PAUL HARTMANN AG
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HARTMANN
Helps. Cares. Protects.

Izjava EU o skladnosti

Heidenheim, 17. Avgust, 2021

S tem izjavljamo, da

Predmet izjave: Rokavice Peha-soft nitrile (1944),

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: 40495001944L8

Registracijska številka: DE/0000007683 (registracijska številka DIMDI)

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

EU-Declaration of Conformity

Heidenheim, 17. August 2021

We herewith declare,

Object of declaration: Peha-soft nitrile (1944)

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: 40495001944L8

Registration Number: DE/0000007683 (Registration number DIMDI)

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

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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 2777/10894-04/E04-01.
Za osebno varovalno opremo velja postopek ugotavljanja skladnosti, ki temelji na notranjem nadzoru proizvodnje in nadzorovanih preskusih proizvodov v naključno izbranih časovnih presledkih (modul C2) pod nadzorom priglašenega organa SATRA Technology Europe Ltd (2777).

- 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/E04-01.
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

i.V.

Jörg Enk
Director Product Development Risk Prevention

ppa.

Stefan Fischer
Head of Regulatory Affairs

Ta dokument velja do: 2023-07-27
This document is valid until: 2023-07-27