Hartalega

Innovation & Quality

EU Declaration of Conformity

Manufacturer	:	Hartalega Sdn. Bhd.
Manufacturer's Address	:	C-G-9, Jalan Dataran SD1, Dataran SD PJU9, Bandar Sri Damansara, 52200 Kuala Lumpur, Malaysia.
EU Representative	:	Medical Device Safety Service (MDSS) 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	:	955524480HSBTFMD002A5A
Authorised Representative SRN	:	DE-AR-000005430
Manufacturer SRN	:	MY-MF-000010461
Product Description (PPER)	:	≥2.0mil Powder Free Nitrile disposable five fingered glove Available in a longer cuff variant
Device Classification (PPER)	:	Category III (Type C)
EU Type-Examination Certificate Number (PPER)	:	2777/13926-04/E00-00
Intended Purpose	:	Nitrile Powder Free Examination Glove is 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 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 C2 set out in Annex VII 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 Sdn. Bhd.

Place and Date of Issue : Hartalega Sdn. Bhd./ 03rd January 2023

Signed for and on Behalf of Hartalega 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	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 1041:2008+A1:2013	Information Supplied by the Manufacturer of Medical Devices
BS EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
ISO 15223-1:2016	Medical Devices – Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied Part 1: General Requirements
ISO 10993-1:2018	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
ISO 10993-10:2021	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
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
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 D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems

STANDARD REFERENCE (PPER)

Standard	Title
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 374-5:2016	Protective gloves against dangerous chemicals and micro-organisms — Part 5: Terminology and performance requirements for micro-organisms risks

For Reference Only

ATTACHMENT II

Product or Trade Name	Reference Number
PEPPLER NITRIL ROSE 441	XS: 441XS S: 441S M: 441M L: 441L

For Reference Only