Hartalega

Innovation & Quality

EU DECLARATION OF CONFORMITY

Manufacturer	:	Hartalega NGC Sdn. Bhd.
Manufacturer's Address	:	No.1, Persiaran Tanjung, Kawasan Perindustrian Tanjung, 43900 Sepang, Selangor Darul Ehsan, Malaysia.
EU Representative	:	MDSS GmbH Schiffgraben 41, 30175 Hannover, Germany.
Product Description (EU MDR)	:	Nitrile Powder Free Examination Gloves
Device Classification (EU MDR)	:	Class I, according to Annex VIII of Regulation (EU) 2017/745
Rule(s)	:	1 and 5
Conformity Assessment Procedure	:	Annex II and Annex III
Basic UDI-DI	:	955100777HNGCTFMD005AQ8
Authorized Representative SRN	:	DE-AR-000005430
Manufacturer SRN	:	MY-MF-000010459
Product Description (EU PPER)	:	Nitrile Powder Free Examination Gloves (≥ 2.2 mil) Available in standard minimum 240mm length or a longer cuff variant of 280mm
Device Classification (EU PPER)	:	Category III (Type B)
EU Type-Examination Certificate Number (EU PPER)	:	2777/11578-04/E00-00
Intended Purpose	:	Nitrile Powder Free Examination Gloves are intended to be used to contribute to prevent cross contaminations in the framework of medical examinations and diagnostic/ therapeutic procedures conducted under non-sterile conditions. and Nitrile Powder Free Examination Gloves is intended to protect users from substances and mixtures which are hazardous to health and harmful biological agents that may cause very serious consequences or irreversible damage to health.
Standard Reference	:	Attachment I
Reference to Trade Name	:	Attachment II

Heruntergeladen von Gast (IP 216.73.217.12) am 08.11.2026 um 23:51 Uhr · sana.swiss

We, Hartalega NGC Sdn. Bhd. herewith declared that above mentioned device:

- is in conformity with the Regulation (EU) 2017/745 of The European Parliament and of The Council of medical devices.
- is in conformity with the provisions of Regulation (EU) 2016/425 on personal protective equipment.
- is subject to the conformity assessment procedure Module D set out in Annex VIII of Regulation (EU) 2016/425, under the surveillance of the notified body SATRA Technology Europe Limited, Bracetown Business Park, Clonee D15YN2P, Republic of Ireland (Notified Body number 2777).

This EU declaration of conformity is issued under the sole responsibility of the manufacturer, Hartalega NGC Sdn. Bhd.

Place and Date of Issue : Hartalega NGC Sdn. Bhd./ 13th August 2026

Signed on Behalf of Hartalega NGC Sdn. Bhd. :

Name : NURUL AISYAH KONG
Position : GENERAL MANAGER - QUALITY ASSURANCE

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ATTACHMENT I

STANDARD REFERENCE (MDR)

Standard	Title
ISO 9001:2015/Amd 1:2024	Quality Management Systems – Requirements Amendment 1: Climate action changes
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN 455-1:2020+A2:2024	Medical Gloves for Single Use Part 1: Requirements and Testing for Freedom from Holes
BS EN 455-1:2020+A2:2024	Medical Gloves for Single Use Part 1: Requirements and Testing for Freedom from Holes
EN 455-2:2024	Medical Gloves for Single Use Part 2: Requirements and Testing for Physical Properties
BS EN 455-2:2024	Medical Gloves for Single Use Part 2: Requirements and Testing for Physical Properties
EN 455-3:2023	Medical Gloves for Single Use Part 3: Requirements and Testing for Biological Evaluation
BS EN 455-3:2023	Medical Gloves for Single Use Part 3: Requirements and Testing for Biological Evaluation
EN 455-4:2009	Medical Gloves for Single Use Part 4: Requirements and Testing for Shelf-Life Determination
BS EN 455-4:2009	Medical Gloves for Single Use Part 4: Requirements and Testing for Shelf-Life Determination
EN 455-5:2025	Medical gloves for single use Part 5: Extractable chemical residues
BS EN 455-5:2025	Medical gloves for single use Part 5: Extractable chemical residues
BS EN ISO 20417:2021	Medical devices – Information to be Supplied by the Manufacturer
BS EN ISO 14971:2019+A11:2021	Medical Devices – Application of Risk Management to Medical Devices
IEC 62366-1: 2015/Amd 1:2020	Medical devices — Part 1: Application of usability engineering to medical devices
EN 62366 – 1: 2015+A1:2020	Medical devices — Part 1: Application of usability engineering to medical devices
IEC/TR 62366 – 2:2016	Medical devices — Part 2: Guidance on the application of usability engineering to medical devices
ISO 15223-1:2021/Amd1:2025	Medical Devices –Symbol to be Used with Information to be Supplied by the Manufacturer

