KINGFA MEDICAL
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EU DECLARATION OF CONFORMITY

We, the manufacturer,

GUANGDONG KINGFA SCI.&TECH. CO., LTD. NO.28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China SRN: CN-MF-000009520

declare under our sole responsibility that following CE marked products,

Nitrile examination gloves

Sizes	XS	S	M	L	XL
Basic UDI –DI: BIO-G01-697316340 BIO-G01ED;BIO-G02：697316340 BIO-G02Ef;BIO-G05：697316340 BIO-G01EM					
Intended Purpose: The nitrile examination gloves are intended to be worn on the hands of health care and similar personnel to prevent contamination between health care personnel and the patient's body.This is a single-use, powder-free, non-sterile device.					
 BIO-G01/BIO-G02/BIO-G05					

all belong to

- Class I according to Annex VIII of the Regulation (EU)2017/745 on medical devices
- Category III according to the Regulation (EU) 2016/425 on personal protective equipment

to which this declaration relates,are in conformity with Regulation (EU)2017/745 on medical devices as well as of the Regulation (EU) 2016/425 on personal protective equipment ,and with following harmonized standards and common specifications:

EN ISO 13485 :2016 Medical devices — quality management systems — requirements for regulatory purposes **EN ISO 14971 :2019** Medical devices — application of risk management to medical devices **EN 1041 :2008** Information supplied by the manufacturer of medical devices **EN ISO 15223-1 :2016** Medical devices — symbols to be used with medical device labels, labelling and information to be supplied — part 1: general requirements **EN 455-1:2020** Medical gloves for single use - Part 1: Requirements and testing for freedom from holes

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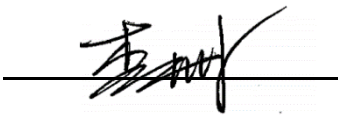
EN 455-2:2015 Medical gloves for single use - Part 2: Requirements and testing for physical properties
EN 455-3:2015 Medical gloves for single use - Part 3: Requirements and testing for biological evaluation
EN 455-4: 2009 Medical gloves for single use - Part 4: Requirements and testing for shelf life determination
EN ISO 21420 :2020 Protective gloves — general requirements and test methods
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 374-5 :2016 Protective gloves against dangerous chemicals and micro-organisms — Part 5: Terminology and performance requirements for micro-organisms risks

The products are subject to the conformity assessment procedure conformity to type based on Module D under the surveillance of the notified body 2777 SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland, and issued the EU Type Examination Certificate No. 2777/22430-01/E00-00.Type B glove according to EN ISO 374-1 :2016.

Place and date of issue: Qingyuan, China 2022-12-12

Name and signature of authorized person:



Linanjing
General Manager