



## APPLICATION FOR TEST REPORT

### On Behalf of

Prepared For : Fujian YingDaWo Medical Technology Co., Ltd  
1/F, Plant No. 30, TianShui Road, GaiShan Town, CangShan District,  
Fujian Province, China

Product Name : Surgical Mask

Model : SFM30-01, SFM20-01, SFM20-02, SFM10-01, SFM10-02

Prepared By : SHENZHEN CTO TECHNOLOGY SERVICE CO., LTD  
9/F, Block B, 196 Tangtou Avenue, Langxin Community, shiyan Street,  
Baoan District, Shenzhen, China

Test Date : Mar. 16, 2020 to Apr. 14, 2020

Date of Report : Apr. 14, 2020

Report No. : CTO200414020KRS

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

**Report Reference No**.....: `CTO200414020KRS

**Compiled by (+ signature)**.....: Laurent Wu



**Approved by (+ signature)**.....: Mike Wang

**Date of issue**.....: Apr. 14, 2020

**Testing Laboratory**.....: SHENZHEN CTO TECHNOLOGY SERVICE CO., LTD

**Address**.....: 9/F, Block B, 196 Tangtou Avenue, Langxin Community, shiyan Street, Baoan District, Shenzhen, China

**Applicant's name**.....: FuJian YingDaWo Medical Technology Co., Ltd

**Address**.....: 1/F, Plant No. 30, TianShui Road, GaiShan Town, CangShan District, Fujian Province, China

**Test specification:**

**Standard**.....: EN 14683: 2019

**Non-standard test method**.....: N/A

**Test item description**.....: Surgical Mask

**Trade Mark**.....: ENDEAVOUR

**Manufacturer**.....: FuJian YingDaWo Medical Technology Co., Ltd

**Address**.....: 1/F, Plant No. 30, TianShui Road, GaiShan Town, CangShan District, Fujian Province, China

**Model/Type reference**.....: SFM30-01, SFM20-01, SFM20-02, SFM10-01, SFM10-02

**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 ..... Mar. 16, 2020

Date(s) of performance of tests ..... Mar. 16, 2020 to Apr. 14, 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:****Copy of marking plate:**

Surgical Mask  
Model: SFM30-01  
Classification: Type II  
Standard: EN 14683:2019



Fujian YingDaWo Medical Technology Co., Ltd  
1/F, Plant No. 30, TianShui Road, GaiShan Town, CangShan  
District, Fujian Province, 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: 98.9% Sample 4: 99.1% Sample 5: 99.0% Sample 6: 99.2%	P
5.2.3	Breathability	Sample 1: 28.4Pa/cm <sup>2</sup> Sample 2: 28.0Pa/cm <sup>2</sup> Sample 3: 28.1Pa/cm <sup>2</sup> Sample 4: 27.5Pa/cm <sup>2</sup> Sample 5: 28.1Pa/cm <sup>2</sup> Sample 6: 27.5Pa/cm <sup>2</sup>	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: 17cfu/g	P
5.2.6	Biocompatibility	classification in EN ISO 10993-1,	P
5.2.7	Summary of performance requirements		P



6	Marking, labelling and packaging		--
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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 <sup>a</sup>	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm <sup>2</sup> )	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30
<sup>a</sup> 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**

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

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