UK Declaration of Conformity

Manufacturer	:	Hartalega NGC Sdn. Bhd.
Manufacturer's Address	:	No.1, Persiaran Tanjung, Kawasan Perindustrian Tanjung, 43900 Sepang, Selangor Darul Ehsan, Malaysia.
UK Responsible Person	:	MDSS-UK RP Ltd. 6 Wilmslow Road, Rusholme, Manchester M14 5TP, United Kingdom
Product Description (MDR)	:	Biodegradable Nitrile Powder Free Examination Gloves
Intended Purpose (MDR)	:	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.
Device Classification	:	Class I, according to Regulation 7 of The Medical Devices Regulations 2002
Conformity Assessment Procedure	:	Annex II and Annex III of Regulation (EU) 2017/745, Regulation 19C of The Medical Devices Regulations 2002
Reference to Trade Name (MDR)	:	Attachment I
Standard Reference (MDR)	:	Attachment II
Product Description (PPER)	:	Biodegradable Nitrile Powder Free Examination Gloves Five fingered, ambidextrous, powder free, biodegradable, nitrile examination gloves with beaded cuff.
Device Classification (PPER)	:	Category III (Type C)
UKCA Type-Examination Certificate Number (PPER)	:	AB0321/16748-01/E00-00
Reference to Trade Name (PPER)	:	Attachment III
Standard Reference (PPER)	:	EN 420:2003+A1:2009 EN ISO 374-1:2016+A1:2018 EN ISO 374-5:2016 EN 421:2010 (excluding clause 4.3)

We, Hartalega NGC Sdn. Bhd. herewith declared that above mentioned device:

- is in conformity with The Medical Devices Regulations 2002
- is in conformity with the provisions of Regulation (EU) 2016/425 (as brought into UK law and amended) on personal protective equipment.
- is subject to the conformity assessment procedure Module C2 set out in Annex VII of Regulation (EU) 2016/425 (as brought into UK law and amended), under the surveillance of the approved body SATRA Technology Centre Limited, Wyndham Way, Telford Way, Kettering, Northamptonshire, NN16 8SD, United Kingdom (Approved Body number 0321).

This UK declaration of conformity is issued under the sole responsibility of the manufacturer, Hartalega NGC Sdn. Bhd.

Place and Date of Issue : Hartalega NGC Sdn. Bhd./ 24th June 2022

Signed for and on Behalf of Hartalega NGC Sdn. Bhd. :

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

ATTACHMENT I

Product or Trade Name	Reference Number

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
ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems

ATTACHMENT III

Product or Trade Name	Reference Number