CH DECLARATION OF CONFORMITY

Manufacturer	:	Hartalega NGC Sdn. Bhd. No. 1, Persiaran Tanjung Kawasan Perindustrian Tanjung 43900 Sepang, Selangor Darul Ehsan Malaysia
Facility	:	Hartalega NGC Sdn. Bhd. No. 1, Persiaran Tanjung Kawasan Perindustrian Tanjung 43900 Sepang, Selangor Darul Ehsan Malaysia
CH Authorized Representative	:	MDSS CH GmbH Laurenzenvorstadt 61 5000 Aarau Switzerland
Device Name	:	Biodegradable Nitrile Powder Free Examination Gloves Refer to Attachment I for Trade Name
Intended Use	:	Biodegradable Powder Free Nitrile Examination Gloves are intended to be used to contribute to prevent cross contaminations between healthcare personnel and the patient in the framework of medical examinations and diagnostic / therapeutic procedures conducted under non-sterile conditions
Rule	:	1 and 5
Device Classification	:	Class I, according to Article 15 of Medical Devices Ordinance (MedDO)
Conformity Assessment Procedure	:	Annex II and III
Designated Standard	:	Refer to attachment II

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

Start of CH Marking	:	November 15, 2021
Place and Date of Issue	:	Hartalega NGC Sdn. Bhd./ 3rd March 2023
Signed on Behalf of Hartalega NGC Sdn. Bhd.	:	

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

ATTACHMENT I

Product or Trade Name	Reference Number
MEDBRUN NITRILE EXPERT BIO VIOLET BLUE	XS: 28702 S: 28631 M: 28632 L: 28633 XL: 28634

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+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	Information Supplied by the Manufacturers of Medical Devices
ISO 15223 – 1:2021	Medical devices – Symbols to Be Used with Medical Device Labels, Labeling and Information to be Supplied Part 1: General Requirement
BS EN ISO 14971:2019+A11:2021	Medical Devices — Application of Risk Management to Medical Devices
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/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
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