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HARTMANN
Going further for health

EU-Declaration of Conformity

Heidenheim, 16. December 2020

We herewith declare,

Object of declaration: Atrauman Silicone (1390)

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 (4) and Annex IX 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 conformity assessment procedure is under the supervision of the Notified Body:

TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123.

The product has been identified as a medical device in risk class IIb according to Rule 4 indent 2 in Annex VIII of Regulation (EU) 2017/745.

Basic UDI-DI: 40495001390KH

Registration Number: DE/0000007683 (Registration number DIMDI)

PAUL HARTMANN AG

ppa.

François Georgelin

Head of Business Division
Wound Management

Stefan Fischer

Head of Regulatory Affairs