



EU Declaration of Conformity

Heidenheim, 2025-11-18

| | |
|-----------------------------|--------------------------------------------------------------------------|
| Product Group Number | 1143 |
| 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 | Single-use, non-active, non-implantable devices for wound and skin care | |
| Classification | Risk Class | Rule |
| | Class Is | Rule 4 main paragraph + 1st indent |
| 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: M020101 - COTTON GAUZES, CUT, Device Properties: MDS 1005.2 - Sterilisation by irradiation | |
| Single Registration Number | Manufacturer: DE-MF-000005861 | |
| Basic UDI-DI | 40495001143JW | |
| EMDN | Code | Term |
| | M020101 | COTTON GAUZES, CUT |
| GMDN | 48134 | Woven gauze pad |
| UMDNS | 10-966 | Kompresse, Mull (Compresses, Gauze) |

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

PAUL HARTMANN AG
Paul-Hartmann-Strasse 12
89522 Heidenheim

P.O. Box 1420
89504 Heidenheim
Germany

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



Helps. Cares. Protects.

PAUL HARTMANN AG

ppa.

ppa.

Jochen Bauer

Vice President R&D Wound Care & Consumer
Health

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 |
|--------|----------------------------------------|
| 205100 | Verbandmull BW st ges 17fd 50x80cm P1 |
| 205103 | Verbandmull BW st ges 17fd 25x80cm P1 |
| 205106 | Verbandmull BW st ges 17fd 100x80cm P1 |

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