



APPLICATION FOR TEST REPORT

On Behalf of

Prepared For : SHANGHAI SEVEN SENSE FOODS LIMITED
Building 1, No. 9, Songqiu Road, Qingpu District, Shanghai, China

Product Name : Disposable protective mask

Model : Ear hanging type 17.5 * 9.5 cm blue, Ear hanging type 17.5 * 9.5 cm black

Prepared By : SHENZHEN CTO TECHNOLOGY CO., LTD
9/F, block B, SME incubation center, Tangtou Avenue, Shiyan Town,
Bao'an District, Shenzhen City, Guangdong Province, China

Test Date : Feb. 26, 2020 –Mar. 18, 2020

Date of Report : Mar. 18, 2020

Report No. : CTO200318078KRS

**MDD TEST REPORT
EN 14683: 2019
Surgical masks – Requirements and test methods**

| | |
|----------------------------------|---|
| Report Reference No | CTO200318078KRS |
| Compiled by (+ signature)..... | Laurent Wu  |
| Approved by (+ signature)..... | Mike Wang  |
| Date of issue..... | Mar. 18, 2020 |
| Testing Laboratory | SHENZHEN CTO TECHNOLOGY CO., LTD |
| Address..... | 9/F, block B, SME incubation center, Tangtou Avenue, Shiyan Town, Bao'an District, Shenzhen City, Guangdong Province, China |
| Applicant's name | SHANGHAI SEVEN SENSE FOODS LIMITED |
| Address..... | Building 1, No. 9, Songqiu Road, Qingpu District, Shanghai, China |
| Test specification: | |
| Standard..... | EN 14683: 2019 |
| Non-standard test method..... | N/A |
| Test item description..... | Disposable protective mask |
| Trade Mark..... | N/A |
| Manufacturer..... | SHANGHAI SEVEN SENSE FOODS LIMITED |
| Address..... | Building 1, No. 9, Songqiu Road, Qingpu District, Shanghai, China |
| Model/Type reference..... | Ear hanging type 17.5 * 9.5 cm blue, Ear hanging type 17.5 * 9.5 cm black |
| Classification | Type II |



Possible test case verdicts:

- test case does not apply to the test object ... N (Not apply)
- test object does meet the requirement P (Pass)
- test object does not meet the requirement... F (Fail)

Testing

Date of receipt of test item Feb. 26, 2020

Date(s) of performance of tests Feb. 26, 2020 –Mar. 16, 2020

General remarks:

The test results presented in this report relate only to the object tested.

This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.

“(See Enclosure #)” refers to additional information appended to the report.

“(See appended table)” refers to a table appended to the report.

General product information:

The all models are same except their model number, and all tests are based on Ear hanging type 17.5 * 9.5 cm blue

Copy of marking plate:**Disposable protective mask**

Model: Ear hanging type 17.5 * 9.5 cm blue

Classification: Type II

Standard: EN 14683:2019



SHANGHAI SEVEN SENSE FOODS LIMITED

Building 1, No. 9, Songqiu Road, Qingpu District, Shanghai,
China**Made in China**

| EN 14683 | | | |
|----------|--|-----------------|---------|
| Clause | Requirement – Test | Result - Remark | Verdict |
| 4 | Classification | | -- |
| | Medical face masks specified in this European Standard are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is splash resistant, The 'R' signifies splash resistance. | Type II | P |

| | | | |
|-------|--|--|----|
| 5 | Requirements | | -- |
| 5.1 | General | | P |
| 5.1.1 | Materials and construction | | P |
| 5.1.2 | Design | | P |
| | The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides | | P |
| | Medical face mask may have different shapes and constructions as well as additional features such as a face shield(to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours). | Type II; to enhance fit by conforming to the nose contours | P |
| 5.2 | Performance requirements | | P |
| 5.2.1 | General | | P |
| | All tests shall be carried out on finished products or samples cut from finished products. | | P |
| 5.2.2 | Bacterial filtration efficiency (BFE) | Sample 1: 98.7% Sample 2: 98.8% Sample 3: 98.7% Sample 4: 99.0% Sample 5: 99.3% Sample 6: 99.1% | P |
| 5.2.3 | Breathability | Sample 1: 28.4Pa/cm ² Sample 2: 28.0Pa/cm ² Sample 3: 27.1Pa/cm ² Sample 4: 27.5Pa/cm ² Sample 5: 26.1Pa/cm ² Sample 6: 27.8Pa/cm ² | P |
| 5.2.4 | Splash resistance | Not required | P |
| 5.2.5 | Microbial cleanliness (Bioburden) | Sample 1: 17cfu/g Sample 2: 21cfu/g Sample 3: 20cfu/g Sample 4: 21cfu/g Sample 5: 20cfu/g Sample 6: 18cfu/g | P |
| 5.2.6 | Biocompatibility | classification in EN ISO 10993-1, | P |
| 5.2.7 | Summary of performance requirements | | P |

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|---|----------------------------------|--|----|
| 6 | Marking, labelling and packaging | | -- |
|---|----------------------------------|--|----|

