

PAUL HARTMANN AG
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Going further
for health

EU-Declaration of Conformity

Heidenheim, 29. July 2020

We herewith declare,

Foliodress mask Comfort Loop (1311)

which was first placed on the market by PAUL HARTMANN AG, meets the applicable provisions, in particular the General Safety and Performance Requirements of 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 I according to Rule 1 in Annex VIII of Regulation (EU) 2017/745.

Basic UDI-DI: 40495001311JT

Registration Number: DE/0000007683 (Registration number DIMDI)

ppa.

A handwritten signature in black ink, appearing to read "Christian Sievert".

Christian Sievert

Head of Business Division
Risk Prevention

ppa.

A handwritten signature in blue ink, appearing to read "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