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
hartmann.info

HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity

Heidenheim, 2021-09-09

Object(s) of the declaration:

HydroClean cavity (3199)

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: 40495003199L7

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