

EU Declaration of Conformity

Heidenheim, 2024-10-31

Product Group Number	1008
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 legislation. The conformity assessment procedure has been performed and the Technical Documentation is kept available.

Applied legislative act

Medical Device Regulation (EU) 2017/745

High Level Intended Purpose	Non-active, non-implantable devices for incontinence care, worn on the body	
Classification	Risk Class	Rule
	Class I	Rule 1
Conformity Assessment Procedure	Article 52 (7)	
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001008JP	
EMDN	Code	Term
	T04010102	SHAPED INCONTINENCE NAPPIES
GMDN	35817	Incontinence pants liner
UMDNS	16-498	Incontinence Pants Liners

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

PAUL HARTMANN AG
Paul-Hartmann-Strasse 12
89522 Heidenheim

P.O. Box 1420
89504 Heidenheim
Germany

Phone: +49 (0) 7321 36-0dddd
Fax: +49 (0) 7321 36-3636
www.hartmann.info



Helps. Cares. Protects.

PAUL HARTMANN AG

Stefan Grote

Member of the Management Board

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Stefan Fischer

Senior Vice President Regulatory Affairs

Valid until: 2030-10-31

List of products falling under the respective Product Group Number:

REF	Name - Description
148600	Strampelpeter® Flockenwindeln P56
148610	Strampelpeter® Flockenwindeln Saugstärke 1 P56
148620	Strampelpeter® Flockenwindeln Saugstärke 2 P56

GLN 404 9500 00000 0

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