PAUL HARTMANN AG
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HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity

Heidenheim, 2025-05-06

Product Group Number	2109
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	Single-use, non-active, non-implantable devices for wound and skin care	
Classification	Risk Class	Rule
	Class IIa	Rule 7 | main paragraph
Conformity Assessment Procedure	Article 52 (6) and Annex IX	
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany ID-No. 0123	
EU Certificates	EU Quality Management System Certificate (MDR) No. G10 011858 0065 Rev. 04 Device Group: T010101 - LATEX SURGICAL GLOVES	
Single Registration Number	Manufacturer: DE-MF-000005861	
Basic UDI-DI	40495002109K5	
	Code	Term
EMDN	T01010102	Non-powdered latex surgical gloves
GMDN	47178	Hevea-latex surgical glove, non-powdered, non-antimicrobial
UMDNS	11-883	Gloves, Surgical

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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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 internal production control plus supervised product checks at random intervals (module C2) set out in Annex VII 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	2777/10572-04/E01-02
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, PRRC
Risk Prevention

Valid from: 2025-05-06
Valid until: 2028-05-22

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List of products falling under the respective Product Group Number:

REF	Name - Description
942510	Peha-underglove latex, size 5.5, 50 pairs Powderfree surgical gloves made of natural rubber latex
942511	Peha-underglove latex, size 6, 50 pairs Powderfree surgical gloves made of natural rubber latex
942512	Peha-underglove latex, size 6.5, 50 pairs Powderfree surgical gloves made of natural rubber latex
942513	Peha-underglove latex, size 7, 50 pairs Powderfree surgical gloves made of natural rubber latex
942514	Peha-underglove latex, size 7.5, 50 pairs Powderfree surgical gloves made of natural rubber latex
942515	Peha-underglove latex, size 8, 50 pairs Powderfree surgical gloves made of natural rubber latex
942516	Peha-underglove latex, size 8.5, 50 pairs Powderfree surgical gloves made of natural rubber latex
942517	Peha-underglove latex, size 9, 50 pairs Powderfree surgical gloves made of natural rubber latex

GLN 404 9500 00000 0
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