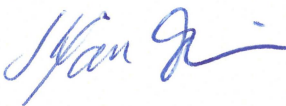


PAUL HARTMANN AG

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**Jochen Bauer**  
Vice President R&D Wound Care & Consumer Health

  
**Stefan Fischer**  
Senior Vice President Regulatory Affairs

Valid from: 2025-05-06

Valid until: 2030-05-05

List of products falling under the respective Product Group Number:

| REF    | Name - Description                                    |
|--------|-------------------------------------------------------|
| 409713 | VivanoMed Foam Kit o. Tablett L st P5                 |
| 409716 | VivanoMed Foam Kit o. Tablett M st P5                 |
| 409719 | VivanoMed Foam Kit o. Tablett S st P5                 |
| 409722 | VivanoMed Foam Kit L st P3                            |
| 409723 | VivanoMed Foam Kit L st P5                            |
| 409724 | VivanoMed Foam Kit L st P10                           |
| 409725 | VivanoMed Foam Kit M st P3                            |
| 409726 | VivanoMed Foam Kit M P5<br>VivanoMed Foam Kit M st P5 |
| 409727 | VivanoMed Foam Kit M st P10                           |
| 409728 | VivanoMed Foam Kit S st P3                            |
| 409729 | VivanoMed Foam Kit S st P5                            |
| 409730 | VivanoMed Foam Kit S st P10                           |
| 409731 | VivanoMed Foam Kit XL st P3                           |
| 409732 | VivanoMed Foam Kit XL st P5                           |
| 409733 | VivanoMed Foam Kit XL st P10                          |
| 409741 | VivanoMed Foam Kit Rund st P5                         |
| 409743 | VivanoMed Foam Kit Thin st P5                         |

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