



EU Declaration of Conformity

Heidenheim, 2025-04-09

Product Group Number	1355
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	40495001355KF	
EMDN	Code	Term
	M020199	COTTON GAUZES - OTHER
GMDN	48128	Gauze strip, antimicrobial
UMDNS	15-557	Binde

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
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
205033	Tamponadebinde st 1cmx2m P5
205034	Tamponadebinde st 2cmx2m P5
205035	Tamponadebinde st 1cmx5m P5
205036	Tamponadebinde st 2cm x 5m P5
288019	Tamponadebinde st 2cmx5m P1
370800	Tamponadebinde st 1cmx5m P1

GLN 404 9500 00000 0

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