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HARTMANN
Going further for health

EU-Declaration of Conformity

Heidenheim, 29. April 2020

We herewith declare,

Object of declaration: Tensocrepe (238) (3407)

which was first placed on the market by PAUL HARTMANN AG, meets 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 Conformity Assessment Procedure according to Article 52 (7) has been performed and the Technical Documentation is kept available.

This EU-Declaration of Conformity is issued under the sole responsibility of the PAUL HARTMANN AG.

The product has been identified as a medical device in risk class I according to Rule 1 in Annex VIII of Regulation (EU) 2017/745.

Basic UDI-DI: 40495003407KP

Registration Number: DE/0000007683 (Registration number DIMDI)

PAUL HARTMANN AG

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