Longcane industries

EU Declaration of Conformity
According to the Medical Device Regulation (EU) 2017/745
Personal Protective Equipment Regulation (EU) 2016/425

We, Longcane Industries Sdn Bhd declare under our sole responsibility that the medical device stated below meets all the provisions of the Medical Device Regulation (EU) 2017/745 and Personal Protective Equipment Regulation (EU) 2016/425.

Manufacturer	: LONGCANE INDUSTRIES SDN BHD
Address	: LOT 5783, JALAN SELADANG, ALMA 14000 BUKIT MERTAJAM, PENANG, MALAYSIA.
EC Representative	: OBELIS S.A. BD GENERAL WAHIS, 53 B-1030 BRUSSELS, BELGIUM.
Product(s)	: 1. Nitrile Examination Glove, Powder-free, Non-sterile
Device Classification (As per MDR 2017/745)	: Class I under Rule 1 according to Annex VIII
CE Marking applied date	: August 2020
GMN(UDI-DI BASIC)	: 955548260800LG
UMDNS Code	: 11882 (Gloves, Examination/Treatment)
GMDN Code	: 56286 (Powder Free Nitrile Examination Gloves)
Brand	: First Touch, Procare
Product Code	: NBR-001
Conformity Assessment	: Annexes II and III as per MDR 2017/745

This Declaration of Conformity is also issued on the basis of fulfilment the requirements of the Personal Protective Equipment Regulation (EU) 2016/425 for Category III (Module B):

- Certificate number: 2777/14945-02/E00-00 (Nitrile Examination Glove)
- Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Notified Body : SATRA Technology Europe Limited (2777)
Bracetown Business Park. Clonee. D15YN2P Republic of Ireland.

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List of Applicable Regulations and Standards

No.	Regulation/ Standard Number	Regulation/ Standard Name
1	MDR (EU) 2017/745	Medical Device Regulation
2	PPE (EU) 2016/425	Personal Protective Equipment Regulation
3	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
4	ISO 9001: 2015	Quality management systems – requirements
5	ISO 14971: 2019	Medical devices - application of risk management to medical devices
6	EN 455-1: 2000	Requirements and testing for freedom from holes
7	EN 455-2: 2015	Requirements and testing for physical properties
8	EN 455-3: 2015	Requirements and testing for biological evaluation
9	EN 455-4 : 2009	Requirements and testing for shelf life determination
10	EN 1041: 2008+A1: 2013	Information supplied by the manufacturer of medical devices
11	EN ISO 15223-1: 2016	EN ISO 15223-1 Symbols to be used with medical device labels, labelling and information to be supplied
12	EN 420: 2003+A1: 2009	Protective gloves - General requirements and test methods
13	PAHs	Polycyclic Aromatic Hydrocarbons Testing (PAH)
14	EN 374-2: 2014	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
15	EN ISO 374-4: 2013	Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals
16	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks
17	EN 16523-1: 2015+A1: 2018	Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact
18	ISO 16604:2004	Resistance to penetration by blood-borne pathogens

Verified and checked by,

LONGCANE INDUSTRIES S/B

Person : Mr Hozen Lim Z.M. (General Manager)
Date : 07 September 2021
Place of issued: LONGCANE INDUSTRIES SDN BHD, PENANG, MALAYSIA.
DoC validity : 5 years from the date of issued