

EU Declaration of Conformity

Heidenheim, 2024-10-31

Product Group Number	1005
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	Non-active, non-implantable devices for wound and skin care	
Classification	Risk Class	Rule
	Class I	Rule 4 1st indent
Conformity Assessment Procedure	Article 52 (7)	
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001005JH	
EMDN	Code	Term
	M020203	NON-WOVEN GAUZE PADS
GMDN	48131	Non-woven gauze pad
UMDNS	15-252	Sponges, Other

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PAUL HARTMANN AG

ppa.



Jochen Bauer

Vice President R&D Wound Care & Consumer
Health



Stefan Fischer

Senior Vice President Regulatory Affairs

Valid until: 2030-10-31

List of products falling under the respective Product Group Number:

REF	Name - Description
143213	Pur-Zellin ust 4x5cm 11f P1x500
143223	Pur-Zellin economy P1x500

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