

EU Declaration of Conformity

Heidenheim, 2025-03-18

Product Group Number	1438
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 Quality Assurance Certificate (MDR) No. G21 011858 0069 Rev. 05, 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	40495001438KL	
EMDN GMDN UMDNS	Code	Term
	M040101	ADHESIVE DRESSINGS, WITH ABSORBENT PAD
	34864	Adhesive bandage
	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

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PAUL HARTMANN AG

ppa.

ppa.

Jochen Bauer

Vice President R&D Wound Care & Consumer Health

Stefan Fischer

Senior Vice President Regulatory Affairs

Valid until: 2025-11-29

List of products falling under the respective Product Group Number:

REF	Name - Description
900707	Cosmopor Steril SP 10x8 P5
900800	Cosmopor Steril 7,2x5cm P50 Cosmopor sterile 7,2x5cm st P50
900802	Cosmopor Steril 10x6cm P25 Cosmopor Steril 10x6cm st P25
900804	Cosmopor Steril 15x6cm P25
900806	Cosmopor Steril 10x8cm P25 Cosmopor Steril 10x8cm st P25
900808	Cosmopor Steril 15x8cm P25 Cosmopor Steril 15x8cm st P25
900810	Cosmopor Steril 20x8cm P25
900812	Cosmopor Steril 20x10cm P25
900814	Cosmopor Steril 25x10cm P25
900816	Cosmopor Steril 35x10cm P25
900820	Cosmopor Steril 10x10cm P25
900823	Cosmopor Steril 15x15cm P25
900833	Cosmopor Steril 7,2x5cm P10 Cosmopor Steril 7,2x5cm st P10
901040	Cosmopor St PPay 7,2x5 P5 DE,FR,IT,NL Cosmopor Steril 7,2x5cm st P5 D,FR,IT,NL

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901041	Cosmopor St PPay 10x8 P5 DE,FR,IT,NL Cosmopor Steril 10x8cm st P5 DE,FR,IT,NL
901090	Cosmopor St PPay 7,2x5 P5 ES, PT, IT Cosmopor Steril 7,2x5cm st P5 ES,PT,IT
901091	Cosmopor St PPay 10x8 P5 ES, PT, IT Cosmopor Steril 10x8cm st P5 ES,PT,IT
901092	Cosmopor St PPay 10x6 P5 ES, DE, PT, IT Cosmopor St 10x6cm st P5 ES, DE, PT, IT
901093	Cosmopor St PPay 15x8 P5 ES, DE, PT, IT Cosmopor Steril 15x8cm st P5 ES,DE,PT,IT
901094	Cosmopor St PPay 20x10 P5 ES, DE, PT, IT

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