PAUL HARTMANN AG
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89522 Heidenheim

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Germany

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HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity

Heidenheim, 2025-11-18

Product Group Number	3523
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	40495003523KS	
	Code	Term
EMDN	M040101	ADHESIVE DRESSINGS, WITH ABSORBENT PAD
GMDN	34864	Bandage, adhesive
UMDNS	10-288	Bandages, Self-Adherent

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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

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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List of products falling under the respective Product Group Number:

REF	Name - Description
901100	Cosmopor silicone 7,2x5cm P50
901101	Cosmopor silicone 7,2x5cm P25
901102	Cosmopor silicone 10x8cm P25
901103	Cosmopor silicone 15x8cm P25
901104	Cosmopor silicone 20x10cm P25
901105	Cosmopor silicone 35x10cm P25
901106	Cosmopor silicone 7,2x5cm P10
901107	Cosmopor silicone 10x8cm P10
901108	Cosmopor silicone 15x8cm P10
901109	Cosmopor silicone 20x10cm P10
901110	Cosmopor silicone 35x10cm P10
901111	Cosmopor silicone 7,2x5cm P5 (E,D,P,E)
901112	Cosmopor silicone 10x8cm P5 (E,D,P,E)
901113	Cosmopor silicone 15x8cm P5 (E,D,P,E)
901114	Cosmopor silicone 20x10cm P5 (E,D,P,E)
901115	Cosmopor silicone 35x10cm P5 (E,D,P,E)
901116	Cosmopor silicone 7,2x5cm P5 (R,P,C,S,S)
901117	Cosmopor silicone 10x8cm P5 (R,P,C,S,S)
901118	Cosmopor silicone 15x8cm P5 (R,P,C,S,S)
901119	Cosmopor silicone 20x10cm P5 (R,P,C,S,S)
901121	Cosmopor silicone 35x10cm P5 (R,P,C,S,S)
901122	Cosmopor silicone 7,2x5cm P5 (RU)
901123	Cosmopor silicone 10x8cm P5 (RU)
901124	Cosmopor silicone 15x8cm P5 (RU)
901125	Cosmopor silicone 20x10cm P5 (RU)
901126	Cosmopor silicone 35x10cm P5 (RU)
901127	Cosmopor silicone 10x8cm P2

GLN 404 9500 00000 0

Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Stefan Grote, Oliver Neubrand
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Declaration of Conformity

PPWR

EU DECLARATION NO.*.. **100729076** Date: **10.08.2026**

Product Identification	
Unique identification of the packaging	RL_PEP_FB
Manufacturer name and address	Paul Hartmann AG Paul-Hartmann-Straße 12 89522 Heidenheim Germany
Sole responsibility statement	This declaration of conformity is issued under the sole responsibility of the manufacturer.
Identification enabling traceability	Applies to all products packaged using this packaging model
Object of the Declaration	
Description of packaging	Product with a release liner in a peel pouch inside a folding box
Relevant Union Legislation	
Reference to Regulation (EU) 2025/40 and applicable articles	Regulation (EU) 2025/40 of the European Parliament and of the Council, Article 5
Harmonized Standards	
Harmonised standards applied	Not applicable
References to common specifications used	Not applicable
Additional Information	
Heidenheim, 10.08.2026	Heidenheim, 10.08.2026
(Place and Date of Issue)	(Place and Date of Issue)
i.V. Rüdiger Kliewer Rüdiger Kliewer Director Packaging/Materials Handling	i.V. Georgina Bischur Georgina Bischur Teamlead Packaging Development
(Name, Function) (Signature)	(Name, Function) (Signature)