PAUL HARTMANN AG
Paul-Hartmann-Strasse 12
89522 Heidenheim

P.O. Box 1420
89504 Heidenheim
Germany

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

HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity

Heidenheim, 2022-04-25

Object(s) of the declaration:

DermaPlast Universal (1480)

We herewith declare under our sole responsibility that the medical devices listed above, first placed on the market by PAUL HARTMANN AG, comply with 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 objects of the declaration also comply with the applicable:

- Essential Health and Safety Requirements of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment
- Requirements of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

The objects of the declaration have been identified as medical devices in risk class I according to classification rule 4 indent 1 in Annex VIII of Regulation (EU) 2017/745. The conformity assessment procedure according to Article 52 (7) has been performed and the Technical Documentation is kept available.

(High-Level) Intended Purpose: Non-active, non-implantable devices for wound and skin care

Basic UDI-DI: 40495001480KK

SRN: Single Registration Number of Manufacturer: 40495003888M5

PAUL HARTMANN AG

(ppa.)

François Georgelin
Member of the Management Board

ppa.

Stefan Fischer
Senior Vice President Regulatory Affairs

Valid until (yyyy-mm-dd): 2023-03-01

ILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Stefan Grote, Stefan Müller
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