PAUL HARTMANN AG
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HARTMANN
Helps. Cares. Protects.

## EU Declaration of Conformity

Heidenheim, 2025-03-25

| | |
|---|---|
| **Product Group Number** | 1004 |
| **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 | 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 | n/a | |
| Single Registration Number | Manufacturer: DE-MF-000005861 | |
| Basic UDI-DI | 40495001004JF | |
| EMDN | Code | Term |
| | V9099 | VARIOUS DEVICES NOT INCLUDED IN OTHER CLASSES - OTHER |
| GMDN | 64506 | Dressing dispenser |
| UMDNS | 11-313 | Standgefäß, Verbandmaterial (Jars, Dressing) |

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ppa.

**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 |
|---|---|
| 996857 | Pur-Zellin Box leer P1 |