



## EU Declaration of Conformity

Heidenheim, 2026-01-13

<b>Product Group Number</b>	<b>2140</b>
<b>Manufacturer</b>	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	<b>Risk Class</b>	<b>Rule</b>
	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 Production Quality Assurance Certificate No. G26 011858 0077 Rev. 00,  Device Group: T0399 - PROTECTION DEVICES (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT PPE) - OTHER	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495002140JX	

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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Germany



Helps. Cares. Protects.

<b>Product Group Number</b>	<b>2140</b>	
	<b>Code</b>	<b>Term</b>
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

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**Martin Walther**  
Senior Vice President  
Risk Prevention

i.V

**Christiana Hofmann**  
Head of Regulatory Affairs, PRRC  
Risk Prevention

**Valid until: 2030-11-29**

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List of products falling under the respective Product Group Number:

**2140**

REF	Name - Description
277500	Foliodrape Protect Surgical drape
277501	Foliodrape Protect Surgical drape
277502	Foliodrape Protect Surgical drape
277504	Foliodrape Protect Surgical drape
277505	Foliodrape Protect Surgical drape
277506	Foliodrape Protect Surgical drape
277516	Foliodrape Protect Surgical drape
277547	Foliodrape Protect Surgical drape
277548	Foliodrape Protect Surgical drape
936152	Foliodrape Protect Surgical drape
936155	Foliodrape Protect Surgical drape
936252	Foliodrape Protect Patient underlay with 2 bags
936652	Foliodrape Protect Patient underlay with bag
938810	Foliodrape Protect Surgical drape
936250	Foliodrape Protect Patient underlay
936653	Foliodrape Protect Patient underlay

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