PAUL HARTMANN AG
Paul-Hartmann-Strasse 12
89522 Heidenheim

P.O. Box 1420
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Germany

Phone: +49 (0) 7321 36-0
Fax: +49 (0) 7321 36-3636
www.hartmann.info

HARTMANN
Helps. Cares. Protects.

## EU Declaration of Conformity

Heidenheim, 2025-11-20

| | |
|---|---|
| **Product Group Number** | **2233** |
| **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 legislations. The conformity assessment procedures have been performed and the Technical Documentation is kept available.

### Applied legislative acts

Medical Device Regulation (EU) 2017/745

| | | |
|---|---|---|
| High Level Intended Purpose | General single-use, non-active, non-implantable devices used in health care | |
| Classification | Risk Class | Rule |
| | I s | Rule 1 |
| Conformity Assessment Procedure | Article 52 (7) and Annex XI part A with respect to sterility | |
| Notified Body | TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123 | |
| EU Certificates | EU Production Quality Assurance Certificate<br>No. G26 011858 0077 Rev. 00,<br><br>Device Group: T0202 - SURGICAL PROCEDURAL KITS (EXCLUDING SURGICAL INSTRUMENT KITS) | |
| Single Registration Number | Manufacturer: DE-MF-000005861 | |
| Basic UDI-DI | 40495002233K7 | |

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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|---|---|---|
| | Code | Term |
| EMDN | T0202 | SURGICAL PROCEDURAL KITS (EXCLUDING SURGICAL INSTRUMENT KITS) |
| GMDN | 47783 | Patient surgical drape, single-use, sterile |
| UMDNS | 15-646 | Drapes, Surgical, Disposable |

PAUL HARTMANN AG

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**Martin Walther**
Senior Vice President
Risk Prevention

i.V

**Christiana Hofmann**
Head of Regulatory Affairs, PRRC
Risk Prevention

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

GLN 404 9500 00000 0
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List of products falling under the respective Product Group Number: **2233**

| REF | Name - Description |
|---|---|
| 936733 | Foliodrape Protect Shoulder/Arthroscopy set I, crepe |
| 936741 | Foliodrape Protect Knee/Arthroscopy set III |
| 938703 | Foliodrape Protect Knee/Arthroscopy set IV |
| 938726 | Foliodrape Protect Shoulder/Arthroscopy set II |
| 938729 | Foliodrape Protect Knee/Arthroscopy set II |
| 938909 | Foliodrape Protect Knee/Arthroscopy set I, crepe |
| 250033 | Foliodrape Protect Shoulder/Arthroscopy set II |
| 250039 | Foliodrape Protect Knee/Arthroscopy set V |

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