

PAUL HARTMANN AG
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Going further
for health

EU-Declaration of Conformity

Heidenheim, 11. March 2020

We herewith declare,

Object of declaration: Safix plus Plaster Dressings (1245)

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: 40495001245K7

Registration Number: DE/0000007683 (DIMDI)

PAUL HARTMANN AG

I.V. Laurent Roche

ppa.

A blue ink signature of François Georgelin, consisting of a stylized 'F' and 'G' followed by a horizontal line.

François Georgelin

Head of Business Division
Wound Management

A blue ink signature of Stefan Fischer, consisting of a stylized 'S' and 'F' followed by a horizontal line.

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