

PAUL HARTMANN AG  
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Helps. Cares. Protects.

## EU-Declaration of Conformity

Heidenheim, 12. April 2022

We herewith declare,

### Object of declaration:

#### **Peha-soft nitrile white, Peha-soft nitrile white semilong (1032)**

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) 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 product has been identified as a medical device in risk class I according to Rule 5 indent 1 in Annex VIII of Regulation (EU) 2017/745.

Basic UDI-DI: 40495001032JL

Registration Number (SRN): DE-MF-000005861

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



### Personal Protective Equipment Regulation:

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 2777/12049-02/E01-01 and 2777/10896-03/E01-01.

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 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: 2023-07-18

ILN 040 9500 00000 0

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