

## EU Declaration of Conformity

Heidenheim, 2025-06-16

<b>Product Group Number</b>	1946
<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	Single-use, non-active, non-implantable devices for anaesthesia, emergency and intensive care	
Classification	Risk Class	Rule
	Class Is	Rule 5
Conformity Assessment Procedure	Article 52 (7) and Annex XI part A with respect to sterility (a)	
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany ID-No. 0123	
EU Certificates	EU Quality Management System Certificate (MDR) No. G21 011858 0069 Rev. 05 Device Group: T010202 - SYNTHETIC EXAMINATION / TREATMENT GLOVES	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001946LC	
	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 VIII, and conformity to type based on quality assurance of the production process (module D) set out in Annex VIII 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	2777/11513-03/E08-01
Applicable Harmonised Standards (acc. to Certificate)	
EN 420: 2003+A1: 2009	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 374-4:2013	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**  
Senior Vice President  
Risk Prevention

i.V.

**Thomas Haeni**  
Vice President R&D, PRRC  
Risk Prevention

Valid from: 2025-03-13

Valid until: 2025-11-29

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

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](http://www.hartmann.info)



List of products falling under the Product Group Number 1946:

REF	Name - Description
942211	Peha-soft Nitrile sterile, size S Powder-free disposable examination gloves made of nitrile
942212	Peha-soft Nitrile sterile, size M Powder-free disposable examination gloves made of nitrile
942213	Peha-soft Nitrile sterile, size L Powder-free disposable examination gloves made of nitrile

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