



EU Declaration of Conformity

Heidenheim, 2024-10-31

Product Group Number	3155
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	40495003155KK	
EMDN	Code	Term
	T04010103	INCONTINENCE NAPPIES WITH INTEGRATED FIXING SYSTEM
GMDN	41588	Incontinence pants, single-use
UMDNS	12-111	Incontinence Pants

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

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
166261	HARTMANN Pants Day Medium P15
166262	HARTMANN Pants Day Large P15
166263	HARTMANN Pants Night Medium P15
166264	HARTMANN Pants Night Large P15
166265	HARTMANN Pants Night X-Large P15
168153	MoliCare® Pants Day Medium P15
168154	MoliCare® Pants Day Large P15
168155	MoliCare® Pants Night Medium P15
168156	MoliCare® Pants Night Large P15
915655	MoliCare® Pants 6 drops Medium P20
915705	MoliCare® Pants 6 drops Large P20
915715	MoliCare® Pants 6 drops X-Large P15
915720	MoliCare® Pants 8 drops Medium P20
915725	MoliCare® Pants 8 drops Large P20

GLN 404 9500 00000 0

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