



## EU Declaration of Conformity

Heidenheim, 2025-04-09

<b>Product Group Number</b>	3087
<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

<b>High Level Intended Purpose</b>	Single-use, non-active, non-implantable devices for wound and skin care	
<b>Classification</b>	<b>Risk Class</b>	<b>Rule</b>
	Class IIa	Rule 4   main paragraph + 3rd indent
<b>Conformity Assessment Procedure</b>	Article 52 (6) and Annex IX	
<b>Notified Body</b>	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123	
<b>EU Certificates</b>	EU Quality Management System Certificate (MDR) No. G10 011858 0065 Rev. 04, Device Group: M040403 - HYDROCOLLOID DRESSINGS	
<b>Single Registration Number</b>	Manufacturer: DE-MF-000005861	
<b>Basic UDI-DI</b>	40495003087KT	
<b>EMDN</b>	<b>Code</b>	<b>Term</b>
	M040403	HYDROCOLLOID DRESSINGS
<b>GMDN</b>	62873	exudate-absorbent dressing, hydrophilic-gel, non-sterile
<b>UMDNS</b>	10-288	Bandages, Self-Adherent

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 from: 2025-05-06

Valid until: 2030-05-05

List of products falling under the respective Product Group Number:

REF	Name - Description
536840	DermaPlast Effect Cold 17x12mm West P16

GLN 404 9500 00000 0

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