PAUL HARTMANN AG
Paul-Hartmann-Strasse 12
89522 Heidenheim

P.O. Box 1420
89504 Heidenheim
Germany

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

HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity

Heidenheim, 2025-11-18

Product Group Number	1439
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	40495001439KN	
	Code	Term
EMDN	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

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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

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

REF	Name - Description
900870	Cosmopor E st 7,2x5cm P50 CSM TENDER Cosmopor E Pfl VL w LF st 7,2x5cm P50
900871	Cosmopor E Pfl VL w LF st 10x6cm P25 Cosmopor E LF VL w 10x6cm st P25
900872	Cosmopor E Pfl VL w LF st 15x6cm P25
900873	Cosmopor E Pfl VL w LF st 10x8cm P25
900874	Cosmopor E Pfl VL w LF st 15x8cm P25
900875	Cosmopor E Pfl VL w LF st 20x8cm P25
900876	Cosmopor E Pfl VL w LF st 20x10cm P25
900877	Cosmopor E Pfl VL w LF st 25x10cm P25
900878	Cosmopor E Pfl VL w LF st 35x10cm P25
900891	Cosmopor E Pfl LF st 7,2x5cm P10 BX/GR Cosmopor E Pfl VL w LF st 7,2x5cm P10 F Cosmopor E LF VL w 7,2x5cm st P10 FR Cosmopor E Pfl VL w LF st 7,2x5cm P10 SP Cosmopor E LF VL w 7,2x5cm st P10 BX,GR Cosmopor E LF VL w 7,2x5cm st P10 SP
900892	Cosmopor E Pfl VL w LF st 10x6cm P10 SP Cosmopor E LF VL w 10x6cm st P10 SP
900893	Cosmopor E Pfl VL w LF st 10x8cm P10 F Cosmopor E LF VL w 10x8cm st P10 FR Cosmopor E Pfl LF st 10x8cm P10 BX/GR Cosmopor E Pfl VL w LF st 10x8cm P10 SP Cosmopor E LF VL w 10x8cm st P10 SP
900894	Cosmopor E LF VL w 15x8cm st P10 SP Cosmopor E Pfl VL w st 15x8cm P10 SP
900895	Cosmopor E Pfl LF st 20x10cm P10 BX/GR Cosmopor E Pfl VL w LF st 20x10cm P10 F Cosmopor E Pfl VL w LF st 20x10cm P10 SP
900899	Cosmopor E Pfl LF st 15x9cm P10 BX/GR Cosmopor E Pfl VL w LF st 15x9cm P10 F
901008	Cosmopor E MDR RU P50 7,2x5
901009	Cosmopor E MDR RU P25 10x6
901019	Cosmopor E MDR RU P25 15x6
901020	Cosmopor E MDR RU P25 10x8

GLN 404 9500 00000 0

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901021	Cosmopor E MDR RU P25 15x8
901022	Cosmopor E MDR RU P25 20x10
901023	Cosmopor E MDR RU P25 25x10
901024	Cosmopor E MDR RU P25 35x10
901025	Cosmopor E MDR RU P25 20x8
901028	Cosmopor E ster 7.2x50 P50
901029	Cosmopor E ster 10x6 P25
901030	Cosmopor E ster 15x6 P25
901035	Cosmopor E ster 20x10 P25
901036	Cosmopor E ster 25x10 P25
901037	Cosmopor E ster 35x10 P25
901070	Cosmopor E 7,2x5cm P5 (PL,SL,HR,EN) Cosmopor E st 7,2x5cm P5 (PL,SL,HR,EN)
901071	Cosmopor E 10x8cm P5 (PL,SL,HR,EN) Cosmopor E 10x8cm st P5 (EN,PL,SL,HR)
901072	Cosmopor E 7,2x5cm P5 (RO,HU,BG,GR) Cosmopor E 7,2x5cm st P5 (RO,HU,BG,GR)
901073	Cosmopor E 10x8cm P5 (RO,HU,BG,GR) Cosmopor E 10x8cm st P5 (RO,HU,SK,GR)
901084	Cosmopor E RUS PrivPay 7,2x5cm P10
901085	Cosmopor E RUS Priv Pay 10x8cm P10
901086	Cosmopor E RUS PrivPay 20x10cm P10
901087	Cosmopor E RUS Priv Pay 15x8cm P10
901820	Cosmopor Entry 7,2x5cm P10 Steril
685005	Cosmopor E Pfl VL w LF st 7,2x5cm P10 F

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