

<h2>EU Declaration of Conformity</h2> <p>according to the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL <i>Class I Medical Device(non-sterile)</i> And the REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL <i>Category III Personal Protective Equipment</i></p>		
Manufacturer:	GUANGDONG KINGFA SCI.&TECH. CO., LTD.	
Address:	No.28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China	
Single Registration Number (SRN) of the Manufacturer:	CN-MF-000009520	
European Representative (ER):	Share Info GmbH	
Address:	Heerdter Lohweg 83, 40549 Düsseldorf	
Single Registration Number (SRN) of ER:	DE-AR-000005132	
We, the manufacturer, declare under our sole responsibility that		
Product Name:	Nitrile examination gloves	
Type/model, identification of product allowing traceability (Where applicable):	KS-ST RT021	
Intended Purpose:	The nitrile examination gloves are intended used for the health care personnel to prevent contamination during close contact with the patient. The products are single- use, powder-free and non-sterile.	
the medical device(s)	Classification: (Annex VIII of the MDR)	Class I Medical Device
	Basic UDI-DI:	697316340KS-STRT021D9
	Conformity assessment route:	EU Declaration of Conformity + Technical Documentation (Annex II) + Technical Documentation on Post-Market Surveillance (Annex III)

<p>is/are in conformity with the relevant provisions and requirements of the Council and the parliament regulation (EU) 2017/745 for medical device and all applicable harmonized standards and Common Specification. All supporting documents are retained under the premises of the manufacturer.</p>		
<p>Applied harmonized standards and Common Specification</p>	Regulation (EU) 2017/745	EN 455-1:2020
	EN ISO 14971:2019	EN 455-2:2015
	EN ISO 13485:2016	EN 455-3:2015
	EN 1041:2008	EN 455-4:2009
	EN ISO 15223-1:2016	
<p>the personal protective equipment(s)</p>	<p>Classification: (ANNEX I of the REGULATION (EU) 2016/425)</p>	<p>Category III Personal Protective Equipment</p>
	<p>Conformity assessment procedures:</p>	<p>EU type-examination (module B) set out in Annex V, and either of the following:</p> <p>(i) conformity to type based on internal production control plus supervised product checks at random intervals (module C2) set out in Annex VII; (ii)conformity to type based on quality assurance of the production process (module D) set out in Annex VIII.</p>
<p>is/are in conformity with the relevant provisions and requirements of the Council and the parliament regulation (EU) 2016/425 on personal protective equipment and all applicable harmonized standards and Common Specification. All supporting documents are retained under the premises of the manufacturer.</p>		
<p>Applied harmonized standards and Common Specification</p>	Regulation (EU) 2016/425	EN ISO 21420:2020
	EN ISO 374-1:2016+A1 2018	EN ISO 374-2:2019
	EN16523-1: 2015+A1: 2018	EN ISO 374-4:2019
	EN ISO 374-5:2016	
<p>Notified Body:</p>	<p>SATRA Technology Europe Limited</p>	
<p>Address:</p>	<p>Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland</p>	

Identification Number:	Notified body:2777
EC Certificate(s):	EU type-examination (Module B) Certificate Number: 2777/15747-02/E00-00 (Expiry date: 08/02/2026) and is subject to the conformity assessment to type based on quality assurance of the production process (module D) of Regulation (EU) 2016/425, under the supervision of SATRA Technology Europe, Bracetown Business Park, Clonee, D15 YN2P, Ireland (Notified Body 2777)
<p>Signed on:  Place: Qingyuan, China</p> <p>2022-12-21</p> <p>Signature (on behalf of the manufacturer) : GUANGDONG KINGFA SCI.&TEC CO., LTD.</p> <p>Name of authorized signatory: Linanjing</p> <p>Position held in the company: General Manager</p> <div style="text-align: right;">  </div>	