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Going further  
for health

## EU-Declaration of Conformity

Heidenheim, 29. July 2020

We herewith declare,

### **Foliodress mask Protect Special (1313)**

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: 40495001313JX

Registration Number: DE/0000007683 (Registration number DIMDI)

ppa.

**Christian Sievert**

Head of Business Division  
Risk Prevention

ppa.

**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