PAUL HARTMANN AG
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89522 Heidenheim

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Germany

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HARTMANN
Helps. Cares. Protects.

## EU Declaration of Conformity

Heidenheim, 2025-11-18

| | |
|---|---|
| **Product Group Number** | 1012 |
| **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, non-active, non-implantable devices for wound and skin care | |
| Classification | Risk Class | Rule |
| | Class Is | Rule 1 |
| Conformity Assessment Procedure | Article 52 (7) and Annex XI part A with respect to sterility (a) | |
| Notified Body | TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123 | |
| EU Certificates | EU Production Quality Assurance Certificate (MDR) No. G26 011858 0077 Rev. 00, Device Group: A0699 - DRAINAGE AND FLUID COLLECTION DEVICES - OTHER, Device Properties: MDS 1005.1 - Ethylene Oxide sterilization | |
| Single Registration Number | Manufacturer: DE-MF-000005861 | |
| Basic UDI-DI | 40495001012JE | |
| EMDN | Code | Term |
| | A0699 | DRAINAGE AND FLUID COLLECTION DEVICES - OTHER |
| GMDN | 47404 | Negative-pressure wound-therapy system canister |
| UMDNS | 15-270 | Drains, sump |

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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ppa.

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

ppa.

**Stefan Fischer**
Senior Vice President Regulatory Affairs

Valid from: 2025-11-30
Valid until: 2030-11-29

List of products falling under the respective Product Group Number:

| REF | Name - Description |
|---|---|
| 409520 | VivanoTec Sekretbehälter 800ml st, P3 |
| 409521 | VivanoTec Sekretbehälter 800ml st, P5 |
| 409522 | VivanoTec Sekretbehälter 800ml st, P10 |
| 409523 | VivanoTec Sekretbehälter 300ml st, P3 |
| 409524 | VivanoTec Sekretbehälter 300ml st, P5 |
| 409525 | VivanoTec Sekretbehälter 300ml st, P10 |

GLN 404 9500 00000 0
Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Stefan Grote, Oliver Neubrand
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