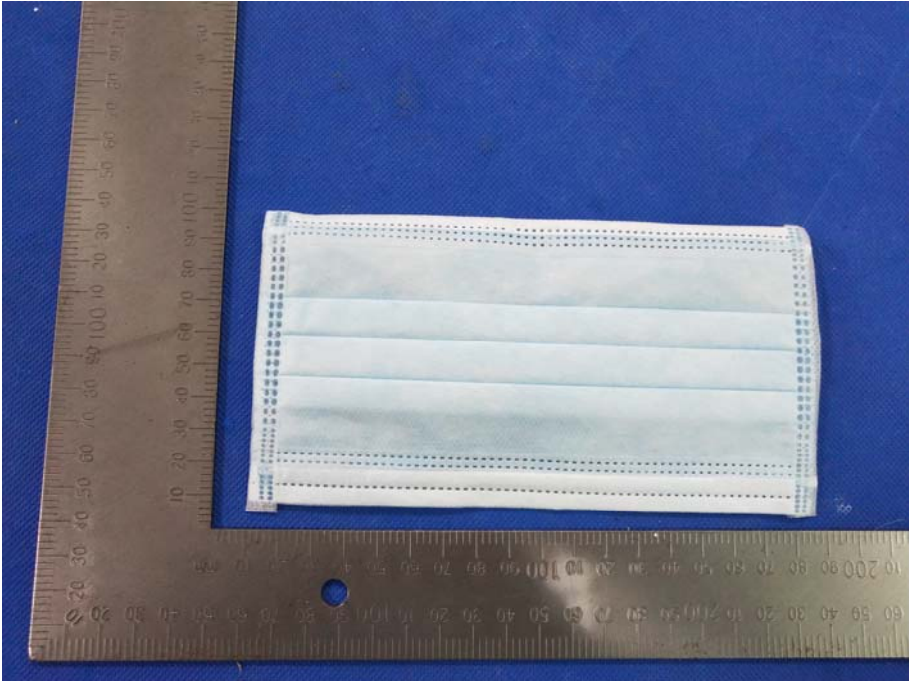
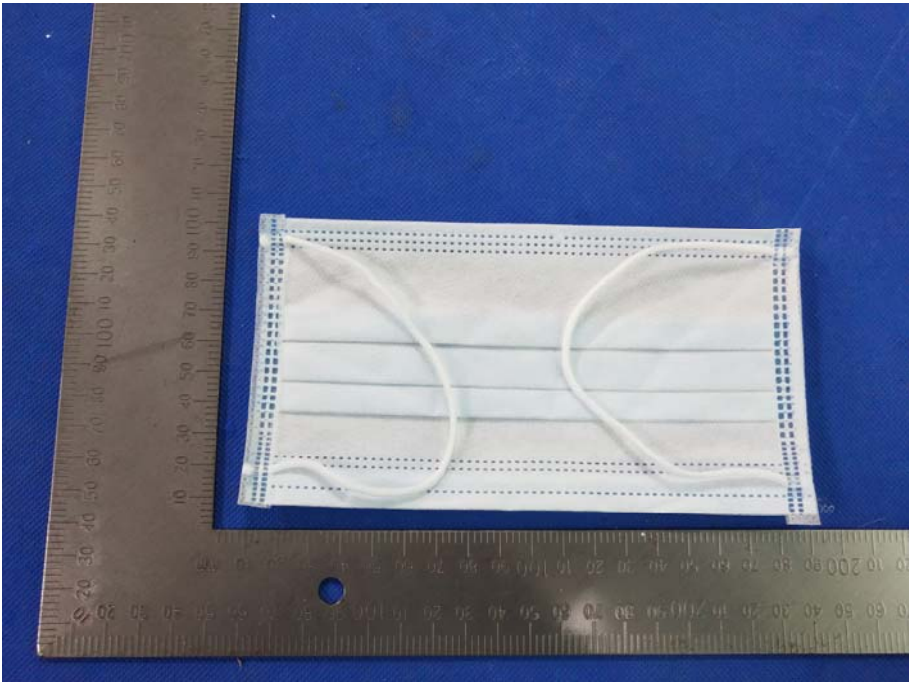
| EN 14683 | | | |
|----------|--|-----------------|---------|
| Clause | Requirement – Test | Result - Remark | Verdict |
| | Annex I, § 13, of the medical Devices Directive (93/42/EEC) or Annex I § 23, of the Medical Device Regulation(EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied. | See packaging | P |
| | The following information shall be supplied: | | P |
| | a) number of this European Standard; | EN14683:2019 | P |
| | b) type of mask(as indicated in Table1). | Type II | P |
| | ENISO 15223-1: 2016 and EN1041: 2008+A1: 2013 should be considered. | | P |

Table 1 – Performance requirements for medical face masks

| Test | Type I ^a | Type II | Type IIR |
|---|---------------------|--------------|----------|
| Bacterial filtration efficiency (BFE), (%) | ≥ 95 | ≥ 98 | ≥ 98 |
| Differential pressure (Pa/cm ²) | < 40 | < 40 | < 60 |
| Splash resistance pressure (kPa) | Not required | Not required | ≥ 16,0 |
| Microbial cleanliness (cfu/g) | ≤ 30 | ≤ 30 | ≤ 30 |

^a Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

ANNEX A: Photo-documentation

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|--|--|
| <p>Photo 1 view</p> <p><input checked="" type="checkbox"/> front <input type="checkbox"/> back <input type="checkbox"/> side <input type="checkbox"/> top <input type="checkbox"/> internal <input type="checkbox"/> bottom</p> |  |
| <p>Photo 2 view</p> <p><input type="checkbox"/> front <input checked="" type="checkbox"/> back <input type="checkbox"/> side <input type="checkbox"/> top <input type="checkbox"/> internal <input type="checkbox"/> bottom</p> |  |

----- End of Report -----