

2 September 2024
Dr. Dr/Ni-bau

UNBEDENKLICHKEITSERKLÄRUNG
CERTIFICATE OF COMPLIANCE
CERTIFICAT DE CONFORMITE

eingetragen
registered no.
registré

62869 U 24

für
for
pour

Paul Hartmann AG
Paul-Hartmann-Straße 12
89522 Heidenheim
Germany

Produkt
Product
Produit

Peha-soft nitrile (Lot: 399902008)
Peha-soft nitrile Guard (Lot: 298605000)

The blue nitrile gloves distributed by the company mentioned above are used in the food industry during the preparation and handling of food.

They were examined by us according to the

Methoden zur Untersuchung von Kunststoffen, soweit sie als Bedarfsgegenstände im Sinne des Lebensmittel- und Bedarfsgegenständegesetzes verwendet werden, einschließlich der 62. Mitteilung des BfR zur Untersuchung von Hochpolymeren, Bundesgesundheitsblatt 50, 524 (2007), Stand vom April 2007,

(Methods for testing plastics as far as they are used as consumer goods as defined by the Foodstuffs and Consumer Goods Act, including the 62nd memorandum of the BfR on the examination of high polymers, Bundesgesundheitsblatt 50, 524 (2007), state of April 2007),

for the composition as well as for the release of substances which might endanger health and to the

Series of standards EN 1186, EN 13130 and CEN/TS 14234 "Materials and Articles in Contact with Foodstuffs – Plastics", current state,

for the migration behaviour.

The glove grades are in compliance with the rules of the

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, Official Journal of the European Union L 338/4 of 13.11.2004, lastly modified by article 5 of the Regulation (EU) 2019/1381 of 20 June 2019, Official Journal of the European Union L 231/1 of 6 September 2019, article 3, 1. (a) and (b),

as well as of the

Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuches (Lebensmittel- und Futtermittelgesetzbuch - LFGB) in der Fassung der Bekanntmachung vom 15. September 2021 (BGBl. I S. 4253; 2022 I S. 28), zuletzt geändert durch Artikel 11 des Gesetzes vom 6. Mai 2024 (BGBl. 2024 I Nr. 149), §§ 30 und 31,

(Foodstuffs, Consumer Goods and Animal Feed Code (Foodstuffs and Animal Feed Code - LFGB) in the version of the notification of 15 September 2021 (BGBl. I. p. 4253; 2022 I p.28), last amended by article 11 of the act of 6 May 2024 (BGBl. 2024 I no. 149), §§ 30 and 31).

They conform to the

BfR-Empfehlung XXI. Bedarfsgegenstände auf Basis von Natur- und Synthetikgummi, neugefasst durch 225. Mitteilung, Bundesgesundheitsblatt 65 (2022) 525-526, Stand vom 01.04.2022, zuletzt geändert durch 226. Mitteilung, Bundesgesundheitsblatt 66 (2023) 216-217, Stand vom 01.02.2023,

(BfR Recommendation XXI. Commodities based on Natural and Synthetic Rubber, recast by 225th Announcement, Bundesgesundheitsblatt 65 (2022) 525-526, as of 1 April 2022), last amended by 226th Announcement, Bundesgesundheitsblatt 66 (2023) 216-217, as of 1 February 2023),

as well as to the

BfR-Empfehlung XXI/1. Bedarfsgegenstände auf Basis von Natur- und Synthetikgummi, neugefasst durch 225. Mitteilung, Bundesgesundheitsblatt 65 (2022) 525-526, Stand vom 01.04.2022, zuletzt geändert durch 226. Mitteilung, Bundesgesundheitsblatt 66 (2023) 216-217, Stand vom 01.02.2023,

(BfR Recommendation XXI/1. Commodities based on Natural and Synthetic Rubber, recast by 225th Announcement, Bundesgesundheitsblatt 65 (2022) 525-526, as of 1 April 2022), last amended by 226th Announcement, Bundesgesundheitsblatt 66 (2023) 216-217, as of 1 February 2023),

and keep the applicable limits of the

Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, Official Journal of the European Union L 12/1 of 15 January 2011, last amended by Commission Regulation (EU) 2023/1627 of 10 August 2023, Official Journal of the European Union L 201/4 of 11 August 2023,

regarding individual constituents.

Thus, the blue nitrile gloves **Peha-soft nitrile (Lot: 399902008)** and **Peha-soft nitrile Guard (Lot: 298605000)** according to the sample material submitted may be used safely in the food industry during the preparation and handling of food. They may stand in direct contact with all types of food for a short period of time.

The maximum ratio of the food contact surface of the gloves and the amount of food shall not exceed 8.4 dm² per 5 kg food. This is equivalent to a contact of the palm and back of both hands including fingers with 5 kg food.

This certificate of compliance represents the latest technical standard and is based on the certificate of compliance no. 50457 U 19 of 26 September 2019 in connection with a new partial examination of the product.

It has a validity of 2 years and consists of 4 pages.

Certification decision



Staatlich anerkannter Sachverständiger
zur Untersuchung der Gegenproben von
Verpackungsmitteln aus Papier, Pappe,
Kunststoffen, Glas, Weißblech und
sonstigen Metallverpackungen auf ihre
lebensmittelrechtliche Unbedenklichkeit

(Dr. Hillmann)

Authorized food chemist

The translation of the above stamps is given on page 4.
La traduction des estampilles est donnée en page 4.



