



EU Declaration of Conformity

Heidenheim, 2025-11-18

Product Group Number	3547
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: M040101 - ADHESIVE DRESSINGS, WITH ABSORBENT PAD, Device Properties: MDS 1005.1 - Ethylene Oxide sterilization MDS 1005.2 - Sterilisation by irradiation	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495003547L8	
EMDN	Code	Term
	M040101	ADHESIVE DRESSINGS, WITH ABSORBENT PAD
GMDN	34864	Adhesive bandage
UMDNS	10-288	Bandages, Self-Adherent

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



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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: 2025-11-30

Valid until: 2030-11-29

List of products falling under the respective Product Group Number:

REF	Name - Description
531310	DP MEDICAL Ster dress. breathable 7,2x5 DP MEDICAL atmungsaktiv st 7,2x5cm P5
531311	DP MEDICAL Ster dres. breathable 10x8cm DP MEDICAL atmungsaktiv st 10x8cm P5
531312	DP MEDICAL Ster dres. breathable 15x9cm

GLN 404 9500 00000 0

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