PAUL HARTMANN AG
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89522 Heidenheim

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HARTMANN
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EU Declaration of Conformity

Heidenheim, 2024-10-31

Product Group Number	3188
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	40495003188L2	
EMDN	Code	Term
	T04010103	INCONTINENCE NAPPIES WITH INTEGRATED FIXING SYSTEM
GMDN	11239	Adult nappy
UMDNS	12-111	Incontinence Pants

Heruntergeladen von Gast (IP 216.73.217.10) am 22.11.2026 um 14:07 Uhr · sana.swiss

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ppa.

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
923111	Vzorek MoliCare Elastic 6 kapek M
923112	Vzorek MoliCare Elastic 6 kapek L
923113	Vzorek MoliCare Elastic 6 kapek XL
923122	Vzorek MoliCare Elastic 8 kapek S
923123	Vzorek MoliCare Elastic 8 kapek M
923124	Vzorek MoliCare Elastic 8 kapek L
923125	Vzorek MoliCare Elastic 8 kapek XL
923129	Vzorek MoliCare Elastic 9 kapek S
923130	Vzorek MoliCare Elastic 9 kapek M
923131	Vzorek MoliCare Elastic 9 kapek L
923132	Vzorek MoliCare Elastic 9 kapek XL
165000	MoliCare® Premium Elastic 6 drops Medium DPL72
165002	MoliCare® Premium Elastic 6 drops Large DPL60
165003	MoliCare® Premium Elastic 7 drops Medium DPL72
165004	MoliCare® Premium Elastic 7 drops Large DPL60
165006	MoliCare® Premium Elastic 8 drops Medium DPL72
165008	MoliCare® Premium Elastic 8 drops Large DPL60
165009	MoliCare® Premium Elastic 9 drops Medium DPL72
165010	MoliCare® Premium Elastic 9 drops Large DPL60
165050	MoliCare® Premium Elastic 5 drops Small P1

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
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165051	MoliCare® Premium Elastic 5 drops Medium P1
165052	MoliCare® Premium Elastic 5 drops Large P1
165054	MoliCare® Premium Elastic 6 drops Small P1
165055	MoliCare® Premium Elastic 6 drops Medium P1
165056	MoliCare® Premium Elastic 6 drops Large P1
165057	MoliCare® Premium Elastic 6 drops X-Large P1
165058	MoliCare® Premium Elastic 7 drops Small P1
165059	MoliCare® Premium Elastic 7 drops Large P1
165060	MoliCare® Premium Elastic 7 drops X-Large P1
165061	MoliCare® Premium Elastic 8 drops Small P1
165062	MoliCare® Premium Elastic 8 drops Medium P1
165063	MoliCare® Premium Elastic 8 drops Large P1
165064	MoliCare® Premium Elastic 8 drops X-Large P1
165065	MoliCare® Premium Elastic 9 drops Small P1
165066	MoliCare® Premium Elastic 9 drops Medium P1
165067	MoliCare® Premium Elastic 9 drops Large P1
165068	MoliCare® Premium Elastic 9 drops X-Large P1
165069	MoliCare® Premium Elastic 10 drops Small P1
165070	MoliCare® Premium Elastic 10 drops Medium P1
165071	MoliCare® Premium Elastic 10 drops Large P1
165072	MoliCare® Premium Elastic 10 drops X-Large P1
165090	MoliCare® Premium Elastic 7 drops Medium P1
165171	MoliCare® Premium Elastic 5 drops Small P30
165172	MoliCare® Premium Elastic 5 drops Medium P30
165173	MoliCare® Premium Elastic 5 drops Large P30
165181	MoliCare® Premium Elastic 5 drops Small P30
165182	MoliCare® Premium Elastic 5 drops Medium P30
165183	MoliCare Premium Elastic 5d L PLC30
165191	MoliCare® Premium Elastic 5 drops Small P2
165192	MoliCare® Premium Elastic 5 drops Medium P2
165193	MoliCare® Premium Elastic 5 drops Large P2
165271	MoliCare® Premium Elastic 6 drops Small P30
165272	MoliCare® Premium Elastic 6 drops Medium P30
165273	MoliCare® Premium Elastic 6 drops Large P30

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165274	MoliCare® Premium Elastic 6 drops X-Large P14
165281	MoliCare® Premium Elastic 6 drops Small P30
165282	MoliCare® Premium Elastic 6 drops Medium P30
165284	MoliCare® Premium Elastic 6 drops X-Large P14
165291	MoliCare® Premium Elastic 6 drops Small P2
165292	MoliCare® Premium Elastic 6 drops Medium P2
165293	MoliCare® Premium Elastic 6 drops Large P2
165294	MoliCare® Premium Elastic 6 drops X-Large P2
165371	MoliCare® Premium Elastic 7 drops Small P30
165372	MoliCare® Premium Elastic 7 drops Medium P30
165373	MoliCare® Premium Elastic 7 drops Large P30
165374	MoliCare® Premium Elastic 7 drops X-Large P14
165381	MoliCare® Premium Elastic 7 drops Small P30
165382	MoliCare® Premium Elastic 7 drops Medium P30
165383	MoliCare® Premium Elastic 7 drops Large P30
165391	MoliCare® Premium Elastic 7 drops Small P2
165393	MoliCare® Premium Elastic 7 drops Large P2
165394	MoliCare® Premium Elastic 7 drops X-Large P2
165471	MoliCare® Premium Elastic 8 drops Small P26
165472	MoliCare® Premium Elastic 8 drops Medium P26
165473	MoliCare® Premium Elastic 8 drops Large P24
165474	MoliCare® Premium Elastic 8 drops X-Large P14
165481	MoliCare® Premium Elastic 8 drops Small P26
165482	MoliCare® Premium Elastic 8 drops Medium P26
165483	MoliCare® Premium Elastic 8 drops Large P24
165484	MoliCare Premium Elastic 8d XL PLC14
165491	MoliCare® Premium Elastic 8 drops Small P2
165492	MoliCare® Premium Elastic 8 drops Medium P2
165493	MoliCare® Premium Elastic 8 drops Large P2
165494	MoliCare® Premium Elastic 8 drops X-Large P2
165571	MoliCare® Premium Elastic 9 drops Small P26
165572	MoliCare® Premium Elastic 9 drops Medium P26
165573	MoliCare® Premium Elastic 9 drops Large P24
165574	MoliCare® Premium Elastic 9 drops X-Large P14

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165581	MoliCare® Premium Elastic 9 drops Small P26
165582	MoliCare Premium Elastic 9d M PLC26
165583	MoliCare® Premium Elastic 9 drops Large P24
165584	MoliCare® Premium Elastic 9 drops X-Large P14
165591	MoliCare® Premium Elastic 9 drops Small P2
165592	MoliCare® Premium Elastic 9 drops Medium P2
165594	MoliCare® Premium Elastic 9 drops X-Large P2
165671	MoliCare® Premium Elastic 10 drops Small P22
165672	MoliCare® Premium Elastic 10 drops Medium P14
165673	MoliCare® Premium Elastic 10 drops Large P14
165674	MoliCare® Premium Elastic 10 drops X-Large P14
165683	MoliCare® Premium Elastic 10 drops Large P14
165691	MoliCare® Premium Elastic 10 drops Small P2
165692	MoliCare® Premium Elastic 10 drops Medium P2
165693	MoliCare® Premium Elastic 10 drops Large P2
165694	MoliCare® Premium Elastic 10 drops X-Large P2

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