

**EU Declaration of Conformity**

Heidenheim, 2025-11-20

<b>Product Group Number</b>	<b>2023</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: T0202 - SURGICAL PROCEDURAL KITS (EXCLUDING SURGICAL INSTRUMENT KITS)	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495002023JS	



Product Group Number	2023	
	Code	Term
EMDN	T0202	SURGICAL PROCEDURAL KITS (EXCLUDING SURGICAL INSTRUMENT KITS)
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 from:** 2025-11-30

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

PAUL HARTMANN AG  
Paul-Hartmann-Strasse 12  
89522 Heidenheim

Phone: +49 (0) 7321 36-0  
Fax: +49 (0) 7321 36-3636  
[www.hartmann.info](http://www.hartmann.info)

P.O. Box 1420  
89504 Heidenheim  
Germany



Helps. Cares. Protects.

List of products falling under the respective Product Group Number:

**2023**

REF	Name - Description
938710	Foliodrape Protect Plus Gynaecology/Abdomino-Perineal set II
938719	Foliodrape Protect Plus Gynaecology/Perineal set II
938910	Foliodrape Protect Plus Gynaecology/Perineal set I, crepe
938934	Foliodrape Protect Plus Gynaecology/Abdomino-Perineal set I, crepe

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