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
www.hartmann.info

HARTMANN
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Izjava EU o skladnosti

Heidenheim, 6. 5. 2025

Številka skupine izdelkov	2109
Proizvajalec	PAUL HARTMANN AG Paul-Hartmann-Str. 12 89522 Heidenheim NEMČIJA

Na lastno odgovornost izjavljamo, da zgoraj navedeni izdelek, ki ga je prvič dalo na trg podjetje PAUL HARTMANN AG, izpolnjuje veljavne določbe naslednjih naštetih zakonodaj. Postopki ugotavljanja skladnosti so bili izvedeni, tehnična dokumentacija pa je na voljo.

Uporabljeni zakonodajni akti

Uredba o medicinskih pripomočkih (EU) 2017/745

Previdenj namen visoke stopnje	Neaktivni, nevsadljivi pripomočki za nego ran in kože, ki so predvideni za enkratno uporabo	
Razvrstitev	Razred tveganja	Pravilo
	Razred IIa	Pravilo 7 | glavni odstavek
Postopek ugotavljanja skladnosti	Člen 52 (6) in Priloga IX	
Priglašeni organ	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Nemčija ID. št. 0123	
Certifikati EU	Certifikat sistema vodenja kakovosti EU (MDR) Št.. G10 011858 0065 rev. 04 Skupina pripomočka: T010101 – KIRURŠKE ROKAVICE IZ LATEKSA	
Enotna registrska številka	Proizvajalec: DE-MF-000005861	
Osnovni UDI-DI	40495002109K5	
	Koda	Izraz
EMDN	T01010102	Kirurške rokavice iz lateksa brez pudra
GMDN	47178	Kirurške rokavice iz lateksa Hevea, brez pudra, ne-protimikrobne
UMDNS	11-883	Rokavice, kirurške

Provod

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

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Uredba o osebni varovalni opremi (EU) 2016/425

Kategorija	Kategorija III
Postopek ugotavljanja skladnosti	EU-pregled tipa (modul B), določen v Prilogi V, in skladnost s tipom na podlagi notranje kontrole proizvodnje in nadzorovanih pregledov proizvoda v naključnih časovnih presledkih (modul C2), določen v Prilogi VII, pod nadzorom spodaj navedenega priglašenega organa
Priglašeni organ	SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, D15YN2P. Irska ID št. 2777
Certifikat o EU-pregledu tipa	2777/10572-04/E01-02
Veljavni harmonizirani standardi (v skladu s certifikatom)	
EN ISO 21420:2020	Varovalne rokavice – Splošne zahteve in preskusne metode
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 374-4:2019	Varovalne rokavice za zaščito pred nevarnimi kemikalijami in mikroorganizmi – 4. del: Določanje odpornosti proti razgradnji s kemikalijami
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 421:2010 (razen določbe 4.3)	Varovalne rokavice za zaščito pred ionizirnim sevanjem in radioaktivno kontaminacijo

PAUL HARTMANN AG

ppa.
Martin Walther
Vodja poslovnega divizije
Risk Prevention

po pooblastilu
Christiana Hofmann
Vodja regulativnih zadev (PRRC)
Risk Prevention

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

Veljavno od: 6. 5. 2025
Veljavno do: 22. 5. 2028

GLN 404 9500 00000 0
Vorstand/Management Board: Britta Fünfstück
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Seznam izdelkov, ki spadajo pod ustrezno številko skupine izdelkov:

REF	Ime – opis
942510	Peha-underglove latex, velikost 5,5, 50 parov Kirurške rokavice brez pudra, izdelane iz naravnega kavčukovega lateksa
942511	Peha-underglove latex, velikost 6, 50 parov Kirurške rokavice brez pudra, izdelane iz naravnega kavčukovega lateksa
942512	Peha-underglove latex, velikost 6,5, 50 parov Kirurške rokavice brez pudra, izdelane iz naravnega kavčukovega lateksa
942513	Peha-underglove latex, velikost 7, 50 parov Kirurške rokavice brez pudra, izdelane iz naravnega kavčukovega lateksa
942514	Peha-underglove latex, velikost 7,5, 50 parov Kirurške rokavice brez pudra, izdelane iz naravnega kavčukovega lateksa
942515	Peha-underglove latex, velikost 8, 50 parov Kirurške rokavice brez pudra, izdelane iz naravnega kavčukovega lateksa
942516	Peha-underglove latex, velikost 8,5, 50 parov Kirurške rokavice brez pudra, izdelane iz naravnega kavčukovega lateksa
942517	Peha-underglove latex, velikost 9, 50 parov Kirurške rokavice brez pudra, izdelane iz naravnega kavčukovega lateksa

