



## EU Declaration of Conformity

Heidenheim, 2025-04-09

<b>Product Group Number</b>	2842
<b>Manufacturer</b>	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	40495002842L6	
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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**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
685140	RespoSorb Sil Border 10x10cm P10
685150	RespoSorb Sil Bor 12,5x12,5cm
685160	RespoSorb Sil Bor 17,5x17,5cm
685170	RespoSorb Sil Border 15x25cm P10
685180	RespoSorb Sil Border 20x25cm P

GLN 404 9500 00000 0

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