

EU Declaration of Conformity

Heidenheim, 2024-10-31

Product Group Number	3652
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	40495003652L6	
EMDN	Code	Term
	T04010102	SHAPED INCONTINENCE NAPPIES
GMDN	35817	Incontinence pants liner
UMDNS	16-498	Incontinence Pants Liners

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

ppa.



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
168197	MoliCare® premium Form STOOL P32
168198	MoliCare® premium Form STOOL P1
168203	MoliCare® premium Form 3 drops P2
168204	MoliCare® premium Form 4 drops P2
168205	MoliCare® premium Form 5 drops P2
168206	MoliCare® premium Form 6 drops P2
168207	MoliCare® premium Form 7 drops P2
168208	MoliCare® premium Form 8 drops P2
168209	MoliCare® premium Form 9 drops P2
168303	MoliCare® premium Form 3 drops P1
168304	MoliCare® premium Form 4 drops P1
168305	MoliCare® premium Form 5 drops P1
168306	MoliCare® premium Form 6 drops P1
168307	MoliCare® premium Form 7 drops P1
168308	MoliCare® premium Form 8 drops P1
168309	MoliCare® premium Form 9 drops P1
168403	MoliCare® premium Form 3 drops P32
168404	MoliCare® premium Form 4 drops P32
168405	MoliCare® premium Form 5 drops P32
168406	MoliCare® premium Form 6 drops P32

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168407	MoliCare® premium Form 7 drops P32
168408	MoliCare® premium Form 8 drops P32
168409	MoliCare® premium Form 9 drops P16
168804	MoliCare® premium Form 4 drops DPL 96
168805	MoliCare® premium Form 5 drops DPL96
168806	MoliCare® premium Form 6 drops DPL72
168808	MoliCare® premium Form 8 drops DPL72
168904	MoliCare® premium Form 4 drops DPL96
168905	MoliCare® premium Form 5 drops DPL96
168906	MoliCare® premium Form 6 drops DPL60
168907	MoliCare® premium Form 7 drops DPL60
168908	MoliCare® premium Form 8 drops DPL60

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