PAUL HARTMANN AG
Paul-Hartmann-Strasse 12
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Germany

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www.hartmann.info

HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity

Heidenheim, 27-Aug-2026

Product Group Number	1032
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	General non-active, non-implantable devices used in health care and other non-active, non-implantable devices	
Classification	Risk Class	Rule
	Class I	Rule 5 (1)
Conformity Assessment Procedure	Article 52 (7)	
Notified Body	n.a.	
EU Certificate	n.a.	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001032JL	
	Code	Term
EMDN	T01020204	Nitrile Examination / Treatment Gloves
GMDN	56286	Nitrile examination / treatment glove, non-powdered, non-antimicrobial
UMDNS	11-882	Gloves, Examination / Treatment

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

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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 quality assurance of the production process (Module D) set out in Annex VIII.
Notified Body	SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, D15YN2P. Ireland ID-No. 2777
EU Type-Examination Certificate	2777/27384-02/E00-00
Applicable Harmonised Standards (acc. to Certificate)	
EN ISO 21420:2020+A1:2024	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 (Radioactive contamination only)	Protective gloves against ionizing radiation and radioactive contamination

PAUL HARTMANN AG

i.V.

Thomas Haeni
Vice President R&D, PRRC
Risk Prevention

i.V.

Christiana Hofmann
Head of Regulatory Affairs, PRRC
Risk Prevention

Valid until: 13-Nov-2030

GLN 404 9500 00000 0
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List of products falling under the Product Group Number: **1032**

REF	Name - Description
942070	Peha-soft Nitrile White, size XS, 150 pcs Powderfree disposable examination gloves made of nitrile
942071	Peha-soft Nitrile White, size S, 150 pcs Powderfree disposable examination gloves made of nitrile
942072	Peha-soft Nitrile White, size M, 150 pcs Powderfree disposable examination gloves made of nitrile
942073	Peha-soft Nitrile White, size L, 150 pcs Powderfree disposable examination gloves made of nitrile
942074	Peha-soft Nitrile White, size XL, 150 pcs Powderfree disposable examination gloves made of nitrile
942135	Peha-soft Nitrile White One, size XS, 200 pcs Powderfree disposable examination gloves made of nitrile
942138	Peha-soft Nitrile White One, size S, 200 pcs Powderfree disposable examination gloves made of nitrile
942139	Peha-soft Nitrile White One, size M, 200 pcs Powderfree disposable examination gloves made of nitrile
942140	Peha-soft Nitrile White One, size L, 200 pcs Powderfree disposable examination gloves made of nitrile
942141	Peha-soft Nitrile White One, size XL, 200 pcs Powderfree disposable examination gloves made of nitrile
942142	Peha-soft Nitrile White One, size XS, 200 pcs Powderfree disposable examination gloves made of nitrile
942143	Peha-soft Nitrile White One, size S, 200 pcs Powderfree disposable examination gloves made of nitrile
942144	Peha-soft Nitrile White One, size M, 200 pcs Powderfree disposable examination gloves made of nitrile
942145	Peha-soft Nitrile White One, size L, 200 pcs Powderfree disposable examination gloves made of nitrile
942146	Peha-soft Nitrile White One, size XL, 180 pcs Powderfree disposable examination gloves made of nitrile
942205	Peha-soft Nitrile White, size XS, 200 pcs Powderfree disposable examination gloves made of nitrile
942206	Peha-soft Nitrile White, size S, 200 pcs Powderfree disposable examination gloves made of nitrile
942207	Peha-soft Nitrile White, size M, 200 pcs Powderfree disposable examination gloves made of nitrile
942208	Peha-soft Nitrile White, size L, 200 pcs Powderfree disposable examination gloves made of nitrile

GLN 404 9500 00000 0
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942209	Peha-soft Nitrile White, size XL, 180 pcs Powderfree disposable examination gloves made of nitrile
942216	Peha-soft Nitrile White, size S, 100 pcs Powderfree disposable examination gloves made of nitrile
942217	Peha-soft Nitrile White, size M, 100 pcs Powderfree disposable examination gloves made of nitrile
942218	Peha-soft Nitrile White, size L, 100 pcs Powderfree disposable examination gloves made of nitrile

GLN 404 9500 00000 0
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