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Helps. Cares. Protects.

PAUL HARTMANN AG, P.O. Box 1420, 89504 Heidenheim, Germany

EU Declaration of Conformity

Heidenheim, 2023-03-21

Manufacturer Information:

Manufacturer:	PAUL HARTMANN AG
Single Registration Number (SRN):	DE-MF-000005861

We hereby declare under our sole responsibility that the medical devices listed below comply with the applicable provisions of the

- General Safety and Performance Requirements (Annex I) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices

Objects [and Scope] of this Declaration:

Objects	Product Name(s)	Basic UDI-DI
4037	DermaPlast Isopor	40495004037KK

(High-Level) Intended Purpose and Device Nomenclature

Single-use, non-active, non-implantable devices for wound and skin care.

Nomenclature	Code	Term
EMDN	M050199	Surgical plasters - other
GMDN	16866	Basic adhesive tape
UMDNS	10-028	Adhesive Strips, Hypoallergenic

The objects of the declaration have been qualified as medical devices, and the risk classification has been determined according to the classification rules in Annex VIII of Regulation (EU) 2017/745. The risk classification, the classification rule and the conformity assessment procedure used to demonstrate conformity are listed below. The technical documentation is kept available.

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Risk Classification	Classification Rule	Conformity Assessment Procedure
I	1	Article 52(7)

Relevant Certificates

EU QMS Certificate(s) (MDR): (G10 011858 0065, Class IIa, IIb)

ISO QMS Certificate(s): (Q5 011858 0062, EN ISO 13485:2016)

PAUL HARTMANN AG

ppa.

Francois Georgelin
Head of Business Division
Wound Care

ppa.

Stefan Fischer
Senior Vice President Regulatory Affairs

GLN 404 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