



EC Declaration of Conformity



according to the Medical Devices Directive 93/42/EEC

Class I Medical Device.

(non-sterile, without measuring function)

Manufacturer:

CANGGU MEDICAL TECH CO.,LTD.

Address:

NO.16 Longxiang Road, Jinchuan Street, Changshan County, Quzhou, Zhejiang

Tel:

0570-5660391

Fax

/

EC Rep:

Wellkang Ltd

16 Castle Street, Dover, CT16 1PW, England, UK

We, the manufacturer, declare under our sole responsibility that

the medical device(s)	Product Name	Face Mask
	Type/model, identification of product allowing traceability (Where applicable)	1A3100
of class	according to annex IX of directive 93/42/EEC	Class I Medical Device (non-sterile, without measuring function)

is/are in conformity with the relevant provisions and requirements of directive 93/42/EEC, as amended by Directive 2007/47/EC.

Applied harmonised standards, national standards or other normative documents

EN ISO 15223-1:2016
EN 1041:2008
EN ISO 14971:2012

ISO 13485:2016;EN ISO 10993-1-2009;ISO 10993-5: 2009;ISO 10993-10;EN 14683:2019

Conformity assessment procedure

Module A (EC Declaration of Conformity (Annex VII) + Technical Files)

NOT applicable

Notified Body (name & number)
Certificate & number

Signed on: 3. April. 2010. Place: Zhejiang. China

Signature (on behalf of the manufacturer) : Hanbing Dou

Name of authorized signatory: Hanbing Dou

Position held in the company: General Manager

Official Seal:

