PAUL HARTMANN AG
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HARTMANN
Helps. Cares. Protects.

EU-Declaration of Conformity

Heidenheim, 17. March 2022

We herewith declare,

Object of declaration:

Peha-soft nitrile sterile (1946)

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

and Essential Health and Safety Requirements of the following EU-legislation(s):

- Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment

The Conformity Assessment Procedure according to Article 52 (7) and according to Annex XI part A with respect to sterility 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 sterilization Processes are 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 Is according to Rule 5 indent 1 in Annex VIII of Regulation (EU) 2017/745.

Basic UDI-DI: 40495001946LC

Registration Number: DE-MF-000005861

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The object of the declaration is in conformity with the relevant Union harmonization legislation:

- EN ISO 374-1:2016+ A1:2018
  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 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 2777/10894-04/E02-01.

The PPE 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).

Paul Hartmann AG

ppa.

Martin Walther

Head of Business Division
Risk Prevention

ppa.

Stefan Fischer

Head of Regulatory Affairs

Valid until (yyyy-mm-dd): 2023-07-27

ILN 040 9500 00000 0

Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Stefan Grote, 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