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Standard	Title
	Part 1: General Requirements Amendment 1: Addition of defined term for authorized representative and modified EC REP symbol to not be country or region specific
BS EN ISO 15223-1:2021+A1:2025	Medical devices – Symbols to be used with information to be supplied by the manufacturer Part 1: General Requirements
ISO 10993-1:2025	Biological Evaluation of Medical Devices Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process
BS EN ISO 10993 – 1: 2025	Biological Evaluation of Medical Devices Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process
ISO 10993-5:2009	Biological Evaluation of Medical Devices Part 5: Tests for In Vitro Cytotoxicity
BS EN ISO 10993 – 5:2009+A11:2025	Biological Evaluation of Medical Devices Part 5: Tests for In Vitro Cytotoxicity
ISO 10993-10:2021	Biological Evaluation of Medical Devices Part 10: Tests for Skin Sensitization
BS EN ISO 10993 – 10:2023	Biological Evaluation of Medical Devices Part 10: Tests for Skin Sensitization
ISO 10993-11:2017	Biological Evaluation of Medical Devices Part 11: Tests for Systemic Toxicity
BS EN ISO 10993 – 11:2018	Biological Evaluation of Medical Devices Part 11: Tests for Systemic Toxicity
ISO 10993-18:2020/ Amd 1:2022	Biological Evaluation of Medical Devices Part 18: Chemical Characterization of Medical Device Materials Within A Risk Management Process Amendment 1: Determination of the uncertainty factor
BS EN ISO 10993 – 18:2020+A1:2023	Biological Evaluation of Medical Devices Part 18: Chemical Characterization of Medical Device Materials Within A Risk Management Process
ISO 10993-23:2021/ Amd1: 2025	Biological Evaluation of Medical Devices Part 23: Tests for Irritation Amendment 1: Additional in vitro reconstructed human epidermis model
BS EN ISO 10993 – 23:2021+A1: 2025	Biological Evaluation of Medical Devices Part 23: Tests for Irritation
ISO 2859-1:2026	Sampling Procedures for Inspection by Attributes Part 1: Sampling Schemes Indexed by Acceptance Quality Limit (AQL) for Lot-By-Lot Inspection

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Standard	Title
ASTM D4169-23e1	Standard Practice for Performance Testing of Shipping Containers and Systems

STANDARD REFERENCE (PPER)

Standard	Title
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 374-5:2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks
EN 421:2010	Protective gloves against ionizing radiation and radioactive contamination

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ATTACHMENT II

Product or Trade Name	Reference Number
SANA SWISS BLUE NITRILE PF EXAM GLOVE	XS: 470099-1N S: 470100-1N M: 470101-1N L: 470102-1N XL: 470103-1N
SANA SWISS BLACK NITRILE PF EXAM GLOVES	XS: 470007-1N S: 470008-1N M: 470009-1N L: 470010-1N XL: 470011-1N
SANA SWISS WHITE NITRILE PF EXAM GLOVES	XS: 470104-1N S: 470104-2N M: 470105-1N L: 470106-1N XL: 470107-1N

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