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
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Consolidated EU Declaration of Conformity for Medical Devices in Class Is

Heidenheim, 01. March 2021

We herewith declare under our sole responsibility that the Class I sterile medical devices listed below, first placed on the market by PAUL HARTMANN AG (Registration Number DE/0000007683 [BfArM]), 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 (7) and Annex XI part A with respect to sterility have been performed and the Technical Documentation is kept available.

The sterilization processes are under the supervision of the Notified Body TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany, ID-Nr. 0123. Certificate No.: G21 011858 0069.

PAUL HARTMANN AG

Dr. Raymund Heinen
CPO

ppa.

Stefan Fischer
Head of Regulatory Affairs

Valid until: 2022-03-01

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Class I sterile medical devices in conjunction with the EU Quality Management System Certificate (MDR) No. G21 011858 0069

Device Group	MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care
Device Properties	MDS 1005.2 – Sterilisation by irradiation
Intended Purpose	Non-active, non-implantable devices for anaesthesia, emergency and intensive care

Product Name	Product Group Number	Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)	Basic-UDI-DI
Peha-soft nitrile	1946	5 (1)	40495001032JL

ILN 040 9500 00000 0

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