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HARTMANN
Going further for health

EU-Declaration of Conformity

Heidenheim, 29. April 2020

We herewith declare,

Object of declaration: DermaPlast CoFix (3318)

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: 40495003318KP

Registration Number: DE/0000007683 (Registration number DIMDI)

Paul Hartmann AG

i.V. Laurent Roche

François Georgelin

Head of Business Division
Wound Management

i.V.

Jens Hahn

Head of Regulatory Affairs Operations

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