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 Class IIa

Heidenheim, 2024-06-12

We herewith declare under our sole responsibility that the class IIa medical device listed below, first placed on the market by PAUL HARTMANN AG, Single Registration Number of Manufacturer DE-MF-000005861, satisfy the applicable provisions, in particular, the General Safety and Performance Requirements, of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices.

The conformity assessment procedures according to Article 52 (6) and Annex IX have been performed and the Technical Documentation is kept available.

The conformity assessment procedures are under the supervision of the Notified Body TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123. Certificate No.: G10 011858 0065.

Device Group	H900102 – BANDAGES FOR SUTURES		
Intended Purpose	Single-use, non-active, non-implantable devices for wound and skin care		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic UDI-DI**
Omnistrip sterile	2502	4 (4)	40495002502KB

PAUL HARTMANN AG

i.V.

François Georgelin
Member of the Management Board

i.V.

Jens Hahn
Director Regulatory Affairs Excellence

Valid until: 2025-06-30