

EU Declaration of Conformity

Heidenheim, 2025-06-30

Product Group Number	1945
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	40495001945LA	
	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 for EU type-examination certificate 2777/11513-04/E15-01 - based on internal production control plus supervised product checks at random intervals (Module C2) set out in Annex VII for EU type-examination certificate 2777/13277-04/E01-01
Notified Body	SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, D15YN2P. Ireland ID-No. 2777
EU Type-Examination Certificate	2777/11513-04/E15-01 2777/13277-04/E01-01
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

ppa.



Martin Walther

Head of Business Division
Risk Prevention

i.V.



Christiana Hofmann

Head of Regulatory Affairs
Risk Prevention

Valid until: 2028-08-09

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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List of products falling under the Product Group Number: **1945**

REF	Name - Description
942200	Peha-soft Nitrile Guard, XS Powder-free disposable examination gloves made of nitrile
942201	Peha-soft Nitrile Guard, S Powder-free disposable examination gloves made of nitrile
942202	Peha-soft Nitrile Guard, M Powder-free disposable examination gloves made of nitrile
942203	Peha-soft Nitrile Guard, L Powder-free disposable examination gloves made of nitrile
942204	Peha-soft Nitrile Guard, XL Powder-free disposable examination gloves made of nitrile

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