



EU Declaration of Conformity

Heidenheim, 2024-10-31

| | |
|-----------------------------|--|
| Product Group Number | 1406 |
| Manufacturer | PAUL HARTMANN AG Paul-Hartmann-Str. 12 89522 Heidenheim 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 | Risk Class | Rule |
| | Class I | Rule 1 |
| Conformity Assessment Procedure | Article 52 (7) | |
| Notified Body | TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123 | |
| Single Registration Number | Manufacturer: DE-MF-000005861 | |
| Basic UDI-DI | 40495001406K7 | |
| EMDN | Code | Term |
| | M040201 | ABSORBENT DRESSINGS WITH CELLULOSE PAD AND NON-WOVEN WRAPS |
| GMDN | 44970 | Exudate-absorbent dressing, non-gel, non-antimicrobial |
| UMDNS | 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
 Commercial Register of the District Court of Ulm file no. HRB
 661090

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Helps. Cares. Protects.

PAUL HARTMANN AG

ppa.

Jochen Bauer

Vice President R&D Wound Care & Consumer
Health

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 |
|--------|--------------------------------|
| 413860 | Zetuvit E unsteril 10x10cm P50 |
| 413861 | Zetuvit E unsteril 10x20cm P50 |
| 413862 | Zetuvit E unsteril 15x20cm P50 |
| 413863 | Zetuvit E unsteril 15x25cm P50 |
| 413864 | Zetuvit E 20x20cm P50 |
| 413865 | Zetuvit E unsteril 20x25cm P50 |
| 413866 | Zetuvit E unsteril 20x40cm P30 |

GLN 404 9500 00000 0

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