PAUL HARTMANN AG
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HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity

Heidenheim, 2024-11-12

Product Group Number	1507
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
	Class Is	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. 04 Device Group: T0202 – SURGICAL PROCEDURAL KITS (EXCLUDING SURGICAL INSTRUMENT KITS)	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001507KE	
	Code	Term
EMDN	T0202	SURGICAL PROCEDURAL KITS (EXCLUDING SURGICAL INSTRUMENT KITS)
GMDN	47783	Patient surgical drape, single-use
UMDNS	15-646	Drapes, Surgical, Disposable

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PAUL HARTMANN AG

ppa.

Martin Walther
Senior Vice President
Risk Prevention

i.V.

Andreas Hartmann
Director Quality
Risk Prevention

Valid until: 2025-11-29

List of products falling under the respective Product Group Number:

REF	Name - Description
936279	Foliodrape Protect Plus Abdomino-Perineal set VII, crepe
936804	Foliodrape Protect Plus Abdomino-Perineal set V
936805	Foliodrape Protect Plus Abdomino-Perineal set IV, crepe
936807	Foliodrape Protect Plus Abdomino-Perineal set II
936808	Foliodrape Protect Plus Abdomino-Perineal set III
938707	Foliodrape Protect Plus Universal set IV
938708	Foliodrape Protect Plus Universal split sheet set II
938709	Foliodrape Protect Plus Laparoscopy set I
938712	Foliodrape Protect Plus Universal set III
938713	Foliodrape Protect Plus Laparoscopy set II, leggings
938714	Foliodrape Protect Plus Abdomino-Perineal set VI
938734	Foliodrape Protect Plus Abdominal / Spinal set
938739	Foliodrape Protect Plus Universal split sheet set III
938743	Foliodrape Protect Plus Universal/Paediatrics set II
938744	Foliodrape Protect Plus Universal set VI
938901	Foliodrape Protect Plus Universal set II, crepe
938911	Foliodrape Protect Plus Abdomino-Perineal set I, crepe
938930	Foliodrape Protect Plus Universal set I, crepe
938931	Foliodrape Protect Plus Universal set VII, extra reinforced, crepe
938932	Foliodrape Protect Plus Universal split sheet 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