

# Declaration of Conformity

## For the following products:

Neonatal Resuscitation Circuit

(Product Name)

No.	Size (Length)	Model code
1	100	800100
2	150	800150

(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)*

## Applicable harmonized standards are:

EN ISO 15223-1:2016

EN ISO 10993-1:2020

EN 1041:2008 + A1:2013

EN ISO 10993-5:2009

EN 12342:1998+A1:2009

## Applicable non-harmonized standards are:

ISO 14971:2019

ISO 5356-1:2015

IEC 62366-1:2015 + COR 1:2016 + AMD 1 :  
2020

ISO 10993-10 :2010

## Conformity Assessment Route:

Annex V of Medical Device Directive

## Notified Body:

DNV Product Assurance AS (NB No. 2460)

Veritasveien 3, 1363 Høvik, Norway

## The following European Authorized Representative is stated to the declaration:

Company Name: Wellkang Ltd.

Company Address: Enterprise Hub, NW Business Complex, 1 Beraghmore Rd., Derry, BT48 8SE,  
Northern Ireland, UK

## The following manufacturer is exclusively responsible for making this declaration:

Company Name: Three Lions Limited

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



(Legal Signature)

General manager

(Position/title)

2021.10.12

(Date)