



BIOSIS HEALING  
博辉瑞进

# Medical Surgical Mask

EN14683 Type II R



GMMIT GmbH Wiesenstr.5 , 63225 Langen, [info@gmmit.com](mailto:info@gmmit.com), [www.gmmit.com](http://www.gmmit.com)



## Professionelle Produktion

- Renommierter Hersteller für PSA
- Modernste Produktionsanlagen und Sicherheitskonzepte
- Speziell für den EU-Markt entwickeltes Qualitätsprodukt
- <http://en.biosishealing.com>





## Zertifizierter Vertriebspartner

- 15 Jahre Erfahrung im Handel zwischen Deutschland und China
- Vertriebsbüros in Beijing , Shanghai und Hongkong
- Eignes Lager und Logistik
- <https://www.gmmiit.com>



## ISO & CE Declaration of Conformity

BIOSIS HEALING  
博辉瑞进

TÜV SÜD CERTIFICATE • 認證證書 • CERTIFIKAT • TÜV SÜD CERTIFICATE • TÜV SÜD CERTIFICATE



**DAKKS**  
Deutsche  
Akkreditierungsstelle  
D-24113 KT-03





Product Service

# Certificate

**No. Q5 101395 0001 Rev. 00**

**Holder of Certificate:** **Beijing Biosis Healing Biological Technology Co., Ltd.**  
 No.6 plant west  
 Valley No.1 Bio-medicine Industry Park, Daxing District  
 102600 Beijing  
 PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):** **Beijing Biosis Healing Biological Technology Co., Ltd.**  
 No.6 plant west, Valley No.1 Bio-medicine Industry Park, Daxing District, 102600 Beijing, PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



[www.tuv.com.cn](http://www.tuv.com.cn)

**Scope of Certificate:** **Design, Development, Production, Distribution and Sales of Disposable Circular Stapler, Disposable Linear Stapler and Reloads, Disposable Hemorrhoidal Stapler, Disposable Linear Cutter Stapler and Reloads, Disposable Circumcision Stapler, Wound Protector, Disposable Skin Staplers, Disposable Specimen Retrieval Bag, Disposable Laparoscope trocar, Disposable Endoscopic Linear Cutter Stapler and Reloads, Disposable Hemorrhoid Ligator, Veress needle, Scar Silicon gel, Chitosan Gel, Clip Appliers and Removers, Band-aid, Ligating clip, Surgical Mesh.**

**Applied Standard(s):** **EN ISO 13485:2016**  
 Medical devices - Quality management systems - Requirements for regulatory purposes  
 (ISO 13485:2016)  
 DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

<b>Report No.:</b>	<b>BJ1823301</b>
<b>Valid from:</b>	<b>2019-04-15</b>
<b>Valid until:</b>	<b>2022-04-14</b>

**Date,**                      **2019-04-15**

  
**Stefan Preiß**

<h2>Declaration of Conformity</h2>	
<p><b>Manufacturer Address</b></p> <p><b>European Representative</b></p>	<p>BEIJING BIOSIS HEALING BIOLOGICAL TECHNOLOGY CO., LTD No.5 plant west, Valley No.1 Bio-medicine Industry Park, Daxing District, 102600 Beijing, PEOPLE'S REPUBLIC OF CHINA.</p> <p>SHANGHAI INTERNATIONAL HOLDING CORP.GMBH (EUROPE) EFFETSTRASSE 80, 20537 HAMBURG, GERMANY</p>
<p>We, the manufacturer, herewith declare that the products</p> <p><u>Medical Surgical Mask</u></p> <p>BH-EGF- (12x7,14.5x9,17.5x9.5) BH-BDF- (12x7,14.5x9,17.5x9.5)</p> <p>meet the provisions of Directive 93/42/EEC and 2007/47/EC which apply to them. The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark</p> <div style="text-align: center; font-size: 48px; margin: 20px 0;"> </div> <p>WE, AS THE MANUFACTURER, ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY</p>	
<p>Valid from: 2020 - 03 - 03 Valid until: 2024 - 06 - 27</p> <p>Standard NO. EN 14083-2014 Type IIR</p> <p style="text-align: center;">Bo Zhao</p> <p>Signature of General Director</p>	



