



# EC Declaration of Conformity



according to the Medical Devices Directive 93/42/EEC

*Class I Medical Device*

*(non-sterile, without measuring function)*

**Manufacturer:** ZHANGZHOU EASEPAL INNOVATION CO., LTD

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Maria-Göppert-Str. 5, 23562 Lübeck, Germany  
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**Importer** KSi International GmbH, Zellescher Weg 3, 01069 Dresden, Germany

**We, the manufacturer, declare under our sole responsibility that**

<b>the medical device(s) of class</b>	<b>Product Name</b>	Disposable Face Mask
	Type/model, identification of product allowing traceability (Where applicable)	BRI-5200
	according to annex IX of directive 93/42/EEC	<b>Class I Medical Device</b> (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  
EN 10993-5: 2009; ISO 10993-10: 2010  
EN 14683:2019

Conformity assessment procedure

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

**NOT applicable**

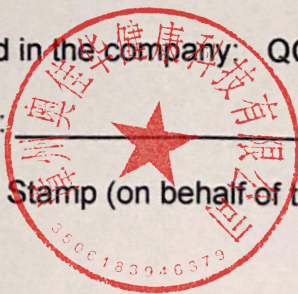
Notified Body (name & number)  
Certificate & number

Signed on: 07 May 2020. Place: Zhangzhou, Fujian, China

Name of authorized signatory: **Robin Ding**

Position held in the company: **QC Manager**

Official Seal:



Signature & Stamp (on behalf of the manufacturer):