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
Address:	No36. Longkun Road, Hongjian Village, Jiaomei Town, Zhangzhou Taiwanese Investment Zone, Fujian
Tel:	(+86) 13696989964
EC Rep:	HÄLSA Pharma GmbH Maria-Göppert-Str. 5, 23562 Lübeck, Germany (+49) 451 290382 300
Importer	KSi International GmbH, Zellescher Weg 3, 01069 Dresden, Germany

We, the manufacturer, declare under our sole responsibility that

the medical device(s)	Product Name	Disposable Face Mask
	Type/model, identification of product allowing traceability (Where applicable)	BRI-5200
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 EN 10993-5: 2009; ISO 10993-10: 2010 EN 14683:2019
Conformity assessment procedure	**Module A (EC Declaration of Conformity (Annex VII) + Technical Files)**
Notified Body (name & number) Certificate & number	**NOT applicable**

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):