

PAUL HARTMANN AG
Paul-Hartmann-Strasse 12
89522 Heidenheim
P.O. Box 1420
89504 Heidenheim
Germany

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



EU Declaration of Conformity Class I

Heidenheim, 2024-01-31

We herewith declare under our sole responsibility that the Class I medical devices listed below, first placed on the market by PAUL HARTMANN AG, Single Registration Number of Manufacturer DE-MF-000005861, satisfy the applicable provisions, in particular, the General Safety and Performance Requirements, of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices.

The conformity assessment procedures according to Article 52 (7) have been performed and the Technical Documentation is kept available.

Intended Purpose	Non-active, non-implantable devices for incontinence care, worn on the body		
Product Name	Product Group Number	Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)	Basic UDI-DI
MoliCare Premium Mobile	3106	1	40495003106K6
MoliCare Pants	3106	1	40495003106K6
Hartmann Pants	3106	1	40495003106K6

PAUL HARTMANN AG

I.V.

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Stefan Grote
Member of the Management Board

Stefan Fischer
Senior Vice President Regulatory Affairs

Valid until: 2024-06-30

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