

EU Declaration of Conformity

Heidenheim, 2024-10-31

Product Group Number	3106
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	40495003106K6	
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
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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
166260	HARTMANN Pants Day Small P15
915615	MoliCare® Premium Mobile 5 drops Small P2
915616	MoliCare® Premium Mobile 5 drops Medium P2
915617	MoliCare® Premium Mobile 5 drops Large P2
915618	MoliCare® Premium Mobile 6 drops X-Small P2
915619	MoliCare® Premium Mobile 6 drops Small P2
915620	MoliCare® Premium Mobile 6 drops Medium P2
915621	MoliCare® Premium Mobile 6 drops Large P2
915622	MoliCare® Premium Mobile 6 drops X-Large P2
915623	MoliCare® Premium Mobile 8 drops Small P2
915624	MoliCare® Premium Mobile 8 drops Medium P2
915625	MoliCare® Premium Mobile 8 drops Large P2
915634	MoliCare® Premium Mobile 6 drops Small P30
915635	MoliCare® Premium Mobile 6 drops Medium P30
915636	MoliCare® Premium Mobile 6 drops Large P30
915637	MoliCare® Premium Mobile 6 drops X-Large P30
915638	MoliCare® Premium Mobile 6 drops X-Small P30
915639	MoliCare® Premium Mobile 8 drops Small P30
915640	MoliCare® Premium Mobile 8 drops Medium P30
915641	MoliCare® Premium Mobile 8 drops Large P30

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915642	MoliCare® Premium Mobile 5 drops Medium P30
915643	MoliCare® Premium Mobile 5 drops Large P30
915644	MoliCare® Premium Mobile 5 drops Small P30
915645	MoliCare® Premium Mobile 5 drops X-Large P30
915646	MoliCare® Premium Mobile 8 drops X-Large P30
915647	MoliCare® Premium Mobile 10 drops Large P30
915648	MoliCare® Premium Mobile 5 drops X-Large P2
915649	MoliCare® Premium Mobile 10 drops X-Large P30
915652	MoliCare® Premium Mobile 10 drops Medium P30
915656	MoliCare® Premium Mobile 8 drops X-Large P2
915812	MoliCare® Premium Mobile 5 drops Medium P14
915813	MoliCare® Premium Mobile 5 drops Large P14
915822	MoliCare® Premium Mobile 6 drops Medium P14
915823	MoliCare® Premium Mobile 6 drops Large P14
915825	MoliCare® Premium Mobile 10 drops Medium P2
915826	MoliCare® Premium Mobile 10 drops Large P2
915829	MoliCare® Premium Mobile 10 drops X-Large P2
915831	MoliCare® Premium Mobile 6 drops Small P14
915832	MoliCare® Premium Mobile 6 drops Medium P14
915833	MoliCare® Premium Mobile 6 drops Large P14
915834	MoliCare® Premium Mobile 6 drops X-Large P14
915840	MoliCare® Premium Mobile 6 drops X-Small P14
915841	MoliCare® Premium Mobile 6 drops Small P14
915842	MoliCare® Premium Mobile 6 drops Medium P14
915843	MoliCare® Premium Mobile 6 drops Large P14
915844	MoliCare® Premium Mobile 6 drops X-Large P14
915852	MoliCare® Premium Mobile 5 drops Medium P14
915853	MoliCare® Premium Mobile 5 drops Large P14
915854	MoliCare® Premium Mobile 5 drops X-Large P14
915855	MoliCare® Premium Mobile 5 drops X-Large P14
915861	MoliCare® Premium Mobile 5 drops Small P14
915862	MoliCare® Premium Mobile 5 drops Medium P14
915863	MoliCare® Premium Mobile 5 drops Large P14
915871	MoliCare® Premium Mobile 8 drops Small P14

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915872	MoliCare® Premium Mobile 8 drops Medium P14
915873	MoliCare® Premium Mobile 8 drops Large P14
915874	MoliCare® Premium Mobile 8 drops X-Large P14
915875	MoliCare® Premium Mobile 8 drops X-Large P14
915878	MoliCare® Premium Mobile 10 drops Medium P14
915879	MoliCare® Premium Mobile 10 drops Large P14
915880	MoliCare® Premium Mobile 10 drops X-Large P14
915881	MoliCare® Premium Mobile 8 drops Small P14
915882	MoliCare® Premium Mobile 8 drops Medium P14
915883	MoliCare® Premium Mobile 8 drops Large P14

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