

PAUL HARTMANN AG
Paul-Hartmann-Strasse 12
89522 Heidenheim

P.O. Box 1420
89504 Heidenheim
Germany

Phone: +49 (0) 7321 36-0
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www.hartmann.info



EU Declaration of Conformity

Heidenheim, 2025-06-28

Product Group Number	3762
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	Rule 1
Conformity Assessment Procedure	Article 52 (7)	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495003762LE	

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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Helps. Cares. Protects.

Product Group Number	3762	
	Code	Term
EMDN	T0299	PROTECTION DRAPES AND GARMENTS - OTHER
GMDN	12535	Medical equipment drape, single-use
UMDNS	15-707	Sheets, Operating Room, Disposable

PAUL HARTMANN AG

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Martin Walther
Senior Vice President
Risk Prevention

i.V

Christiana Hofmann
Head of Regulatory Affairs
Risk Prevention

Valid until: 2030-05-05

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List of products falling under the respective Product Group Number:

3762

REF	Name - Description
936675	Foliodrape Patient underlayer, non-sterile

GLN 404 9500 00000 0

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