PAUL HARTMANN AG
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HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity

Heidenheim, 2025-03-25

Product Group Number	1531
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 I	Rule 4 | main paragraph + 1st indent
Conformity Assessment Procedure	Article 52 (7)	
Notified Body	n/a	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001531KB	
EMDN	Code	Term
	M040101	ADHESIVE DRESSINGS, WITH ABSORBENT PAD
GMDN	44990	Skin-cover adhesive strip
UMDNS	10-288	Bandages, Self-Adherent

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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
530243	Cosmos flexible 6cm x1m, P1(DE,FR,IT,NL)
530251	Cosmos flexible 6cmx1m (RO,BG,HU,GR)
530260	Cosmos flexible 6cmx1m (EN,PL,SL,HR)
535203	Cosmos flexible 6x10cm, P5 (RU)
535223	Cosmos textil Pfl GWel 2Gr P20 Cosmos flexible 2sizes, P20 (RU)
535230	Cosmos flexible CZ/SK Strips 2sizes, P20 Cosmos flexible CZ/SK 2sizes,P20 (Kaufl)
535236	Cosmos flexible CZ/SK 6x10cm, P5 Cosmos flexible CZ/SK 6x10cm, P5 (Kaufl)
535250	Cosmos flexible LG6 2Gr P20

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