

EU Declaration of Conformity

Heidenheim, 2024-08-21

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

Izjava ES o skladnosti

Heidenheim, 21. 8. 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
- EN ISO 374-5:2016
Varovalne rokavice za zaščito pred nevarnimi kemikalijami in mikroorganizmi – 5. del: Izrazje in

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

Sitz Heidenheim
Amtsgericht Ulm HRB 661090
Registered Office Heidenheim
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661090

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 421:2010 (excluding clause 4.3 /
Radioactive contamination only)
Protective gloves against ionizing
radiation and radioactive
contamination
- EN 21420:2020
Protective gloves - General
requirements and test methods

The notified body SATRA Technology Europe Ltd., 2777 performed the EU type-examination (Module B) and issued the EU type-examination certificate 2777/11513-04/E14-01 and 2777/13230-05/E01-01.

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 2777/13230-05/E01-01 and quality assurance of the production process (Module D) for EU type-examination certificate 2777/11513-04/E14-01 executed under the surveillance of the notified body SATRA Technology Europe Ltd., 2777.

zahtevane lastnosti za zaščito pred
tveganji, povezanimi z
mikroorganizmi

- EN 421:2010 (razen določbe 4.3 /
samo radioaktivna kontaminacija)
Varovalne rokavice za zaščito pred
ionizirnim sevanjem in radioaktivno
kontaminacijo
- EN 21420:2020
Varovalne rokavice – Splošne
zahteve in preskusne metode

Priglašeni organ SATRA Technology Europe Ltd., 2777, je opravil EU-pregled tipa (modul B) in izdal certifikat o EU-pregledu tipa 2777/11513-04/E14-01 in 2777/13230-05/E01-01.

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 2777/13230-05/E01-01 in zagotavljanju kakovosti proizvodnega procesa (modul D) za certifikat o EU-pregledu tipa 2777/11513-04/E14-01, 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
Peha-soft nitrile	1944	5 (1)	40495001944L8

PAUL HARTMANN AG

ppa.

po pooblastilu

Martin Walther

Senior Vice President Risk Prevention

Jens Hahn

Director Regulatory Affairs Excellence

Valid until: 2028-08-09

Velja do: 9. 8. 2028

GLN 404 9500 00000 0

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