

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):	KG-1303、KG-1104、KG-1106、KG-1107、BIO-G01、BIO-G02、BIO-G05
	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.
	Classification: (Annex VIII of the MDR)	Class I Medical Device
	Basic UDI-DI:	KG-1303: 697316340KG-130352 KG-1104: 697316340KG-11044S KG-1106: 697316340KG-11064W KG-1107: 697316340KG-11074Y BIO-G01: 697316340 BIO-G01ED BIO-G02: 697316340 BIO-G02Ef BIO-G05: 697316340 BIO-G01EM

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 455-1:2000
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
EN ISO 10993-11:2017	EN 62366-1:2015
EN ISO 10993-10:2013	MEDDEV 2.7.1: 2016

Notified Body: Not Applicable

Address: Not Applicable

Identification Number: Not Applicable

EC Certificate(s): Not Applicable

Signed on:



2022-4-20

Place: Qingyuan, China

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

Name of authorized signatory: Linanjing

Position held in the company: General Manage

