# Declaration of Conformity

PPWR

EU DECLARATION NO.* **100742560** Date: **11.08.2026**

| | |
|---|---|
| **Product Identification** | |
| Unique identification of the packaging | LABEL |
| Manufacturer name and address | Paul Hartmann AG<br>Paul-Hartmann-Straße 12<br>89522 Heidenheim<br>Germany |
| Sole responsibility statement | This declaration of conformity is issued under the sole responsibility of the manufacturer. |
| Identification enabling traceability | Applies for all packaging materials used to label packaging |
| **Object of the Declaration** | |
| Description of packaging | Self-adhesive labels (pre-printed, neutral, and/or with sterile indicator), papers, inkjet inks and thermal transfer ribbons, documents enclosed envelopes |
| **Relevant Union Legislation** | |
| Reference to Regulation (EU) 2025/40 and applicable articles | Regulation (EU) 2025/40 of the European Parliament and of the Council, Article 5 |
| **Harmonized Standards** | |
| Harmonised standards applied | Not applicable |
| References to common specifications used | Not applicable |
| **Additional Information** | |
| Heidenheim, 11.08.2026 | Heidenheim, 11.08.2026 |
| (Place and Date of Issue) | (Place and Date of Issue) |
| i.V. Rüdiger Kliewer<br>Rüdiger Kliewer<br>Director Packaging/Materials Handling | i.V. Georgina Bischur<br>Georgina Bischur<br>Teamlead Packaging Development |
| (Name, Function) (Signature) | (Name, Function) (Signature) |

HARTMANN

# Declaration of Conformity

PPWR

EU DECLARATION NO.*.. **100729061** Date: **10.08.2026**

| | |
|---|---|
| **Product Identification** | |
| Unique identification of the packaging | PEP_FB |
| Manufacturer name and address | Paul Hartmann AG<br>Paul-Hartmann-Straße 12<br>89522 Heidenheim<br>Germany |
| Sole responsibility statement | This declaration of conformity is issued under the sole responsibility of the manufacturer. |
| Identification enabling traceability | Applies to all products packaged using this packaging model |
| **Object of the Declaration** | |
| Description of packaging | Product in peel pouch packed in a folding box |
| **Relevant Union Legislation** | |
| Reference to Regulation (EU) 2025/40 and applicable articles | Regulation (EU) 2025/40 of the European Parliament and of the Council, Article 5 |
| **Harmonized Standards** | |
| Harmonised standards applied | Not applicable |
| References to common specifications used | Not applicable |
| **Additional Information** | |
| Heidenheim, 10.08.2026 | Heidenheim, 10.08.2026 |
| (Place and Date of Issue) | (Place and Date of Issue) |
| i.V. Rüdiger Kliewer<br>Rüdiger Kliewer<br>Director Packaging/Materials Handling | i.V. Georgina Bischur<br>Georgina Bischur<br>Teamlead Packaging Development |
| (Name, Function) (Signature) | (Name, Function) (Signature) |

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89522 Heidenheim

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HARTMANN
Helps. Cares. Protects.

## EU Declaration of Conformity

Heidenheim, 2025-04-09

| | |
|---|---|
| **Product Group Number** | 2841 |
| **Manufacturer** | 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, sterile, non-medicated dressings suitable for the treatment of wounds | |
| 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: Single-use, sterile, non-medicated dressings suitable for the treatment of wounds | |
| Single Registration Number | Manufacturer: DE-MF-000005861 | |
| Basic UDI-DI | 40495002841L4 | |
| EMDN | Code | Term |
| | M040499 | DRESSINGS FOR WOUNDS, SORES AND ULCERATIONS - OTHER |
| GMDN | 58475 | Sodium chloride dressing |
| UMDNS | 15-216 | Verband, sonstige (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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PAUL HARTMANN AG

ppa.

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

ppa.

**Stefan Fischer**
Senior Vice President Regulatory Affairs

Valid from: 2025-05-06
Valid until: 2030-05-05

List of products falling under the respective Product Group Number:

| REF | Name - Description |
|---|---|
| 609609 | HydroClean advance mini 3cm P10 |

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

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Amtsgericht Ulm HRB 661090
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