

EU Declaration of Conformity

Heidenheim, 2024-12-11

Product Group Number	3098
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	40495003773LK	
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

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PAUL HARTMANN AG

Stefan Grote
Member of the Management Board

ppa.

Stefan Fischer
Senior Vice President Regulatory Affairs

Valid until: 2030-12-11

List of products falling under the respective Product Group Number:

REF	Name - Description
102350	MoliCare® Slip 8D Z8 OP36
102351	MoliCare® Slip 8D E8 OP36
102352	MoliCare® Slip 8D S8 OP30
102353	MoliCare® Slip 5D E5 OP36
102354	MoliCare® Slip 5D S5 OP30
165131	MoliCare® Slip 5 drops extra Small P30
165132	MoliCare® Slip 5 drops extra Medium P30
165133	MoliCare® Slip 5 drops extra Large P30
165134	MoliCare® Slip 5 drops extra X-Large P14
165152	MoliCare® Slip 5 drops extra Medium P2
165230	MoliCare® Slip 5 drops extra plus X-Small P30
165232	MoliCare® Slip 6 drops extra plus Medium P30
165233	MoliCare® Slip 6 drops extra plus Large P30
165234	MoliCare® Slip 6 drops extra plus X-Large P14
165332	MoliCare® Slip 7 drops super Medium P30
165333	MoliCare® Slip 7 drops super Large P30
165431	MoliCare® Slip 8 drops super plus Small P30
165432	MoliCare® Slip 8 drops super plus Medium P30
165433	MoliCare® Slip 8 drops super plus Large P30
165434	MoliCare® Slip 8 drops super plus X-Large P14

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166220	HARTMANN Slip Day X-Large P15
166287	HARTMANN Slip Day Medium P30
166288	HARTMANN Slip Day Large P30
166289	HARTMANN Slip Night Medium P30
166290	HARTMANN Slip Night Large P30
166291	HARTMANN Slip Night X-Large P15
168157	MoliCare® Slip Day Medium P30
168158	MoliCare® Slip Day Large P30
168159	MoliCare® Slip Night Medium P30
168160	MoliCare® Slip Night Large P30
169115	MoliCare® Slip 8 drops super plus Medium P1
169116	MoliCare® Slip 8 drops super plus Large P1
169117	MoliCare® Slip 8 drops super plus X-Large P1
169141	MoliCare® Slip 5 drops extra Medium P1
169142	MoliCare® Slip 5 drops extra Large P1
169143	MoliCare® Slip 5 drops extra X-Large P14
169150	MoliCare® Slip 6 drops extra plus Medium P1
169151	MoliCare® Slip 6 drops extra plus Large P1
169152	MoliCare® Slip 6 drops extra plus X-Large P1
169157	MoliCare® Slip 7 drops super Medium P1
169158	MoliCare® Slip 7 drops super Large P1

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