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HARTMANN
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EU Declaration of Conformity Class Is

Heidenheim, 2023-08-23

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, Single Registration Number of Manufacturer DE-MF-000005861, 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

We herewith declare under our sole responsibility that the Category III personal protective equipment listed below, first placed on the market by PAUL HARTMANN AG, satisfy the applicable provisions, in particular, the Essential Health and Safety Requirements (Annex II) of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment.

The objects of the declaration also comply with the following:

- EN ISO 374-1:2016+ A1:2018 / Type B
  Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
- EN ISO 374-5:2016
  Protective gloves against dangerous chemicals and micro-organisms – Part 5: Terminology and performance requirements for micro-organisms risks
- EN 420:2003+A1:2009
  Protective gloves - General requirements and test methods
- EN 421:2010 (excluding clause 4.3)
  Protective gloves against ionizing radiation and radioactive contamination

The notified body SATRA Technology Europe Ltd., 2777 performed the EU type-examination (Module B) and issued the EU type-examination certificate 2777/11513-03/E08/01.

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The Personal Protective Equipment is subject to the conformity assessment procedure based on internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the notified body SATRA Technology Europe Ltd., 2777.

Intended Purpose	Single-use, non-active, non-implantable devices for wound and skin care		
Product Name	**Product Group Number**	**Classification Rule (according to Annex VIII of Regulation (EU) 2017/745)**	**Basic UDI-DI**
Peha-soft nitrile sterile	1946	5 (1)	40495001946LC

PAUL HARTMANN AG

ppa.

Martin Walther

Senior Vice President Risk Prevention

ppa.

Stefan Fischer

Senior Vice President Regulatory Affairs

Valid until: 2027-08-24