

EU Declaration of Conformity Class I

Heidenheim, 2024-02-28

We herewith declare under our sole responsibility that the Class I 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) have been performed and the Technical Documentation is kept available.

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

GLN 404 9500 00000 0

Vorstand/Management Board: Britta Fünfstück
(Vorsitzende des Vorstands/CEO), François Georgelin,
Stefan Grote, Oliver Neubrand
Aufsichtsratsvorsitzender/Chairman of the Supervisory Board:
Fritz-Jürgen Heckmann

Izjava ES o skladnosti Razred I

Heidenheim, 28. 2. 2024

Na lastno odgovornost izjavljamo, da spodaj navedeni medicinski pripomočki razreda I, ki jih je podjetje PAUL HARTMANN AG, enotna registrska številka proizvajalca DE-MF-000005861, prvič dalo na trg, izpolnjujejo veljavne določbe, zlasti splošne zahteve glede varnosti in učinkovitosti, Uredbe (EU) 2017/745 Evropskega parlamenta in Sveta z dne 5. aprila 2017 o medicinskih pripomočkih.

Postopki ugotavljanja skladnosti v skladu s členom 52(7) so bili izvedeni, tehnična dokumentacija pa je na voljo.

Na lastno odgovornost izjavljamo, da spodaj navedena osebna varovalna oprema kategorije III, ki jo je podjetje PAUL HARTMANN AG prvič dalo na trg, izpolnjuje veljavne določbe, zlasti bistvene zdravstvene in varnostne zahteve (Priloga II) Uredbe (EU) 2016/425 Evropskega parlamenta in Sveta z dne 9. marca 2016 o osebni varovalni opremi.

Predmeti izjave so skladni tudi z naslednjim:

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

Sitz Heidenheim
Amtsgericht Ulm HRB 661090
Registered Office Heidenheim
Commercial Register of the District Court of Ulm file no. HRB
661090



- EN ISO 374-5:2016
Protective gloves against dangerous chemicals and micro-organisms – Part 5: Terminology and performance requirements for micro-organisms risks
- EN 21420:2020
Protective gloves - General requirements and test methods
- EN 421:2010 (excluding clause 4.3)
Protective gloves against ionizing radiation and radioactive contamination
- 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 21420:2020
Varovalne rokavice – Splošne zahteve in preskusne metode
- EN 421:2010 (razen določbe 4.3)
Varovalne rokavice za zaščito pred ionizirnim sevanjem in radioaktivno kontaminacijo

The notified body SATRA Technology Europe Ltd., 2777 performed the EU type-examination (Module B) and issued the EU type-examination certificates 2777/11861-04/E01-01 and 2777/11578-03/E06-01.

Priglašeni organ SATRA Technology Europe Ltd., 2777, je opravil EU-pregled tipa (modul B) in izdal certifikata o EU-pregledu tipa 2777/11861-04/E01-01 in 2777/11578-03/E06-01.

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) for EU type-examination certificate 2777/11861-04/E01-01 and quality assurance of the production process (Module D) for EU type-examination certificate 2777/11578-03/E06-01 executed under the surveillance of the notified body SATRA Technology Europe Ltd., 2777.

Za osebno varovalno opremo velja postopek ugotavljanja skladnosti, ki temelji na notranjem nadzoru proizvodnje in nadzorovanih pregledih izdelkov v naključnih časovnih presledkih (modul C2) za certifikat o EU-pregledu tipa 2777/11861-04/E01-01 in zagotavljanju kakovosti proizvodnega procesa (modul D) za certifikat o EU-pregledu tipa 2777/11578-03/E06-01, ki se izvedeta pod nadzorom priglašene organa SATRA Technology Europe Ltd., 2777.

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Prevideni namen	Neaktivni, nevsadljivi pripomočki za nego ran in kože		
Ime izdelka	Številka skupine izdelkov	Pravilo o razvrstitvi (v skladu s Prilogo VIII k Uredbi (EU) 2017/745)	Osnovni UDI-DI
Rokavice Peha-soft nitrile fino	1024	5 (1)	40495001024JM

PAUL HARTMANN AG

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Martin Walther

Senior Vice President Risk Prevention

Stefan Fischer

Senior Vice President Regulatory Affairs

*[Reference is made to the signed original below/
Sklicujemo se na podpisani izvirnik spodaj]*

Velja do: 1. 9. 2028

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