

Medical Device Technical File Review Report

Report No.: MDD GZES2003013559ME

Applicant: Shenzhen Peninsula Medical Co., Ltd.

Address: 3F Block A, Building F2, Changfeng Industrial Park, Liuxian 3rd Road, 68#
Xin'an Street, Bao'an District, Shenzhen, 518100, P.R.China

Product(s) Name: Disposable Surgical Mask

Type(s)/Model(s): Flat-type

Classification: Class I not sterile or measuring under Directive 93/42/EEC

Review Purpose: Review the completeness of the Technical Documentation in accordance with the requirements of Annex VII of Directive 93/42/EEC as amended by 2007/47/EC

Review Result: During the review of the Technical Documentation (**File No. BDCE-001, Version No. 1.0, date 2020-03-03**) provided for the above listed product(s), no non-compliance was detected according to the requirements of Annex VII of Directive 93/42/EEC

Date of Review: 2020-03-27 to 2020-05-14

Date of Expire: 2021-05-14

Jason Hoo

Laboratory Manager

SGS-CSTC Standards Technical Services Co., Ltd. E&E Lab Guangzhou

Disclaimer: This report relates only to the product(s) as described in the Technical Documentation on the date and version shown. Conformance to all the regulatory requirements is the sole responsibility of the manufacturer including the manufacture, quality control, safety and performance of the product(s).

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The following sample(s) was/were submitted and identified on behalf of the applicant as:

Applicant: Shenzhen Peninsula Medical Co., Ltd
3F Block A, Building F2, Changfeng Industrial Park, Liuxian 3rd Road,
68# Xin'an Street, Bao'an District, Shenzhen, 518100, P.R.China.

Manufacturer: The same as the applicant

Sample Name: Disposable Surgical Mask

Lot No. : 202003001

Quantity: 70 PCS

Model/Type Reference: Flat-type 175mm×95mm

Date of Sample Received: 2020-04-08

Date of Testing: 2020-04-08 to 2020-06-03

The Standards: EN 14683:2019+AC:2019

Test Items: Bacterial filtration efficiency, Differential pressure, Splash resistance
pressure and Microbial cleanliness

Test Result: -Please refer to next page(s)-

Remark: 1. The ISO 22609:2004 testing was performed by SGS-CSTC Standards
Technical Services(Shanghai) Co., Ltd Testing Center(No.CNAS L0599).
2. The EN 14683:2019+AC:2019 Annex B, EN 14683:2019+AC:2019 Annex C
and EN ISO 11737-1:2018 Tests were performed by Taiwan Textile Research
Institute(No.TAF 0491).

Jova Lan

Technical Manager

Medical Laboratory

SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch



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Attention: To check the authenticity of testing / inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Qeccheck@sgs.com

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