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HARTMANN
Helps. Cares. Protects.

EU Declaration of Conformity

Heidenheim, 2025-05-06

Product Group Number	2079
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	40495002079KM	
	Code	Term
EMDN	T01010102	Non-powdered latex surgical gloves
GMDN	47178	Hevea-latex surgical glove, non-powdered, non-antimicrobial
UMDNS	11-883	Gloves, Surgical

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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	2777/10573-04/E01-03
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
942690	Peha-profile latex, size 5.5, 50 pairs Powderfree surgical gloves made of natural rubber latex
942691	Peha-profile latex, size 6, 50 pairs Powderfree surgical gloves made of natural rubber latex
942692	Peha-profile latex, size 6.5, 50 pairs Powderfree surgical gloves made of natural rubber latex
942693	Peha-profile latex, size 7, 50 pairs Powderfree surgical gloves made of natural rubber latex
942694	Peha-profile latex, size 7.5, 50 pairs Powderfree surgical gloves made of natural rubber latex
942695	Peha-profile latex, size 8, 50 pairs Powderfree surgical gloves made of natural rubber latex
942696	Peha-profile latex, size 8.5, 50 pairs Powderfree surgical gloves made of natural rubber latex
942697	Peha-profile latex, size 9, 50 pairs Powderfree surgical gloves made of natural rubber latex

TERANG NUSA
TOP QUALITY, TOP EFFICIENCY

TERANG NUSA (MALAYSIA) SDN. BHD.
GOOD HEALTH, SAFETY FIRST & BE HONEST

Company No.
199101013885 (224197-U)
SST ID: D10-1808-22000001

A member of Top Glove Group: The World's Largest Manufacturer of Gloves

FACTORY 36 : 2, Jalan 8, Pengkalan Chepa 2 Industrial Zone, 16100 Kota Bharu, Kelantan D.N., Malaysia.

+609 774 7171 +609 771 3565/3072 +6012 2896 270 sales@topglove.com.my www.topglove.com

EU DECLARATION OF CONFORMITY

Name of Device: Sterile Latex Surgical Powder Free Gloves

Manufacturing Site
Terang Nusa (Malaysia) Sdn. Bhd.
2, Jalan 8, Pengkalan Chepa 2 Industrial Zone,
16100 Kota Bharu, Kelantan D.N., Malaysia

MDR 2017/745

Single Registration Number	: MY-MF-000023462 (Manufacturing Site SRN)
European Authorized Representative	: Ulma International GmbH Pfaffenweg 35, 89231 Neu-Ulm, Germany.
Single Registration Number	: DE-AR-000010015 (EAR SRN)
Classification Rule	: Rule 7, Class IIa
Conformity Assessment Procedure	: Annex IX (Chapter I)
EC Certificate(s) number	: G10 061155 0020 Rev. 00
EC Certificate(s) valid until	: 26-08-2029
Notified Body	: TÜV SÜD Product Service GmbH, Ridlerstraβe 65, 80339, Munich, Germany.
CE Marking	: CE 0123
Applicable Standards	: Attachment I

Intended use: Sterile Latex Surgical Powder Free Gloves intended to be worn by operating room personnel to prevent the transmission of infections or cross contamination between patient and user.

PPER 2016/425

Device Reference Code	: TNMSA202
Classification	: Category III
Conformity Assessment Procedure	: Annex V (Module B) and Annex VII (Module C2)
EU Type Examination Certificate Number	: 2777/10573-04/E00-00
EU Type Examination Notified Body	: SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P, Ireland.
CE Marking	:CE 2777

Intended Use: Sterile Latex Surgical Powder Free Gloves used as a biological barrier to protect the user's hands against contamination. The gloves are designed to come into contact with the patient and prevent cross-contamination between patient and user.

Conclusion:

We Terang Nusa (Malaysia) Sdn Bhd herewith declare with our own responsibility that above mentioned product with CE mark;

I. Meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is also supported by the Quality Management System approval to ISO 13485 issued by TÜV SÜD Product Service GmbH. All supporting documentation is retained at the premises of the manufacturer.

IIa. Meet to the EU Type Examination and conformity with the provisions of the new PPE Regulations (EU) 2016/425 Category III, Annex V (Module B) and, where such is the case, with the national standard transposing harmonized standard no. EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018 (EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019), EN ISO 374-5:2016, EN ISO 374-5:2016 and EN 421:2010 (excluding clause 4.3).

IIb. The product is subject to the procedures set out in Annex VII (Module C2) of the new PPE Regulations (EU) 2016/425 under the supervision of the notified body SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P, Ireland.

DoC Validity Date : 27th March 2025 – 26th March 2027

Name: Pn Noor Akilah Saidin
Designation: General Manager, RA
Date: 27/3/2025

ATTACHMENT I: LIST OF APPLICABLE STANDARDS AND REFERENCE FOR MDR 2017/745

No	Standard	Descriptions	Date Published
1	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	March 2016
2	EN 455-1:2020+A2:2024	Medical gloves for single use. Part 1: Requirement and testing for freedom from holes.	September 2024
3	EN 455-2:2024	Medical gloves for single use. Part 2: Requirement and testing for physical properties.	May 2024
4	EN 455-3:2023	Medical gloves for single use. Part 3: Requirement and testing for biological evaluation	December 2023
5	EN 455-4:2009	Medical gloves for single use - Part 4: Requirements and testing for shelf life determination	October 2009
6	EN ISO14971:2019/A11:2021	Medical device - Application of risk management to medical devices.	December 2021
7	ISO 2859-1:2011	Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	June 2011
8	EN ISO 11737-1:2018/ A1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)	June 2021
9	EN ISO 11737-2:2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)	May 2020
10	EN ISO 11137-1:2015/ A2:2019	Sterilization of health care products – Requirements for validation and routine control–Radiation sterilization	November 2019
11	EN ISO 11137-2:2015	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)	June 2015
12	EN ISO 10993-1:2020	Biological evaluation for medical device – Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018)	December 2020
13	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-	June 2009

No	Standard	Descriptions	Date Published
		5:2009)	
14	EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)	August 2013
15	EN ISO 10993-11:2018	Biological evaluation of medical devices. Test for systemic toxicity (ISO 10993-11:2017)	May 2018
16	EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)	June 2021
17	EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)	March 2021
18	EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)	January 2020
19	EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)	January 2020
20	EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)	September 2021
21	EN 62366-1/A1:2020	Medical Devices – Part 1: Application of usability engineering to medical devices	August 2020
22	EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021)	May 2021
23	ISO/TR 20416:2020	Medical devices — Post-market surveillance for manufacturers	July 2020
24	ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems	April 2016
25	MDR 2017/745 (Annex VIII)	Classification rules	April 2017
26	MDR 2017/745 (Annex I)	Technical Documentation	April 2017
27	MDR 2017/745 (Annex XIV: Part A)	Clinical Evaluation	April 2017
28	MEDDEV 2.7/1	2.7/1 Clinical Evaluation	Revision 4, June 2016
30	MEDDEV 2.12/1	2.12/1 Medical Device Vigilance System	Revision 8, January 2013

No	Standard	Descriptions	Date Published
31	MDR 2017/745 (Chapter VII: Section 2: Article 87-92)	Vigilance	April 2017
32	MDR 2017/745 (Annex XIV: Part B)	Post Market Clinical Follow-up Studies	April 2017
33	MEDDEV 2.12/2	2.12/2 Post Market Clinical Follow-up Studies	Revision 2, January 2012
34	MDR 2017/745 (Chapter VII: Section 1: Article 83-86) Annex III	Post Marketing Surveillance (PMS)	April 2017