## IVROU

## DISPOSABLE MEDICAL MASK

EN 14683:2019+AC:2019 TYPE IIR
ST-KZ-01
$175 \times 95 \mathrm{~mm}$
Ear Loop / Blue
C

SGS

# Medical Device File Review Report 

| Report No: | SGS/CN/SZX-IT20045/001 |
| :--- | :--- |
| Applicant: | Guangzhou Shuter Technology Co., Ltd. |
| Address: | No.882 South of Gongye Dadao, Haizhu District, Guangzhou City, <br> Guangdong Province, P.R. China |
| Product(s) Name: | Disposable Medical Mask |$\quad$| Type(s)/Model(s): | ST-KZ-01, ST-KZ-03 |
| :--- | :--- |$\quad$| Class I not sterile or measuring under Directive 93/42/EEC (according to the |
| :--- |
| manufacturer's declaration) |



Mendy Zhang
Deputy Director, Medical Device

[^0]
## EC Declaration of Conformity

Document No. ST-TF-FM-020

## Version 01


#### Abstract

Manufacture: Guangzhou Shuter Technology Co., Ltd Address: No. 882 South of Gongye Dadao, Haizhu District, Guangzhou City, Guangdong Province, P.R. China

We declare under our sole responsibility that:

Product Name: Disposable Medical Mask Brand name: Shuter Life Model: ST-KZ-01, ST-KZ-03 Product Type: EN14683:2019+AC:2019, Type IIR Class: Class I based on Rule 1 in Annex IX 93/42/EEC

Meets the provisions of EC directive 93/42/EEC and its transpositions in national laws which apply to it. The designated product with directive $93 / 42 / E E C$ has been assessed by the manufacture following the procedure relating to the EC declaration of conformity set out in Annex VII of $93 / 42 / \mathrm{EEC}$. And affix the CE mark. the technical file report has been assessed as meeting the essential requirement (Annex I) of EC directive $93 / 42 / \mathrm{EEC}$ as amended by 2007/47/EC. The declaration is valid in connection with the "Technical file review report" of the device from SGS Academy.


## EU Authorized Representative:

Company Name: CMC Medical Devices \& Drugs S.L

Company Address: C/Horacio Lengo $\mathrm{N}^{\circ} 18$ CP 29006, Málaga-Spain

Technical file review report No.: SGS/CN/SZX-IT20045/001


Place. Date

## Chen Huixuan.

Name and function of manufacture


Position

Report No.:
Client:
Contact Information:

## 168265888a 001

GUANGZHOU SHUTER TECHNOLOGY CO., LTD
\#,9No. 882 South of Gongye Dadao, Haizhu District, Guangzhou City, Guangdong Province, China

12 Materials
Disposable medical mask(non sterile)
ST-KZ-01, ST-KZ-03
2020-05-21
2020-05-25 to 2020-05-28
Test Specification:

1. Customer's requirement:
Screening of substances of very high concern (SVHC) subject to authorisation,
according to (EU) No $143 / 2011,(\mathrm{EU})$ No $125 / 2012$, (EU) No $348 / 2013$, (EU)
No 895/2014, (EU) No. 2017/999 and (EU) No. 2020/171 (Annex XIV of EC No
1907/2006) and candidate list by European Chemical Agency (ECHA).
according to the EU Court of Justice rules on SVHCs in articles (Guidance on
requirements for substances in articles, June 2017)
2. Polycyclic aromatic hydrocarbons (PAH)
3. Total Lead Content
4. NP and NPEO Content
5. Organotin Compounds Content
6. Total Cadmium Content
7. Flame Retardants Content
8. Banned azo dyes
9. Phthalates Content

## Other information:

1) $17.5 \mathrm{~cm} \times 9.5 \mathrm{~cm}$
2) $14.5 \mathrm{~cm} \times 9.5 \mathrm{~cm}$

For and on behalf of TÖV Rheinland (Shenzhen) Co., Ltd.


## Date

## Name/Position

[^1]
[^0]:    This report relates only to the product(s) as described in the Technical Documentation on the date and version shownt, Conformance to all the regusatory requerments is the soie responglility of the mannfacturer incluting the mampaclure, quallty control safery and performance of the producti(s).
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[^1]:    Sample information is provided by customer. Test result is drawn according to the kind and extent of tests performed. This test report relates to the above mentioned fest sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any safety mark on this or similar products.

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