

EU Declaration of Conformity

Heidenheim, 2025-04-09

Product Group Number	1613
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 IIa	Rule 7 main paragraph
Conformity Assessment Procedure	Article 52 (6) and Annex IX	
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123	
EU Certificates	EU Quality Management System Certificate (MDR) No. G10 011858 0065 Rev. 04, Device Group: M040403 - HYDROCOLLOID DRESSINGS	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001613KE	
EMDN	Code	Term
	M040403	HYDROCOLLOID DRESSINGS
GMDN	62873	Exudate-absorbent dressing, hydrophilic-gel, non-sterile
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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Jochen Bauer

Vice President R&D Wound Care & Consumer
Health

Stefan Fischer

Senior Vice President Regulatory Affairs

Valid from: 2025-05-06

Valid until: 2030-05-05

List of products falling under the respective Product Group Number:

REF	Name - Description
536010	Cosmos Hydro Blister XL 75x45mm P6 RU
536013	Cosmos Heel 76x45 mm P5
536020	Cosmos Hydro Blister Heel 76x45mm P5 RU
536030	Cosmos Hydro Blister medium 19x55mmP6 RU
536040	Cosmos Hydro Blister Mix P7 RU
536043	Cosmos XL 75x45mm P5
536050	Cosmos Hydro Blister small 17x40mm P6 RU
536053	Cosmos Blister Mix P8 3 Gr

GLN 404 9500 00000 0

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