



## EU Declaration of Conformity

Heidenheim, 2025-06-30

<b>Product Group Number</b>	1032
<b>Manufacturer</b>	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	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

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	2777/11578-03/E02-02
<b>Applicable Harmonised Standards (acc. to Certificate)</b>	
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

ppa.



**Martin Walther**  
Head of Business Division  
Risk Prevention

i.V.



**Christiana Hofmann**  
Head of Regulatory Affairs  
Risk Prevention

Valid until: 2028-09-01

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

List of products falling under the Product Group Number: **1032**

REF	Name - Description
942205	Peha-soft nitrile white, XS, 200 pcs Powder-free disposable examination gloves made of nitrile
942206	Peha-soft nitrile white, S, 200 pcs Powder-free disposable examination gloves made of nitrile
942207	Peha-soft nitrile white, M, 200 pcs Powder-free disposable examination gloves made of nitrile
942208	Peha-soft nitrile white, L, 200 pcs Powder-free disposable examination gloves made of nitrile
942209	Peha-soft nitrile white, XL, 200 pcs Powder-free disposable examination gloves made of nitrile
942216	Peha-soft nitrile white, S, 100 pcs Powder-free disposable examination gloves made of nitrile
942217	Peha-soft nitrile white, M, 100 pcs Powder-free disposable examination gloves made of nitrile
942218	Peha-soft nitrile white, L, 100 pcs Powder-free disposable examination gloves made of nitrile

GLN 404 9500 00000 0

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