Hartalega

Innovation & Quality

CH DECLARATION OF CONFORMITY

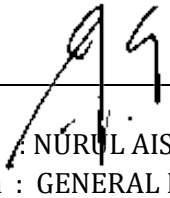
Manufacturer	:	Hartalega Sdn. Bhd. C-G-9, Jalan Dataran SD1, Dataran SD PJU9, Bandar Sri Damansara, 52200 Kuala Lumpur, Malaysia
Facility	:	Hartalega Sdn. Bhd. No. 7, Kawasan Perusahaan Suria, Bestari Jaya, 45600 Selangor Darul Ehsan, Malaysia
CH Authorized Representative	:	MDSS CH GmbH Laurenzenvorstadt 615000 Aarau Switzerland
Device Name	:	Nitrile Powder Free Examination Glove Refer to attachment I for Trade Name
Intended Use	:	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.
Rule (s)	:	1 and 5
Device Classification	:	Class I, according to Annex VIII of Medical Devices Ordinance (MedDO)
Conformity Assessment Procedure	:	Annex II and Annex III
Standard Reference	:	Refer to attachment II

WE, HARTALEGA SDN. BHD. HEREWITH DECLARE THAT THE ABOVE MENTIONED DEVICE IS IN CONFORMITY WITH MEDICAL DEVICES ORDINANCE (MedDO) AND OTHER RELEVANT UNION LEGISLATION THAT PROVIDES FOR THE ISSUANCE OF THIS DECLARATION OF CONFORMITY. THIS DECLARATION IS ISSUED UNDER THE SOLE RESPONSIBILITIES OF THE MANUFACTURER.

Start of CH Marking : November 15, 2021

Place and Date of Issue : Hartalega Sdn. Bhd./ 01st October 2022

Signed on Behalf of Hartalega Sdn. Bhd. :



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

ATTACHMENT I

Product or Trade Name	Reference Number
MEDBRUN NITRILE EXPERT LONG	S: 17199 M: 17200 L: 17201 XL: 17202

ATTACHMENT II

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
ISO 11193-1:2020	Single-Use Medical Examination Gloves Part 1: Specification for Gloves Made from Rubber Latex or Rubber Solution
ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems