

EU Declaration of Conformity

Heidenheim, 2025-06-24

Product Group Number	2141
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 legislations. The conformity assessment procedures have been performed and the Technical Documentation is kept available.

Applied legislative acts

Medical Device Regulation (EU) 2017/745

High Level Intended Purpose	General single-use, non-active, non-implantable devices used in health care	
Classification	Risk Class	Rule
	I s	Rule 1
Conformity Assessment Procedure	Article 52 (7) and Annex XI part A with respect to sterility	
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123	
EU Certificates	EU Quality Management System Certificate (MDR) No. G21 011858 0069 Rev. 05, Device Group: T0399 - PROTECTION DEVICES (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT PPE) - OTHER	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495002141JZ	

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Germany

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Product Group Number	2141	
	Code	Term
EMDN	T0399	PROTECTION DEVICES (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT PPE) - OTHER
GMDN	47783	Patient surgical drape, single-use, sterile
UMDNS	15-646	Drapes, Surgical, Disposable

PAUL HARTMANN AG

ppa.

Martin Walther
Senior Vice President
Risk Prevention

i.V.

Thomas Haeni
Vice President R&D, PRRC
Risk Prevention

Valid from: 2025-03-13

Valid until: 2025-11-29

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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List of products falling under the respective Product Group Number:

2141

REF	Name - Description
277555	Foliodrape Protect Fenestrated drape, adhesive
277509	Foliodrape Protect Two parts variable fenestrated drape, adhesive
277510	Foliodrape Protect Two parts variable fenestrated drape, adhesive
277517	Foliodrape Protect Fenestrated drape, adhesive
277537	Foliodrape Protect Fenestrated drape, adhesive
277545	Foliodrape Protect Adhesive aperture drape
936154	Foliodrape Protect Fenestrated drape, adhesive, crepe
936176	Foliodrape Protect Fenestrated drape, adhesive
936177	Foliodrape Protect Fenestrated drape, adhesive
936183	Foliodrape Protect Fenestrated drape, adhesive, crepe
936184	Foliodrape Protect Fenestrated drape, adhesive
936185	Foliodrape Protect Fenestrated drape, adhesive, crepe
936186	Foliodrape Protect Fenestrated drape, adhesive
936175	Foliodrape Protect Fenestrated drape, adhesive
936179	Foliodrape Protect Fenestrated drape, adhesive, crepe
936180	Foliodrape Protect Fenestrated drape, adhesive
936181	Foliodrape Protect Fenestrated drape, adhesive
936182	Foliodrape Protect Fenestrated drape, adhesive, crepe

GLN 404 9500 00000 0

Vorstand/Management Board: Britta Fünfstück
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