

EU Declaration of Conformity

Heidenheim, 2025-11-18

Product Group Number	1409
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: M040201 - ABSORBENT DRESSINGS WITH CELLULOSE PAD AND NON-WOVEN WRAPS, Device Properties: MDS 1005.3 - Sterilization by moist heat	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001409KD	
EMDN	Code	Term
	M040201	ABSORBENT DRESSINGS WITH CELLULOSE PAD AND NON-WOVEN WRAPS
GMDN	44970	Exudate-absorbent dressing, hydrophilic-gel, non-antimicrobial
UMDNS	15-216	Dressings, other

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

List of products falling under the respective Product Group Number:

REF	Name - Description
413770	Zetuvit E steril, 10x10 cm P25
413771	Zetuvit E steril, 10x20 cm P25
413772	Zetuvit E sterile, 15x20 cm P25
413773	Zetuvit E steril, 15x25 cm P10
413774	Zetuvit E steril, 20x20 cm P15
413775	Zetuvit E steril, 20x25 cm P15
413779	Zetuvit E steril, 10x20 cm P5
413784	Zetuvit E steril, 10x10 cm P10
413786	Zetuvit E steril, 20x40cm P5

GLN 404 9500 00000 0

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