

EU Declaration of Conformity

Heidenheim, 2025-04-09

Product Group Number	1395
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: M020102 - COTTON GAUZES, FOLDED	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001395KT	
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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Jochen Bauer

Vice President R&D Wound Care & Consumer
Health

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
205003	ES-Kompresse st 7,5x7,5 17f 8pl 5xP2(PP)
205004	ES-Kompresse st 10x10 17f 8pl 5xP2 (PP)
205010	ES-Kompr st 10x10 17fd 12f (10xP5)
205011	ES-Kompr st 10x10 17fd 12f (25xP2)
205012	ES-Kompr st 10x20 17fd 8f (25xP2)
205013	ES-Kompr st 7,5x7,5 17fd 16f (20xP5)
205014	ES-Kompr st 7,5x7,5 17fd 12f (20xP5)
205015	ES-Kompr st 10x10 17fd 12f (20xP5)
400030	ES-Kompr st 10x10cm 8f (10xP10)
400426	ES Kompr st 5x5 17fd 12f 100xP1
401515	ES Kompr st 10x10 17fd 12f 50xP1
401621	ES-Kompr st 5x5 17fd 8f (5xP2)
401623	ES-Kompr st 7,5x7,5 17fd 8f (5xP2)
401625	ES-Kompr st 10x10 17fd 8f (5xP2)
401645	ES-Kompr st 10x20 17fd 8f (5xP2)
401721	ES Kompr st 5x5 17fd 8f 25xP2
401723	ES Kompr st 7,5x7,5 17fd 8f 25xP2
401725	ES Kompr st 10x10 17fd 8f 25xP2
401731	ES Kompr st 5x5 17fd 12f 25xP2

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401733	ES Kompr st 7,5x7,5 17fd 12f 25xP2
401745	ES Kompr st 10x20 17fd 8f 25xP2
401798	ES-Kompr st 10x10 17fd 16f (10xP10)
401799	ES Kompr st 10x10 17fd 16f 40xP2
401800	ES-Kompr st 5x5 17fd 16f (10xP10)
401801	ES-Kompr st 5x5 17fd 16f (20xP5)
401802	ES Kompr st 5x5 17fd 16f 40xP2
401803	ES-Kompr st 7,5x7,5 17fd 16f (10xP10)
401805	ES Kompr st 7,5x7,5 17fd 16f 40xP2
401807	ES-Kompr st 9x7,5 17fd 16f (20xP5)
401809	ES Kompr st 10x10 17fd 16f 20xP5
401815	ES-Kompr st 10x12,5 17fd 16f (40xP2)
401818	ES-Kompr st 18x8 17fd 16f (10xP10)
401819	ES-Kompr st 18x8 17fd 16f (20xP5)
401820	ES-Kompr st 18x8 17fd 16f (40xP2)
401900	ES Kpr st 5x5 17fd 8f 50xP2
401901	ES Kpr st 7,5x7,5 17fd 8f 50xP2
401902	ES Kpr st 10x10 17fd 8f 50xP2
475500	ES-Kompr st 5x5cm 12f (20xP5)
475501	ES-Kompr st 5x5cm 12f (10xP10)
475502	ES-Kompr st 5x5 12f (5xP20)
475504	ES-Kompr st 7,5x7,5cm 12f (10xP10)
475505	ES-Kompr st 7,5x7,5 12f (5xP20)
475507	ES-Kompr st 10x10 12f (10xP10)
475508	ES-Kompr st 10x10 12f (P5x20St)
475509	ES-Kompr st 10x20cm 12f (20xP5)