

## EU Declaration of Conformity

Heidenheim, 2025-03-25

|                             |                                                                          |
|-----------------------------|--------------------------------------------------------------------------|
| <b>Product Group Number</b> | 1668                                                                     |
| <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     | Non-active, non-implantable devices for wound and skin care |                            |
| Classification                  | <b>Risk Class</b>                                           | <b>Rule</b>                |
|                                 | Class I                                                     | Rule 1                     |
| Conformity Assessment Procedure | Article 52 (7)                                              |                            |
| Notified Body                   | n/a                                                         |                            |
| Single Registration Number      | Manufacturer: DE-MF-000005861                               |                            |
| Basic UDI-DI                    | 40495001668L7                                               |                            |
| EMDN                            | <b>Code</b>                                                 | <b>Term</b>                |
|                                 | M050101                                                     | PLASTERS ON SPOOLS (ROLLS) |
|                                 | GMDN                                                        | 16866                      |
|                                 | UMDNS                                                       | 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

Commercial Register of the District Court of Ulm file no. HRB  
661090

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PAUL HARTMANN AG

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**Jochen Bauer**

Vice President R&D Wound Care & Consumer  
Health

ppa.

**Stefan Fischer**

Senior Vice President Regulatory Affairs

Valid until: 2030-10-31

List of products falling under the respective Product Group Number:

| REF    | Name - Description                       |
|--------|------------------------------------------|
| 500058 | Omnitape Pflaster GW w 2cmx10m P1 int    |
| 500059 | Omnitape Pflaster GW w 3,75cmx10m P1 int |
| 500060 | Omnitape Pflaster GW w 5cmx10m P1 int    |

GLN 404 9500 00000 0

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