



## EU Declaration of Conformity

Heidenheim, 2025-06-30

<b>Product Group Number</b>	1943
<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	Non-active, non-implantable devices for wound and skin care	
Classification	Class I	Rule 5 (1)
Conformity Assessment Procedure	Article 52 (7)	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495001943L6	
	Code	Term
EMDN	T01020201	Vinyl Examination / Treatment Gloves
GMDN	47176	Vinyl examination/treatment glove, non-powdered
UMDNS	11-882	Gloves, Examination/Treatment

PAUL HARTMANN AG

ppa.

**Martin Walther**

Head of Business Division  
Risk Prevention

i.V.

**Christiana Hofmann**

Head of Regulatory Affairs  
Risk Prevention

Valid until: 2030-06-30

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

Phone: +49 (0) 7321 36-0  
Fax: +49 (0) 7321 36-3636  
[www.hartmann.info](http://www.hartmann.info)

P.O. Box 1420  
89504 Heidenheim  
Germany



Helps. Cares. Protects.

List of products falling under the respective Product Group Number: **1943**

REF	Name - Description
942169	Peha-soft Vinyl Powderfree, XS Powder-free examination gloves made of vinyl
942170	Peha-soft Vinyl Powderfree, S Powder-free examination gloves made of vinyl
942171	Peha-soft Vinyl Powderfree, M Powder-free examination gloves made of vinyl
942172	Peha-soft Vinyl Powderfree, L Powder-free examination gloves made of vinyl
942173	Peha-soft Vinyl Powderfree, XL Powder-free examination gloves made of vinyl

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