

EU Declaration of Conformity

Heidenheim, 2025-11-18

Product Group Number	3300
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	40495003300K4	
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
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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 until: 2030-05-05

GLN 404 9500 00000 0

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List of products falling under the respective Product Group Number:

REF	Name - Description
413900	Zetuvit Plus Silicone Border 8x8cm Zetuvit Plus Silicone Border 8x8cm P10
413901	Zetuvit Plus Silicone Border 10x10cm Zetuvit Plus Silicone Border 10x10cm P10
413902	Zetuvit Plus Silicone Border 12,5x12,5cm Zetuvit Plus Sil Border 12,5x12,5cm P10
413903	Zetuvit Plus Silicone Border 15x15cm Zetuvit Plus Silicone Border 15x15cm P10
413904	Zetuvit Plus Silicone Border 16x26cm Zetuvit Plus Silicone Border 16x26cm P10
413905	Zetuvit Plus Silicone Border 20x20cm Zetuvit Plus Silicone Border 20x20cm P10
413906	Zetuvit Plus Silicone Border Sacr 18x18 Zetuvit Plus Sil Border Sacr 18x18cm P10
413907	Zetuvit Plus Silicone Border Sacr 23x23 Zetuvit Plus Sil Border Sacrum 23x23 P10
413908	Zetuvit Plus Silicone Border Oval 13x15 Zetuvit Plus Sil Border Oval 13x15,5 P10
413909	Zetuvit Plus Silicone Border Oval 12x23 Zetuvit Plus Sil Border Oval 12x23cm P10
413911	Zetuvit Plus Silicone Border Heel 25x25 Zetuvit Plus Sil Border Heel 25x25cm P10
413912	Zetuvit Plus Silicone Border 8x8cm P3
413913	Zetuvit Plus Silicone Border 10x10cm P3
413914	Zetuvit Plus Silicone Border 12,5x12,5P3 Zetuvit Plus Sil Border 12,5x12,5cm P3
413915	Zetuvit Plus Silicone Border 15x15cm P3
413916	Zetuvit Plus Silicone Border 16x26cm P3
413917	Zetuvit Plus Silicone Border 20x20cm P3
413918	Zetuvit Plus Silicone Border Sacr18x18P3 Zetuvit Plus Sil Border Sacrum 18x18cmP3
413919	Zetuvit Plus Silicone Border Sacr23x23P3 Zetuvit Plus Sil Border Sacrum 23x23cmP3
413921	Zetuvit Plus Silicone Bord Oval13x15,5P3 Zetuvit Plus Sil Border Oval 13x15,5cmP3

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413922	Zetuvit Plus Silicone Bord Oval 12x23P3 Zetuvit Plus Sil Border Oval 12x23cm P3
413923	Zetuvit Plus Silicone Border Heel25x25P3 Zetuvit Plus Sil Border Heel 25x25cm P3
413924	Zetuvit Plus Sil Bor 17,5x17,5cm P10 Zetuvit Plus Sil Border 17,5x17,5cm P10
413925	Zetuvit Plus Sil Bor 17,5x17,5cm P3 Zetuvit Plus Sil Border 17,5x17,5cm P3

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