KINGFA | MEDICAL
PROTECTING PEOPLE

EU Declaration of Conformity

according to the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

Class I *Medical Device(non-sterile)*

And

the REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

Category III *Personal Protective Equipment*

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):		KG-1101
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:	697316340KG-11014L
	Conformity assessment route:	EU Declaration of Conformity + Technical Documentation (Annex II) + Technical Documentation on Post-Market Surveillance (Annex III)

<table>
<tr><td colspan="3">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.</td></tr>
<tr><td rowspan="5">Applied harmonized standards and Common Specification</td><td>Regulation (EU) 2017/745</td><td>EN 455-1:2020</td></tr>
<tr><td>EN ISO 14971:2019</td><td>EN 455-2:2015</td></tr>
<tr><td>EN ISO 13485:2016</td><td>EN 455-3:2015</td></tr>
<tr><td>EN 1041:2008</td><td>EN 455-4:2009</td></tr>
<tr><td>EN ISO 15223-1:2016</td><td>EN ISO 10993-1:2018</td></tr>
<tr><td rowspan="2">the personal protective equipment(s)</td><td>Classification:
(ANNEX I of the REGULATION (EU) 2016/425)</td><td>Category III Personal Protective Equipment</td></tr>
<tr><td>Conformity assessment procedures:</td><td>EU type-examination (module B) set out in Annex V, and either of the following:
(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.</td></tr>
<tr><td colspan="3">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.</td></tr>
<tr><td rowspan="4">Applied harmonized standards and Common Specification</td><td>Regulation (EU) 2016/425</td><td>EN ISO 21420:2020</td></tr>
<tr><td>EN ISO 374-1:2016+A1 2018</td><td>EN ISO 374-2:2019</td></tr>
<tr><td>EN16523-1: 2015+A1: 2018</td><td>EN ISO 374-4:2019</td></tr>
<tr><td>EN ISO 374-5:2016</td><td></td></tr>
<tr><td>Notified Body:</td><td colspan="2">SATRA Technology Europe Limited</td></tr>
<tr><td>Address:</td><td colspan="2">Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland</td></tr>
</table>

Identification Number:	Notified body:2777
EC Certificate(s):	EU type-examination (Module B) Certificate Number: 2777/15940-03/E00-00 (Expiry date: 08/03/2026) and is subject to the type based on internal production control plus supervised product checks at random intervals set out in Module C2 of Regulation (EU) 2016/425, under the supervision of SATRA Technology Europe, Bracetown Business Park, Clonee, D15 YN2P, Ireland (Notified Body 2777)

Signed on:  Place: Qingyuan, China

2025-06-17

Signature (on behalf of the manufacturer) : GUANGDONG KINGFA SCI.&TEC CO., LTD.

Name of authorized signatory: Wangzhonglin

Position held in the company: General Manager

CE