



EU Declaration of Conformity

Heidenheim, 25-Sep-2025

Product Group Number	4289
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 Certificates	n.a.	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495004289LG	
	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

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	2777/27224-02/E00-00
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.



Thomas Haeni
Vice President R&D, PRRC
Risk Prevention

Valid from: 25-Sep-2025

Valid until: 10-Sep-2030

List of products falling under the respective Product Group Number 4289:

REF	Name - Description
942016	Peha-soft Nitrile Blue, size S, 100 pcs Powderfree disposable examination gloves made of nitrile
942017	Peha-soft Nitrile Blue, size M, 100 pcs Powderfree disposable examination gloves made of nitrile
942018	Peha-soft Nitrile Blue, size L, 100 pcs Powderfree disposable examination gloves made of nitrile
942019	Peha-soft Nitrile Blue, size XL, 100 pcs Powderfree disposable examination gloves made of nitrile
942036	Peha-soft Nitrile Blue, size XS, 200 pcs Powderfree disposable examination gloves made of nitrile
942037	Peha-soft Nitrile Blue, size S, 200 pcs Powderfree disposable examination gloves made of nitrile
942038	Peha-soft Nitrile Blue, size M, 200 pcs Powderfree disposable examination gloves made of nitrile
942039	Peha-soft Nitrile Blue, size L, 200 pcs Powderfree disposable examination gloves made of nitrile
942040	Peha-soft Nitrile Blue, size XL, 180 pcs Powderfree disposable examination gloves made of nitrile
942041	Peha-soft Nitrile Blue, size XS, 100 pcs Powderfree disposable examination gloves made of nitrile
942060	Peha-soft Nitrile Blue, size XS, 150 pcs Powderfree disposable examination gloves made of nitrile
942061	Peha-soft Nitrile Blue, size S, 150 pcs Powderfree disposable examination gloves made of nitrile
942062	Peha-soft Nitrile Blue, size M, 150 pcs Powderfree disposable examination gloves made of nitrile
942063	Peha-soft Nitrile Blue, size L, 150 pcs Powderfree disposable examination gloves made of nitrile
942064	Peha-soft Nitrile Blue, size XL, 150 pcs Powderfree disposable examination gloves made of nitrile