

PAUL HARTMANN AG
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www.hartmann.info



Helps. Cares. Protects.

UK Declaration of Conformity

Heidenheim, 2022-10-10

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 UK Medical Devices Regulations 2002 (SI 2002 No 618), amended by the Medical Devices (EU Exit) Regulations 2019 and the Medical Devices (EU Exit) Regulations 2020.

UK Representative

PAUL HARTMANN LTD,
Unit P2, Parklands, Heywood Distribution Park, Pilsworth Road
Heywood, Lancs., OL10 2TT

Objects [and Scope] of this Declaration:

Objects	Product Name
Peha-haft latexfree (1229)	Peha-haft

Device Nomenclature:

REF Numbers

9324493, 9324522, 9324415, 9324427, 9324436, 9324446, 9324453

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
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Device Nomenclature:

Nomenclature	Code	Term
EMDN	M030301	Elastic fixing bandages
GMDN	58964	Non-adhesive retention bandage
UMDNS	15-557	Binde

Risk Classification:

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 IX of Council Directive 93/42/EEC. The risk classification, the classification rule and the conformity assessment procedure used to demonstrate conformity are listed below. The technical documentation is kept available.

Risk Classification	Classification Rule	Conformity Assessment Procedure
I	1	Annex 11(5) and Annex VII

PAUL HARTMANN AG

ppa.

François Georgelin

Member of the Management Board

Stefan Fischer

Senior Vice President Regulatory Affairs

This document is valid until: 2023-03-01

GLN 404 9500 00000 0

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