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.

Izjava EU o skladnosti

Heidenheim, 17. avgust, 2021

S tem izjavljamo, da
Predmet izjave: Rokavice Peha-soft nitrile white, Rokavice Peha-soft nitrile white semilong (1032),

ki jih je podjetje PAUL HARTMANN AG prvič dalo na trg, izpolnjujejo veljavne določbe in predvsem splošne zahteve glede varnosti in učinkovitosti Uredbe (EU) 2017/745 Evropskega parlamenta in Sveta z dne 5. aprila 2017 o medicinskih pripomočkih

ter bistvene zdravstvene in varnostne zahteve naslednje zakonodaje EU:

- Uredba (EU) 2016/425 Evropskega parlamenta in Sveta z dne 9. marca 2016 o osebni varovalni opremi

Izveden je bil zahtevani postopek ugotavljanja skladnosti skladno s členom 52 (7), tehnična dokumentacija pa je na voljo.

Za izdajo te izjave EU o skladnosti je izključno odgovorna družba PAUL HARTMANN AG.

Izdelek je bil opredeljen kot medicinski pripomoček razreda tveganja I skladno s 1 alinejo 5. pravila v Prilogi VIII k Uredbi (EU) 2017/745.

Osnovni UDI-DI: 40495001032JL

Registracijska številka: DE/0000007683 (registracijska številka DIMDI)

EU-Declaration of Conformity

Heidenheim, 17. August 2021

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: DE/0000007683 (Registration number DIMDI)

ILN 040 9500 00000 0

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

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Predmet izjave je v skladu z ustrezno usklajevalno zakonodajo Unije:

- EN ISO 374-1:2016+ A1:2018
  Varovalne rokavice za zaščito pred nevarnimi kemikalijami in mikroorganizmi - 1. del: Izrazje in zahtevane lastnosti za zaščito pred kemičnimi tveganji

- EN ISO 374-5:2016
  Varovalne rokavice za zaščito pred nevarnimi kemikalijami in mikroorganizmi - 5. del: Izrazje in zahtevane lastnosti za zaščito pred tveganji, povezanimi z mikroorganizmi

- EN 420:2003+A 1:2009
  Varovalne rokavice - Splošne zahteve in preskusne metode

- EN 421:2010 EN 421:2010 (z izvzetjem klavzule 4.3)
  Varovalne rokavice za zaščito pred ionizirajočim sevanjem in radioaktivno kontaminacijo

Priglašeni organ SATRA Technology Europe Ltd (2777) je izvedel EU-pregled tipa (modul B) in izdal certifikat o EU-pregledu tipa 2777/12049-02/E01-01 in 2777/10896-03/EO 1-01.

Za osebno varovalno opremo velja postopek ugotavljanja skladnosti, ki temelji na notranjem nadzoru proizvodnje in nadzorovanih preskusih proizvodov v naključno izbranih časovnih presledkih

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 2777/12049-01/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

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(modul C2) pod nadzorom priglašenega organa SATRA Technology Europe Ltd (2777).

intervals (Module C2) under surveillance of the notified SATRA Technology Europe Ltd (2777).

Paul Hartmann AG

i.V.

Jörg Enk
Director Product Development Risk Prevention

ppa.

Stefan Fischer
Head of Regulatory Affairs

Ta document velja do: 18.07.2023
This document is valid until: 18.07.2023

ILN 040 9500 00000 0

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