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 (MDR)	:	Nitrile Powder Free Examination Glove
Device Classification (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
Authorised Representative SRN	:	DE-AR-000005430
Manufacturer SRN	:	MY-MF-000010459
Product Description (PPER)	:	≥3.5 mil Powder Free Nitrile disposable five fingered glove Available in a longer cuff variant Available in Non-Sterile
Device Classification (PPER)	:	Category III (Type B)
EU Type-Examination Certificate Number (PPER)	:	2777/11513-04/E00-00
Intended Purpose	:	Nitrile Powder Free Examination Glove 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 Glove 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

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./ 09th February 2024

Signed on Behalf of Hartalega NGC Sdn. Bhd. :

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

ATTACHMENT I

STANDARD REFERENCE (MDR)

Standard	Title
ISO 9001:2015	Quality Management Systems – Requirements
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN 455-1:2020+A1:2022	Medical Gloves for Single Use Part 1: Requirements and Testing for Freedom from Holes
EN 455-2:2015	Medical Gloves for Single Use Part 2: Requirements and Testing for Physical Properties
EN 455-3:2015	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 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
ISO 15223-1:2021	Medical Devices – Symbol to be Used with Information to be Supplied by the Manufacturer Part 1: General Requirements
ISO 10993-1:2018	Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process
BS EN ISO 10993 – 1: 2020	Biological Evaluation of Medical Devices Part 1: Evaluation and Testing 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	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

Standard	Title
	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	Biological Evaluation of Medical Devices Part 18: Chemical Characterization of Medical Device Materials Within A Risk Management Process
ISO 10993-23:2021	Biological Evaluation of Medical Devices Part 23: Tests for Irritation
BS EN ISO 10993 – 23:2021	Biological Evaluation of Medical Devices Part 23: Tests for Irritation
ISO 2859-1:1999/Amd1:2011	Sampling Procedures for Inspection by Attributes Part 1: Sampling Schemes Indexed by Acceptance Quality Limit (AQL) for Lot-By-Lot Inspection
ASTM D4169-22	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

ATTACHMENT II

Product or Trade Name	Reference Number
PEPPLER NITRIL COMFORT PREMIUM (BLAU) 228	XS: 228XS S: 228S M: 228M L: 228L XL: 228XL
PEPPLER NITRIL COMFORT PREMIUM (WEISS) 227	XS: 227XS S: 227S M: 227M L: 227L XL: 227XL