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HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity Class IIb

Heidenheim, 2024-02-28

We herewith declare under our sole responsibility that the class IIb 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 (4) 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	M040499 – DRESSINGS FOR WOUNDS, SORES AND ULCERATIONS - OTHER		
Intended Purpose	Single-use, sterile, non-medicated dressings suitable for the treatment of wounds		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic UDI-DI**
Zetuvit Plus Superabsorber	1407	4 (2)	40495001407K9

PAUL HARTMANN AG

ppa.

François Georgelin
Member of the Management Board

Stefan Fischer
Senior Vice President Regulatory Affairs

Valid until: 2024-06-30