KINGFA MEDICAL
PROTECTING PEOPLE

# EU DECLARATION OF CONFORMITY

We, the manufacturer,

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| GUANGDONG KINGFA SCI.&TECH. CO., LTD.<br>NO.28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China<br>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: 697316340KS-STRT021D9 | | | | | |
| 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. | | | | | |
|  <br>KS-ST RT021 | | | | | |

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:

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| **EN ISO 13485 :2016** Medical devices — quality management systems — requirements for regulatory purposes<br>**EN ISO 14971 :2019** Medical devices — application of risk management to medical devices<br>**EN 1041 :2008** Information supplied by the manufacturer of medical devices<br>**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<br>**EN 455-1:2020** Medical gloves for single use - Part 1: Requirements and testing for freedom from holes |

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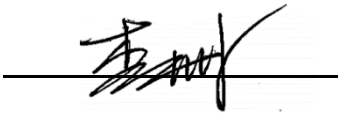
**EN 455-2:2015** Medical gloves for single use - Part 2: Requirements and testing for physical properties
**EN 455-3:2015** Medical gloves for single use - Part 3: Requirements and testing for biological evaluation
**EN 455-4: 2009** Medical gloves for single use - Part 4: Requirements and testing for 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 C2 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. 2777/15747-02/E00-00.Type C glove according to EN ISO 374-1 :2016.

Place and date of issue: Qingyuan, China 2021-08-31

Name and signature of authorized person:



Linanjing
General Manager