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)

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.		
Applied harmonized standards and Common Specification	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	EN ISO 10993-1:2018
the personal protective equipment(s)	**Classification:** (ANNEX I of the REGULATION (EU) 2016/425)	Category III Personal Protective Equipment
	Conformity assessment procedures:	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.
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.		
Applied harmonized standards and Common Specification	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	
Notified Body:	SATRA Technology Europe Limited	
Address:	Bracetown Business Park, Clonee, Dublin D15 YN2P Ireland	

Identification Number:	Notified body:2777
EC Certificate(s):	EU type-examination (Module B) Certificate Number: 2777/15940-02/E00-00 (Expiry date: 08/03/2026) and is subject to the type based on quality assurance of the production process (module D under surveillance of SATRA Technology Europe, Bracetown Business Park, Clonee, D15 YN2P, Ireland (Notified Body 2777)

Signed on:  Place: Qingyuan, China

2023-06-26

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

Name of authorized signatory: Linanjing

Position held in the company: General Manager

CE