PAUL HARTMANN AG
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HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity

Heidenheim, 2026-06-10

Product Group Number	1415
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 IIa	Rule 7 | main paragraph
Conformity Assessment Procedure	Article 52 (6) 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: M020199 - COTTON GAUZES - OTHER	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001415K8	
EMDN	Code	Term
	M020199	COTTON GAUZES - OTHER
GMDN	48134	Woven, gauze pad
UMDNS	13-700	Tupfer, Gaze (Sponges, Gauze)

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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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
481274	Pagasling Tupfer pflg Gr3 P4x20
481284	Pagasling Tupfer pflg Gr3 P5x20
481400	Pagasling extrasize size 5 P10x18
481409	Pagasling Tupfer eig Gr4 P10x18
481414	Pagasling Tupfer pflg Gr3 P20x18
481408	Pagasling plumsize size 3 P5x20
481407	Pagasling Tupfer pflg Gr3 P4 x 20

GLN 404 9500 00000 0
Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Stefan Grote, Oliver Neubrand
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