

EU Declaration of Conformity

Heidenheim, 2025-04-09

Product Group Number	3301
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	40495003301K6	
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

ppa.

Jochen Bauer

Vice President R&D Wound Care & Consumer
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ppa.

Stefan Fischer

Senior Vice President Regulatory Affairs

Valid from: 2025-05-06

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
413000	RespoSorb Silicone Border 8x8cm P10
413001	RespoSorb Silicone Border 10x10cm P10
413002	RespoSorb Silicone Border 12,5x12,5 P10
413003	RespoSorb Silicone Border 15x15cm P10
413004	RespoSorb Silicone Border 16x26cm P10
413005	RespoSorb Silicone Border 20x20cm P10
413006	RespoSorb Silicone Border Sacrum 18x18 RespoSorb Sil Border Sacrum 18x18cm P10
413007	RespoSorb Sil Border Sacrum 23x23 P10 RespoSorb Sil Border Sacrum 23x23cm P10
413008	RespoSorb Sil Border Oval 13x15,5 P10 RespoSorb Sil Border Oval 13x15,5cm P10
413009	RespoSorb Sil Border Oval 12x23 P10 RespoSorb Sil Border Oval 12x23cm P10
413010	RespoSorb Silicone Border Heel 25x25 P10
413011	RespoSorb Silicone Border 8x8cm P3
413012	RespoSorb Silicone Border 10x10cm P3
413013	RespoSorb Silicone Border 12,5x12,5cm P3
413014	RespoSorb Silicone Border 15x15cm P3
413015	RespoSorb Silicone Border 16x26cm P3
413016	RespoSorb Silicone Border 20x20cm P3
413017	RespoSorb Silicone Border Sacrum 18x18P3 RespoSorb Sil Border Sacrum 18x18cm P3
413018	RespoSorb Silicone Border Sacrum 23x23P3 RespoSorb Sil Border Sacrum 23x23cm P3
413019	RespoSorb Silicone Border Oval 13x15,5P3 RespoSorb Sil Border Oval 13x15,5cm P3
413020	RespoSorb Silicone Border Oval 12x23P3 RespoSorb Sil Border Oval 12x23cm P3
413021	RespoSorb Silicone Border Heel 25x25P3
413022	RespoSorb Sil Border 17,5x17,5cm P10
413023	RespoSorb Sil Border 17,5x17,5cm P3

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