Prevod

GLN 404 9500 00000 0
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EU Declaration of Conformity

Heidenheim, 2025-05-06

Product Group Number	2109
Manufacturer	PAUL HARTMANN AG Paul-Hartmann-Str. 12 89522 Heidenheim GERMANY

We herewith declare under our sole responsibility that the product listed above, first placed on the market by PAUL HARTMANN AG, satisfies the applicable provisions of the following listed legislations. The conformity assessment procedures have been performed and the Technical Documentation is kept available.

Applied legislative acts

Medical Device Regulation (EU) 2017/745

High Level Intended Purpose	Single-use, non-active, non-implantable devices for wound and skin care	
Classification	Risk Class	Rule
	Class IIa	Rule 7 | main paragraph
Conformity Assessment Procedure	Article 52 (6) and Annex IX	
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany ID-No. 0123	
EU Certificates	EU Quality Management System Certificate (MDR) No. G10 011858 0065 Rev. 04 Device Group: T010101 - LATEX SURGICAL GLOVES	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495002109K5	
	Code	Term
EMDN	T01010102	Non-powdered latex surgical gloves
GMDN	47178	Hevea-latex surgical glove, non-powdered, non-antimicrobial
UMDNS	11-883	Gloves, Surgical

GLN 404 9500 00000 0
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Personal Protective Equipment Regulation (EU) 2016/425

Category	Category III
Conformity Assessment Procedure	EU type-examination (module B) set out in Annex V, and conformity to type based on internal production control plus supervised product checks at random intervals (module C2) set out in Annex VII under surveillance of the notified body below
Notified Body	SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, D15YN2P. Ireland ID-No. 2777
EU Type-Examination Certificate	2777/10572-04/E01-02
Applicable Harmonised Standards (acc. to Certificate)	
EN ISO 21420:2020	Protective gloves - General requirements and test methods
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 374-4:2019	Protective gloves against dangerous chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals
EN ISO 374-5:2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for microorganisms risks
EN 421:2010 (excluding clause 4.3)	Protective gloves against ionizing radiation and radioactive contamination

PAUL HARTMANN AG
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Martin Walther
Head of Business Division
Risk Prevention

i.V.

Christiana Hofmann
Head of Regulatory Affairs, PRRC
Risk Prevention

Valid from: 2025-05-06
Valid until: 2028-05-22

GLN 404 9500 00000 0
Vorstand/Management Board: Britta Fünfstück (Vorsitzende des Vorstands/CEO), François Georgelin, Stefan Grote, Oliver Neubrand
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List of products falling under the respective Product Group Number:

REF	Name - Description
942510	Peha-underglove latex, size 5.5, 50 pairs Powderfree surgical gloves made of natural rubber latex
942511	Peha-underglove latex, size 6, 50 pairs Powderfree surgical gloves made of natural rubber latex
942512	Peha-underglove latex, size 6.5, 50 pairs Powderfree surgical gloves made of natural rubber latex
942513	Peha-underglove latex, size 7, 50 pairs Powderfree surgical gloves made of natural rubber latex
942514	Peha-underglove latex, size 7.5, 50 pairs Powderfree surgical gloves made of natural rubber latex
942515	Peha-underglove latex, size 8, 50 pairs Powderfree surgical gloves made of natural rubber latex
942516	Peha-underglove latex, size 8.5, 50 pairs Powderfree surgical gloves made of natural rubber latex
942517	Peha-underglove latex, size 9, 50 pairs Powderfree surgical gloves made of natural rubber latex

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