DECLARATION OF CONFORMITY

MANUFACTURER:	Hartalega Sdn. Bhd. C-G-9, Jalan Dataran SD1, Dataran SD PJU9, Bandar Sri Damansara, 52200 Kuala Lumpur, Malaysia Tel: (603) 6277 1733 Fax: (603) 6280 2533
FACILITY:	Hartalega Sdn. Bhd. No. 7, Kawasan Perusahaan Suria, Bestari Jaya, 45600 Selangor Darul Ehsan, Malaysia Tel: (603) 3280 3888 Fax: (603) 3271 0135
EUROPEAN REPRESENTATIVE:	Medical Device Safety Service (MDSS) Schiffgraben 41, D – 30175 Hannover, Germany
PRODUCT:	LAUREL Nitrile Examination Gloves Powder Free
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 OF 14TH JUNE 1993 FOR MEDICAL DEVICES AS AMENDED BY COUNCIL DIRECTIVE 2007/47/EC. ALL SUPPORTING DOCUMENTATIONS IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER

STANDARDS APPLIED:	Refer to Attachment
START OF CE-MARKING:	January 1, 2005
PLACE, DATE OF ISSUE:	Hartalega Sdn. Bhd., 28th May 2014
SIGNATURE:	NAME: KUAN EU JIN POSITION: QUALITY MANAGEMENT REPRESENTATIVE

ATTACHMENT 1

Standard	Title
ISO 9001:2008	Quality Management System – Requirement
EN ISO 13485: 2012+AC:2012	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 – 2:2009+A1:2011	Medical Device for Single Use Part 2: Requirement and Testing for Physical Properties
EN 455 – 3:2006	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	Information Supplied by the Manufacturers with Medical Devices
BS EN ISO 14971:2012	Risk Management for Medical Devices
ISO 15223 – 1:2012	Medical devices – Symbol to be Used with Medical device Labels, Labeling and Information to be Supplied Part 1: General Requirement
ISO 10993 – 1:2009/Cor1:2010	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	Sampling Procedures and Tables for Inspection by Attributes