PAUL HARTMANN AG
Paul-Hartmann-Strasse 12
89522 Heidenheim

P.O. Box 1420
89504 Heidenheim
Germany

Phone: +49 (0) 7321 36-0
Fax: +49 (0) 7321 36-3636
www.hartmann.info

HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity

Heidenheim, 2025-11-18

Product Group Number	3872
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	40495003872LN	
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

PAUL HARTMANN AG
Paul-Hartmann-Strasse 12
89522 Heidenheim

P.O. Box 1420
89504 Heidenheim
Germany

Phone: +49 (0) 7321 36-0
Fax: +49 (0) 7321 36-3636
www.hartmann.info

HARTMANN
Helps. Cares. Protects.

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

List of products falling under the respective Product Group Number:

REF	Name - Description
413811	Zetuvit Plus Silicone 8x8cm P10
413812	Zetuvit Plus Silicone 12,5x12,5cm P10
413813	Zetuvit Plus Silicone 10x20cm P10
413814	Zetuvit Plus Silicone 20x20 cm P10
413815	Zetuvit Plus Silicone 20x25cm P10
413831	Zetuvit Plus Silicone 8x8cm P3
413832	Zetuvit Plus Silicone 12,5x12,5cm P3
413833	Zetuvit Plus Silicone 10x20cm P3
413834	Zetuvit Plus Silicone 20x20cm P3
413835	Zetuvit Plus Silicone 20x25cm P3
906004	Zetuvit Sample Pack

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