符合性声明



Address:

Declaration of Conformity



according to the Medical Devices Directive 93/42/EEC

Manufacturer: Shanghai ZOGEAR Industries Co.,Ltd

Suite 303, Building 4, No. 406 Kang Yi Road, Kang Qiao Town, Pudong New

District,201315,Shanghai ,China

We declare under our sole responsibility that

the Medical Device

Product Name : Face Mask

Type/model,

batch/serial number, PB001 face mask earloop

possibly sources and : number of items

(Where applicable)

of class according to annex IX of : Class I, rule I

meets all the provisions of the directive 93/42/EEC (or 90/358/EEC) which apply to it.

Applied EN 556-1:2007

harmonised EN ISO 14971:2007+A1:2007 standards, EN 980:2003

national standards or other normative

documents

EN 1041:1998 EN 868-1:1997 EN 14079

EN 14079 EN 14683

Conformity assessment 93/42 procedure

93/42/EEC Annex Ⅶ

Notified Body (if consulted)

TUV Rheinland Products Safety Gmb-

2021/4/30

Valid Date

2020/5/01

(place and date)

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