

EU Declaration of Conformity

Heidenheim, 2025-03-25

Product Group Number	1007
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 main paragraph + 1st indent
Conformity Assessment Procedure	Article 52 (7)	
Notified Body	n/a	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001007JM	
EMDN	Code	Term
	M020102	COTTON GAUZES, FOLDED
GMDN	48134	Woven gauze pad
UMDNS	10-966	Kompresse, Mull (Compresses, 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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Helps. Cares. Protects.

PAUL HARTMANN AG

ppa.

Jochen Bauer

Vice President R&D Wound Care & Consumer
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ppa.

Stefan Fischer

Senior Vice President Regulatory Affairs

Valid until: 2030-10-31

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List of products falling under the respective Product Group Number:

REF	Name - Description
401821	ES-Kompressen ust 5x5 8f 17fd comp P100
401823	ES-Kompr ust 7,5x7,5 8f 17fd c. P100 VM
401825	ES-Kompressen ust 10x10 8f compact P100
401831	ES-Kompressen ust 5x5 12f 17fd c.P100 VM
401833	ES-Kompr ust 7,5x7,5 12f 17fd c. P100 VM
401835	ES swabs ust 10x10 12p 17th P100
401836	ES Kompr ust 10x12,5 12f 17fd P100
401837	ES-Kompressen ust 10x20 12f compact P100
401841	ES-Kompressen ust 5x5 16f 17fd c.P100 VM
401843	ES Kompr ust 7,5x7,5 16f 17fd P100
401845	ES-Kompressen ust 10x10 16f compact P100
401846	ES-Kompressen ust 10x12,5 16f comp P100
407821	ES Kompr ust 5x5 8f 17fd P100
407823	ES Kompr ust 7,5x7,5 8f 17fd P100
407825	ES-Kompr ust 10x10 8f 17fd compact P100
407831	ES-Kompressen ust 5x5 12f 17fd c.P100 VK
407833	ES-Kompr ust 7,5x7,5 12f 17fd c. P100 VK
407835	ES Kompr 10x10 12f 17fd P100
407836	ES Kompr ust 10x12,5 12f 17fd P100
407837	ES-Kompressen ust 10x20 12f comp P100
407841	ES-Kompressen ust 5x5 16f 17fd c.P100 VK
407843	ES Kompr ust 7,5x7,5 16f 17fd P100
407845	ES-Kompr ust 10x10 16f 17fd compact P100
407846	ES Kompr ust 10x12,5 16f 17fd P100
481004	ES-Kompressen ust 5x5 8f 17fd comp P100

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