

# THREE LIONS LIMITED

## Declaration of Conformity

For the following products:

Face Mask (Product Name)

2102025O2, 2102025CC, 2102025PB, 2103025CC, 2103025O2

Model	Silicone Face Mask		Cushion Mask	Personal Masks
Type	Reusable	Single Use	Single Use	Single Use
REF. No.	200100	200100D	200700V	2102025O2
	200200	200200D	200750V	2102025CC
	200300	200300D	200800V	2102025PB
	200400	200400D	200850V	2103005CC
	200500	200500D	200900V	2103025O2
	200550	200550D	200950V	
	200600	200600D		
	200650	200650D		

(Model Designation)

is hereinafter confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning Medical Device Directive (93/42/EEC As amended by 2007/47/EC) with the compliance the essential requirement – Annex I and the conformity assessment Annex VII

Classification: Class I

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC Classification Criteria Rule 1,

For the evaluation regarding the Class I product safety aspects, the following harmonized standards are applied:

EN 1041:2008 + A1:2013

EN ISO 10993-1: 2020

EN ISO 15223-1:2016

ISO 5356-1:2015

ISO 14971:2019

The following representative in Europe is responsible for making this declaration:

Company Name: Wellkang Ltd.

Company Address: Enterprise Hub, NW Business Complex, 1 Beraghmore Rd.  
Derry, BT48 8SE, N. Ireland, U.K.

The following manufacturer is responsible for making this declaration:

Company Name: Three Lions Limited

Company Address: No. 21 Qunyi Private Zone, Hengshan Road, Kunshan,  
Jiangsu, P.R. China



General Manager

2021/05/10

(Legal Signature)

(Position/title)

(Date)