PAUL HARTMANN AG
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HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity

Heidenheim, 2025-11-18

Product Group Number	3968
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, non-active, non-implantable devices for wound and skin care	
Classification	Risk Class	Rule
	Class Is	Rule 1
Conformity Assessment Procedure	Article 52 (7) and Annex XI part A with respect to sterility (a)	
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123	
EU Certificates	EU Production Quality Assurance Certificate (MDR) No. G26 011858 0077 Rev. 00, Device Group: M040102 - FIXING DRESSINGS , Device Properties: MDS 1005.1 - Ethylene Oxide sterilization MDS 1005.2 - Sterilisation by irradiation	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495003968M4	
EMDN	Code	Term
	M040102	FIXING DRESSINGS
GMDN	47956	Negative-pressure wound therapy system dressing set
UMDNS	11-305	Drains, Wound

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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: 2025-11-30
Valid until: 2030-11-29

List of products falling under the respective Product Group Number:

REF	Name - Description
409780	VivanoMed Gel Strip 10x7cm P10

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