DECLARATION OF CONFORMITY

MANUFACTURER:	Hartalega NGC Sdn. Bhd. No. 1, Persiaran Tanjung Kawasan Perindustrian Tanjung 43900 Sepang, Selangor, Malaysia Tel: (603) 3280 3888 Fax: (603) 3271 0135
EUROPEAN REPRESENTATIVE:	Medical Device Safety Service (MDSS) Schiffgraben 41 30175 Hannover, Germany
PRODUCT:	Nitrile Powder Free Examination Gloves
CLASSIFICATION:	Class I, according to Annex IX of Directive 93/42/EEC
CONFORMITY ASSESSMENT ROUTE:	Annex VII

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES, ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

STANDARDS APPLIED:	Refer to Attachment
START OF CE-MARKING:	November 15, 2014
PLACE, DATE OF ISSUE:	Hartalega NGC Sdn. Bhd., 09th May 2019

SIGNATURE:

NAME: KUAN EU JIN
POSITION: QUALITY MANAGEMENT REPRESENTATIVE

Rev 4

ATTACHMENT 1

Standard	Title
ISO 9001:2015	Quality Management System – Requirement
EN ISO 13485:2016	Medical Device – Quality Management System – Requirement for Regulatory Purpose
EN 455 – 1:2000	Medical Device for Single Use Part 1: Requirement and Testing for Freedom from Holes
EN 455 – 2:2015	Medical Device for Single Use Part 2: Requirement and Testing for Physical Properties
EN 455 – 3:2015	Medical Device for Single Use Part 3: Requirement and Testing for Biological Evaluation
EN 455 – 4:2009	Medical Device for Single Use Part 4: Requirement and Testing for Shelf Life Claim
BS EN 1041:2008 + A1:2013	Information Supplied by the Manufacturers with Medical Devices
ASTM D6319 – 10(2015)	Standard Specification for Nitrile Examination Gloves for Medical Application
BS EN ISO 14971:2012	Risk Management for Medical Devices
ISO 15223 – 1:2016	Medical devices – Symbol to be Used with Medical device Labels, Labeling and Information to be Supplied Part 1: General Requirement
ISO 10993 – 1:2018	Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management System
ISO 10993 – 5:2009	Biological Evaluation of Medical Devices Part 5: Test for In Nitro Cytotoxicity
ISO 10993 – 10:2010	Biological Evaluation of Medical Devices Part 10: Test for Irritation and Delayed – Type Hypersensitivity
ISO 2859 – 1:1999/Amd.1:2011	Sampling Procedures and Tables for Inspection by Attributes