Staatlich anerkannter Sachverständiger zur Untersuchung der Gegenproben von Verpackungsmitteln aus Papier, Pappe, Kunststoffen, Glas, Weißblech und sonstigen Metallverpackungen auf ihre lebensmittelrechtliche Unbedenklichkeit

Dr. Ralph Derra

Authorized expert for the analyses of packaging materials, attested by the Chamber of Industry and Commerce.

Expert autorisé pour l'analyse des matériaux d'emballage, assermenté par la Chambre d'Industrie et de Commerce.

State registered expert for the analysis of contrasting samples of packaging materials of paper, board, plastics, glass, tin plate and other metallic packaging materials as to their suitability for use with foodstuffs.

Expert public pour l'étude du contrôle des contre-échantillons d'emballages de papier, cartons, plastiques, verre, fer-blanc et d'autres emballages métalliques concernant leur conformité alimentaire.



Dr. Ralph Derra

Authorized expert for the analyses of soil and air, attested by the Aschaffenburg Chamber of Industry and Commerce.

Expert autorisé pour l'analyse du sol et de l'air, assermenté par la Chambre d'Industrie et de Commerce d'Aschaffenburg.

Die Rücklagen des untersuchten Materials werden bei der Gutachterstelle verwahrt.
Dieses Dokument ist eine Übersetzung einer deutschen Originalversion. In Streitfällen ist das Originaldokument die rechtlich bindende Version.
A file sample of the tested material is kept at the expert's office.
This document is a translation of an original in German. In case of dispute, the original document should be taken as authoritative.

9 July 2024
Dr. Dr/Ni-hag

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62450 U 24

für
for
pour

Paul Hartmann AG
Paul-Hartmann-Straße 12
89522 Heidenheim
Germany

Produkt
Product
Produit

Peha-soft® nitrile PF (Lot B19/20231107/S)
Peha-soft® nitrile guard (Lot B20/20231116/S)

The blue nitrile gloves distributed by the company mentioned above are used in the food industry during the preparation and handling of food.

They were examined by us according to the

Methoden zur Untersuchung von Kunststoffen, soweit sie als Bedarfsgegenstände im Sinne des Lebensmittel- und Bedarfsgegenständegesetzes verwendet werden, einschließlich der 62. Mitteilung des BfR zur Untersuchung von Hochpolymeren, Bundesgesundheitsblatt 50, 524 (2007), Stand vom April 2007,

(Methods for testing plastics as far as they are used as consumer goods as defined by the Foodstuffs and Consumer Goods Act, including the 62nd memorandum of the BfR on the examination of high polymers, Bundesgesundheitsblatt 50, 524 (2007), state of April 2007),

for the composition as well as for the release of substances which might endanger health and to the

Series of standards EN 1186, EN 13130 and CEN/TS 14234 "Materials and Articles in Contact with Foodstuffs – Plastics", current state,

for the migration behaviour.

The nitrile gloves are in compliance with the rules of the

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, Official Journal of the European Union L 338/4 of 13.11.2004, lastly modified by article 5 of the Regulation (EU) 2019/1381 of 20 June 2019, Official Journal of the European Union L 231/1 of 6 September 2019, article 3, 1. (a) and (b),

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BfR-Empfehlung XXI. Bedarfsgegenstände auf Basis von Natur- und Synthetikgummi, neugefasst durch 225. Mitteilung, Bundesgesundheitsblatt 65 (2022) 525-526, Stand vom 01.04.2022, zuletzt geändert durch 226. Mitteilung, Bundesgesundheitsblatt 66 (2023) 216-217, Stand vom 01.02.2023,

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regarding individual constituents.

Thus, the blue nitrile gloves **Peha-soft® nitrile PF (Lot B19/20231107/S)** and **Peha-soft® nitrile guard (Lot B20/20231116/S)** according to the sample material submitted may be used safely in the food industry during the preparation and handling of food. They may stand in direct contact with all types of food for a short period of time.

The maximum ratio of the food contact surface of the gloves and the amount of food shall not exceed 8.4 dm² per 5 kg food. This is equivalent to a contact of the palm and back of both hands including fingers with 5kg food.

This certificate of compliance represents the latest technical standard and is based on the certificate of compliance no. 57402 U 22 of 8 July 2022 in connection with a new partial examination of the product.

This certificate of compliance has a validity of 2 years and consists of 4 pages.

Certification decision



staatlich anerkannter Sachverständiger
zur Untersuchung der Gegenproben von
Verpackungsmitteln aus Papier, Pappe,
Kunststoffen, Glas, Weißblech und
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(Dr. Hillmann)
Authorized food chemist

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Die Rücklagen des untersuchten Materials werden bei der Gutachterstelle verwahrt.
Dieses Dokument ist eine Übersetzung einer deutschen Originalversion. In Streitfällen ist das Originaldokument die rechtlich bindende Version.
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This document is a translation of an original in German. In case of dispute, the original document should be taken as authoritative.

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

GLN 404 9500 00000 0

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

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.

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
Commercial Register of the District Court of Ulm file no. HRB
661090

PAUL HARTMANN AG
Paul-Hartmann-Strasse 12
89522 Heidenheim

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Faks: +49 (0) 7321 36-3636

www.hartmann.info



Helps. Cares. Protects.

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

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

Commercial Register of the District Court of Ulm file no. HRB
661090