

## EU Declaration of Conformity

Heidenheim, 2025-11-20

|                             |                                                                          |
|-----------------------------|--------------------------------------------------------------------------|
| <b>Product Group Number</b> | 1946                                                                     |
| <b>Manufacturer</b>         | PAUL HARTMANN AG<br>Paul-Hartmann-Str. 12<br>89522 Heidenheim<br>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                  | 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 Production Quality Assurance Certificate<br>No. G26 011858 0077 Rev. 00<br>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  
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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 |
| 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**

Head of Business Division  
Risk Prevention

Valid from: 2025-11-29

Valid until: 2027-08-24

i.V.



**Christiana Hofmann**

Head of Regulatory Affairs, PRRC  
Risk Prevention

GLN 404 9500 00000 0

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List of products falling under the Product Group Number: 1946

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

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