PAUL HARTMANN AG
Paul-Hartmann-Strasse 12
89522 Heidenheim

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Germany

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HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity

Heidenheim, 2025-03-25

Product Group Number	1693
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	Non-active, non-implantable devices for wound and skin care	
Classification	Risk Class	Rule
	Class I	Rule 1
Conformity Assessment Procedure	Article 52 (7)	
Notified Body	n/a	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001693L6	
EMDN	Code	Term
	M050101	PLASTERS ON SPOOLS (ROLLS)
GMDN	16866	Basic adhesive tape
UMDNS	10-028	Adhesive Strips, Hypoallergenic

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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ppa.

Jochen Bauer
Vice President R&D Wound Care & Consumer Health

ppa.

Stefan Fischer
Senior Vice President Regulatory Affairs

Valid until: 2030-10-31

List of products falling under the respective Product Group Number:

REF	Name - Description
900414	Omnifilm 5cm x 5m RU P1
900421	Omnifilm 1,25cm x 9,2m P1
900422	Omnifilm 2.5cm x 9,2m P1 Omnifilm RUS 2.5cm x 9.2m P1 C240 STO
900423	Omnifilm 5cm x 9,2m P1
900433	Omnifilm 1,25cm x 5m P1 Omnifilm RUS 1,25cm x 5m P1
900434	Omnifilm 2,5cm x 5m P1
900435	Omnifilm 5cm x 5m P1
900464	Omnifilm 1,25cm x 5m RU P1
900474	Omnifilm 2,5cm x 5m RU P1
900630	Omnifilm 2,5cm x 9,2m P12
900689	Omnifilm PPay 2,5cmx5m

GLN 404 9500 00000 0
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HARTMANN

Declaration of Conformity

PPWR

EU DECLARATION NO.*.. **100729106** Date: **10.08.2026**

Product Identification	
Unique identification of the packaging	SP_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 wound onto a plastic spool and packed in 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)

Declaration of Conformity

PPWR

EU DECLARATION NO.* **100742560** Date: **11.08.2026**

Product Identification	
Unique identification of the packaging	LABEL
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 for all packaging materials used to label packaging
Object of the Declaration	
Description of packaging	Self-adhesive labels (pre-printed, neutral, and/or with sterile indicator), papers, inkjet inks and thermal transfer ribbons, documents enclosed envelopes
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, 11.08.2026	Heidenheim, 11.08.2026
(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
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