

PAUL HARTMANN AG
Paul-Hartmann-Strasse 12
89522 Heidenheim

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

P.O. Box 1420
89504 Heidenheim
Germany



Going further
for health

EU-Declaration of Conformity

Heidenheim, 06. March 2020

We herewith declare,

Object of declaration: MoliCare Premium Soft (3130)

which has been first placed on the market by PAUL HARTMANN AG, meets the applicable provisions, in particular, the General Safety and Performance Requirements of the following EU-legislation:

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices

The Conformity Assessment Procedure according to Article 52 (7) has been performed and the Technical Documentation is kept available.

This EU-Declaration of Conformity is issued under the sole responsibility of the PAUL HARTMANN AG.

The product has been identified as a medical device in risk class 1 according to Rule 1 in Annex VIII of Regulation (EU) 2017/745.

Basic UDI-DI: 40495003130K3

Registration Number: DE/0000007683 (DIMDI)

PAUL HARTMANN AG

ppa.

A handwritten signature in black ink, appearing to be "Michel Kuehn".

Michel Kuehn

Head of Business Division
Incontinence Management

A handwritten signature in blue ink, appearing to be "Stefan Fischer".

Stefan Fischer

Head of Regulatory Affairs

IILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück
(Vorsitzende des Vorstands/CEO), François Georgelin,
Dr. Raymund Heinen, Michel Kuehn
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