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)

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:	--
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:**	Medical surgical mask
	Type/model, identification of product allowing traceability (Where applicable):	KF-C P01(R), KF-B P01(R), KF-K P01(R), KF-IP01(R), KF-B P01(R-BD), KF-L P01(R), KF-J P01(R), KF-B P08(R), KF-B P09(WK), KF-B P06(R), KF-B P06B(R)
	Intended Purpose:	Medical surgical masks providing barrier to minimize the direct transmission of infective agent between staff and patients are principally intended for use by healthcare professionals in an operating room and other medical settings with similar requirements, additionally, protect the wearer against splashes of potentially contaminated liquids. This is a single-use, non-sterile device.
	Classification: (Annex VIII of the MDR)	Class I Medical Device
	Basic UDI-DI:	KF-C P01(R): 697316340KF-CP01(R)83 KF-B P01(R): 697316340KF-BP01(R)7J KF-K P01(R): 697316340KF-KP01(R)CB KF-I P01(R): 697316340KF-IP01(R)B9 KF-B P01(R-BD): 697316340KF-BP01(R-BD)W4 KF-L P01(R): 697316340KF-LP01(R)CU KF-J P01(R): 697316340KF-JP01(R)BS KF-B P08(R): 697316340KF-BP08(R)93 KF-B P09(WK): 697316340KF-BP09(WK)TB KF-B P06(R): 697316340KF-BP06(R)8M KF-B P06B(R): 697316340KF-BP06B(R)R8
Conformity assessment route:		EU Declaration of Conformity + Technical Documentation (Annex II) + Technical Documentation on Post-Market Surveillance (Annex III)

KINGFA | MEDICAL
PROTECTING PEOPLE

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 14683: 2019+AC: 2019
	EN ISO 10993-1: 2018	EN 1041: 2008
	EN ISO 10993-5: 2009	EN ISO 14971: 2019
	EN ISO 10993-10: 2010	EN ISO 15223-1: 2016
	EN ISO 13485: 2016	EN 62366-1:2015
	MEDDEV 2.7.1: 2016	
Notified Body:	Not Applicable	
Address:	Not Applicable	
Identification Number:	Not Applicable	
EC Certificate(s):	Not Applicable	

Signed on: Place: Qingyuan, China

2021-6-2

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

Name of authorized signatory: Linanjing

Position held in the company: General Manager

CE