

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)*

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

the medical device(s)	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.
	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)

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 10993-1:2018	EN ISO 15223-1:2016
	MEDDEV 2.7.1: 2016	EN 62366-1:2015
Notified Body:	Not Applicable	
Address:	Not Applicable	
Identification Number:	Not Applicable	
EC Certificate(s):	Not Applicable	

Signed on:

Place: Qingyuan, China



2021-8-11

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

Name of authorized signatory: Linanjing

Position held in the company: General Manager

