

## EU Declaration of Conformity

Heidenheim, 2025-03-25

|                             |                                                                          |
|-----------------------------|--------------------------------------------------------------------------|
| <b>Product Group Number</b> | 1535                                                                     |
| <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 I                                                                 | Rule 4   main paragraph + 1st indent   |
| Conformity Assessment Procedure | Article 52 (7)                                                          |                                        |
| Notified Body                   | n/a                                                                     |                                        |
| Single Registration Number      | Manufacturer: DE-MF-000005861                                           |                                        |
| Basic UDI-DI                    | 40495001535KK                                                           |                                        |
| EMDN                            | <b>Code</b>                                                             | <b>Term</b>                            |
|                                 | M040101                                                                 | ADHESIVE DRESSINGS, WITH ABSORBENT PAD |
|                                 | GMDN                                                                    | 44990                                  |
|                                 | 44990                                                                   | Skin-cover adhesive strip              |
| 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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Vice President R&D Wound Care & Consumer  
Health

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**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                                                                                                                                              |
|--------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 530540 | Cosmos aqua 3sizes, P20 (DE,FR,IT,NL)                                                                                                                           |
| 530550 | Cosmos aqua 3sizes,P20 (RO,BG,HU,GR)                                                                                                                            |
| 530560 | Cosmos aqua 3sizes,P20 (EN,PL,SL,HR)                                                                                                                            |
| 535513 | Cosmos aqua fun, 2 sizes P12 (RU)                                                                                                                               |
| 535523 | Cosmos aqua 3sizes, P10 (RU)                                                                                                                                    |
| 535531 | Cosmos AQUA CZ/SK Strips 3sizes P10<br>Cosmos aqua CZ/SK Strips 3sizes P10<br>Cosmos AQUA CZ/SK Kaufland 3sizes P10<br>Cosmos AQUA CZ/SK 3sizes P10 (Kaufland ) |
| 535532 | Cosmos aqua fun 2 sizes, P12                                                                                                                                    |
| 535533 | Cosmos aqua finger mix, 3sizes P16 (RU)                                                                                                                         |
| 535543 | Cosmos aqua 2,5x7,2cm P12 (RU)                                                                                                                                  |

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