

PAUL HARTMANN AG
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EU Declaration of Conformity

Heidenheim, 2021-09-09

Object(s) of the declaration:

HydroClean (3198)

We herewith declare under our sole responsibility that the medical devices listed above, first placed on the market by PAUL HARTMANN AG, comply with 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 objects of the declaration have been identified as medical devices in risk class IIb according to classification rule 4 indent 2 in Annex VIII of Regulation (EU) 2017/745. The conformity assessment procedure according to Article 52 (4) and Annex IX has been performed and the Technical Documentation is kept available.

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.

(High-Level) Intended Purpose: Single-use, sterile, non-medicated dressings suitable for the treatment of wounds

Basic UDI-DI: 40495003198L5

SRN: Single Registration Number of Manufacturer: DE-MF-000005861

PAUL HARTMANN AG

ppa.

François Georgelin

Head of Business Division

Wound Management

Stefan Fischer

Head of Regulatory Affairs

Valid until (yyyy-mm-dd): 2022-03-01

ILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück
(Vorsitzende des Vorstands/CEO), François Georgelin,
Stefan Grote, Dr. Raymund Heinen, 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
661090