EU Declaration of Conformity

Manufacturer's Name	: QUBE MEDICAL PRODUCTS SDN. BHD.
Manufacturer's Address	: No. 9, Jalan KPK 1/3, Kawasan Perindustrian Kundang, 48020, Kundang Jaya, Selangor Darul Ehsan, Malaysia
European Authorized Representative	: Grixx B.V. Curieweg 15 2408 BZ Alphen aan den Rijn The Netherlands Tel.: +31 (0)172 63 66 66
Product Description	: Qube Nitrile Disposable Examination Gloves
Device Classification (MDR)	: Class I, according to Annex VIII of EU Regulation 2017/745
Device Classification (PPER)	: Category III (Type C)
EU Type-Examination Certificate Number (PPER)	: 2777/15373-01/E00-00
EU Type Conformity PPE Module D	: 2797
Product Part Numbers Conformity Overview	: Attachment A : Attachment B

The manufacturer declares under full responsibility that the products listed in Attachment A are:

- In conformity with the Medical Device Regulation (EU) 2017/745
- In conformity with the provisions of the Regulation (EU) 2016/425 on personal protective equipment
- In conformity with the Regulation (EC) 1935/2004 and (EU) 10/2011 on materials and articles intended to come into contact with food, (EC) 2023/2006 on good manufacturing practices for materials and articles intended to come into contact with food
- Subject to the conformity assessment Module B set out in Annex II of Regulation (EU) 2016/425, under approval of the notified body SATRA Technology Europe Limited (Notified Body number 2777).
- Subject to the conformity assessment procedure Module D set out in Annex VIII of Regulation (EU) 2016/425, under the surveillance of the notified body BSI Group The Netherlands B.V (Notified Body number 2797).

and are in compliance with EN/ISO norms as listed in Attachment B.

Place and date of issue : 3rd of August, 2021 at Selangor, Malaysia.

Signed : Qube Medical Products Sdn Bhd

Name : NURFITRIYAH ABDUL KADIR

Position : QA/QC SENIOR EXECUTIVE

Qube Medical Products Sdn Bhd
(827379-P)
No. 9, Jalan KPK 1/3
Kawasan Perindustrian Kundang
48020 Kundang, Selangor.
Tel: 03-60345857 Fax: 03-60345859

Attachment A

Overview of Product References

Trade name	MPN	Size	REF	Pcs/ box
Nitrile Examination Gloves Long Cuff	-	XS	NBR12PFFTSC1	100
	-	S	NBR12PFFTSC2	100
	-	M	NBR12PFFTSC3	100
	-	L	NBR12PFFTSC4	100
	-	XL	NBR12PFFTSC5	100
Nitrile Examination Gloves	QUBE-NPF-XS-TP(HK)	XS	NBR9PFFTBSC1	100
	QUBE-NPF-S-TP(HK)	S	NBR9PFFTBSC2	100
	QUBE-NPF-M-TP(HK)	M	NBR9PFFTBSC3	100
	QUBE-NPF-L-TP(HK)	L	NBR9PFFTBSC4	100
	QUBE-NPF-XL-TP(HK)	XL	NBR9PFFTBSC5	100
	QUBE-NPF-XS-DQ(HK)	XS	NBR9PFFTBSC1	200
	QUBE-NPF-S-DQ(HK)	S	NBR9PFFTBSC2	200
	QUBE-NPF-M-DQ(HK)	M	NBR9PFFTBSC3	200
	QUBE-NPF-L-DQ(HK)	L	NBR9PFFTBSC4	200
	QUBE-NPF- XL-DQ(HK)	XL	NBR9PFFTBSC5	200

Attachment B

Conformity Overview

Standard	Scope
EN 455-1:2000	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.
EN ISO 374-1:2016+A1:2018	Protective gloves against dangerous chemicals and micro-organisms. Part 1: Terminology and performance requirements for chemical risks.
EN ISO 374-2:2019	Protective gloves against dangerous chemicals and micro-organisms. Part 2: Determination of resistance to penetration.
EN ISO 374-4:2019	Protective gloves against dangerous chemicals and micro-organisms. Part 4: Determination of resistance to degradation by chemicals.
EN ISO 374-5:2016	Protective gloves against dangerous chemicals and micro-organisms. Part 5: Terminology and performance requirements for micro-organisms risks.
EN 16523-1:2015+A1:2018	Determination of material resistance to permeation by chemicals. Part 1: Permeation by potentially hazardous liquid chemicals under conditions of continuous contact.
EN ISO 21420:2020	Protective gloves - General requirements and test methods.
EN 1186-1:2002	Materials and articles in contact with foodstuffs. Plastics. Part 1: Guide to the selection of conditions and test methods for overall migration.
EN 1186-9:2002	Materials and articles in contact with foodstuffs. Plastics. Part 9: Test methods for overall migration into aqueous simulants by article filling.
EN 13130-1:2004	Materials and articles in contact with foodstuffs. Plastics substances subject to limitation. Part 1: Guide to test methods for the specific migration of substances from plastics to foods and food simulants and the determination of substances in plastics and the selection of conditions of exposure to food simulants.
ASTM F1671	Resistance of materials to penetration by blood-borne pathogens.
ASTM D6978	Resistance to permeation by chemotherapy drugs.
ISO 9001:2015	Quality management systems. Requirements.
ISO 13485:2016	Medical devices. Quality management systems. Requirements for regulatory purposes.