

EU Declaration of Conformity

Heidenheim, 2024-10-31

Product Group Number	3189
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	40495003189L4	
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
Paul-Hartmann-Strasse 12
89522 Heidenheim

P.O. Box 1420
89504 Heidenheim
Germany

Phone: +49 (0) 7321 36-00000
Fax: +49 (0) 7321 36-3636
www.hartmann.info



PAUL HARTMANN AG

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Stefan Grote

Member of the Management Board

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
166000	MoliCare® premium Mobile 5 drops Medium P14
166001	MoliCare® premium Mobile 5 drops Large P14
166002	MoliCare® premium Mobile 5 drops X-Large P14
166007	MoliCare® premium Mobile 5 drops Small P1
166008	MoliCare® premium Mobile 5 drops Medium P1
166009	MoliCare® premium Mobile 5 drops Large P1
166010	MoliCare® premium Mobile 5 drops X-Large P1
166011	MoliCare® premium Mobile 5 drops Medium P14
166012	MoliCare® premium Mobile 5 drops Large P14
166013	MoliCare® premium Mobile 6 drops Small P14
166014	MoliCare® premium Mobile 6 drops Medium P14
166015	MoliCare® premium Mobile 6 drops Large P14
166016	MoliCare® premium Mobile 6 drops X-Large P14
166022	MoliCare® premium Mobile 6 drops X-Small P1
166023	MoliCare® premium Mobile 6 drops Small P1
166024	MoliCare® premium Mobile 6 drops Medium P1
166025	MoliCare® premium Mobile 6 drops Large P1
166026	MoliCare® premium Mobile 6 drops X-Large P1
166027	MoliCare® premium Mobile 6 drops Medium P14
166028	MoliCare® premium Mobile 6 drops Large P14
166029	MoliCare® premium Mobile 8 drops Small P14

GLN 404 9500 00000 0

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166030	MoliCare® premium Mobile 8 drops Medium P14
166031	MoliCare® premium Mobile 8 drops Large P14
166032	MoliCare® premium Mobile 8 drops X-Large P14
166037	MoliCare® premium Mobile 8 drops Small P1
166038	MoliCare® premium Mobile 8 drops Medium P1
166039	MoliCare® premium Mobile 8 drops Large P1
166040	MoliCare® premium Mobile 8 drops X-Large P1
166041	MoliCare® premium Mobile 10 drops Medium P14
166042	MoliCare® premium Mobile 10 drops Large P14
166043	MoliCare® premium Mobile 10 drops X-Large P14
166047	MoliCare® premium Mobile 10 drops Medium P1
166048	MoliCare® premium Mobile 10 drops Large P1
166049	MoliCare® premium Mobile 10 drops X-Large P1
166123	MoliCare® premium Mobile 5 drops Small P14
166225	MoliCare® premium Mobile 6 drops X-Small P14
166280	HARTMANN Pants Day Small P15
166421	MoliCare® premium Mobile 5 drops Small P30
166422	MoliCare® premium Mobile 5 drops Medium P30
166423	MoliCare® premium Mobile 5 drops Large P30
166424	MoliCare® premium Mobile 5 drops X-Large P30
166425	MoliCare® premium Mobile 6 drops X-Small P30
166426	MoliCare® premium Mobile 6 drops Small P30
166427	MoliCare® premium Mobile 6 drops Medium P30
166428	MoliCare® premium Mobile 6 drops Large P30
166429	MoliCare® premium Mobile 6 drops X-Large P30
166430	MoliCare® premium Mobile 8 drops Small P30
166431	MoliCare® premium Mobile 8 drops Medium P30
166432	MoliCare® premium Mobile 8 drops Large P30
166433	MoliCare® premium Mobile 8 drops X-Large P30
166434	MoliCare® premium Mobile 10 drops Medium P30
166435	MoliCare® premium Mobile 10 drops Large P30
166436	MoliCare® premium Mobile 10 drops X-Large P30

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