

EU Declaration of Conformity

Heidenheim, 2025-04-09

Product Group Number	1407
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, sterile, non-medicated dressings suitable for the treatment of wounds	
Classification	Risk Class	Rule
	Class IIb	Rule 4 main paragraph + 2nd indent
Conformity Assessment Procedure	Article 52 (4) 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: M040499 - DRESSINGS FOR WOUNDS, SORES AND ULCERATIONS - OTHER, Intended Purpose: Single-use, sterile, non-medicated dressings suitable for the treatment of wounds	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001407K9	
EMDN	Code	Term
	M040499	DRESSINGS FOR WOUNDS, SORES AND ULCERATIONS - OTHER
GMDN	43186	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

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Jochen Bauer

Vice President R&D Wound Care & Consumer
Health

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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
413030	Zetuvit Plus Superabsorber 10x10 cm
413031	Zetuvit Plus Superabsorber 10x20 cm
413032	Zetuvit Plus Superabsorber 15x20 cm
413033	Zetuvit Plus Superabsorber 20x25 cm
413034	Zetuvit Plus Superabsorber 20x40cm
413110	Zetuvit Plus 10x10 P10
413111	Zetuvit Plus 10x20 P10
413112	Zetuvit Plus 15x20 P10
413113	Zetuvit Plus 25x20 P10
413710	Zetuvit Plus 10x10cm P10
413711	Zetuvit Plus 10x20cm P10
413712	Zetuvit Plus 15x20cm P10
413713	Zetuvit Plus 20x25cm P10
413715	Zetuvit Plus 20x40cm P10
413716	Zetuvit Plus 10x10cm P10
413717	Zetuvit Plus 10x20cm P10
413718	Zetuvit Plus 15x20cm P10

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413719	Zetuvit Plus 20x25cm P10
413720	4137201 - Zetuvit Plus 10 x 10 cm P3
413721	Zetuvit Plus 10x10cm P3
413722	Zetuvit Plus Superabsorber 10x10cm P10
413723	Zetuvit Plus Superabsorber 10x20cm P10
413724	Zetuvit Plus Superabsorber 15x20cm P10
413725	Zetuvit Plus Superabsorber 20x25cm P10
413726	Zetuvit Plus 10x10cm P20 LF
413727	Zetuvit Plus 10x20cm P20 LF
413728	Zetuvit Plus 15x20cm P20 LF
413729	Zetuvit Plus 6 x 6 cm P10
413735	Zetuvit Plus 10x10cm P20
413736	Zetuvit Plus 10x20cm P20
413737	Zetuvit Plus 15x20cm P20
413738	Zetuvit Plus 20x25cm P20
413739	Zetuvit Plus 20 x 60 cm P10
413740	Zetuvit Plus Superabsorber 20 x 60cm P10

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