# Test Report of Medical Surgical Mask EN14683:2019 Type IIR



BIOSIS HEALING  
博辉瑞进

Test Report No.: 721652882-1  
Report Date: 25 March 2020



**SUBJECT** Physical & Microbiological Test

**TEST LOCATION** TÜV SÜD China

TÜV SÜD Products Testing (Shanghai) Co., Ltd.  
B-3/4, No.1999 Du Hui Road, Minhang District  
Shanghai 201108, P.R. China

**CLIENT NAME** Beijing Biosis Healing Biological Technology Co., Ltd.

**CLIENT ADDRESS** No.6 plant west, Valley No.1 Bio-medicine Industry Park, Daxing District, 102600  
Beijing, PEOPLE'S REPUBLIC OF CHINA

**TEST PERIOD** 12-Mar-2020~23-Mar-2020

Prepared By

Bella Xu

(Bella Xu)  
Report Drafter

Authorized By



(Leo Liu)  
Authorized Signatory

## Differential pressure of a medical face mask

### 1.Purpose

The purpose of the test was to measure the differential pressure of a medical face mask.

### 2.Sample description was given by the client

Medical Surgical Mask  
Type : BH-EG-17.5X9.5  
Lot : 620021301

### 3.References

EN 14683:2019

### 4.Apparatus

Differential pressure testing instrument

### 5.Test specimen

5.1 Test specimen are complete masks or shall be cut from masks. Each specimen shall be able to provide 5 different circular test areas of 2.5 cm in diameter.

5.2 Each test specimen shall be conditioned at (21±5)°C and (85±5) % relative humidity for the time required to bring them into equilibrium with atmosphere prior to testing.

### 6. Procedure

6.1 The test specimen is placed across the 2.5 cm diameter orifice (total area 4.9 cm<sup>2</sup>) and clamped into place so as to minimize air leaks and that the tested area of the specimen will be in line and across the flow of air.

6.2 The pump is started and the that tested area of the specimen will be in line and across the flow of air.

6.3 The manometers M1 and M2 are read and recorded.

6.4 The procedure described in steps 6.1-6.3 is carried out on 5 different areas of the mask and readings averaged.

### 7. Calculation

For each test specimen calculate the different pressure ΔP as follows:

$$\Delta P = \frac{(X_{m1} - X_{m2})}{4.9}$$

X<sub>m1</sub>: is pressure in Pa, manometer M1, mean of 5 test areas, low pressure side of the material;

X<sub>m2</sub>: is pressure in Pa, manometer M2, mean of 5 test areas, high pressure side of the material;

4.9 is the cm<sup>2</sup> area of the test material;

ΔP is the different pressure per cm<sup>2</sup> of the test material expressed in Pa.



## EN14683:2019 Type II R

Product Name	Standard CN	Standard EU
Medical Surgical Mask	YY 0469-2011	EN14683:2019 Type II R
	For medical staffs to prevent the spread of respiratory microbes to the open surgical wound, and the transmission of surgical patients' fluid to the wearer.	
<p>Please noted specifications for some other countries :</p> <ul style="list-style-type: none"><li>• 1.Synthetic blood penetration test (anti-droplet blood body fluid) level 2 <math>\geq 120\text{mmHg}</math>, level 3 <math>\geq 160\text{mmHg}</math>;</li><li>• 2.Bacterial filtration efficiency ( BEF) <math>\geq 95\%</math> ;</li><li>• 3.Particulate Filtration Efficiency <math>\geq 30\%</math></li></ul>		



## EN14683 ype II R

Test	Type I	Type II	Type II R	Biosis Healing Medical Sugical Mask
BFE (%)	$\geq 95$	$\geq 98$	$\geq 98$	$\geq 99.7$
Pressure Difference (Pa/cm <sup>2</sup> )	29.4	29.4	49.0	49.0
Blood penetration (kPa)	-	-	$\geq 16$ (120mmHg)	No penetration at 120mmHg
Microbial cleanliness (cfu/g)	$\leq 30$	$\leq 30$	$\leq 30$	$\leq 20$





# Introduction of Product Performance



BIOSIS HEALING  
博辉瑞进



BIOSIS HEALING



## Medical Surgical Mask

- ※ Consists of mask, nose-clip and tie-bands, made of non-woven fiber fabric.
- ※ Isolation and protection through filtration.

Biosis Healing The Medical Surgical Mask complies with CE & ISO .  
Particle filtration and bacterial filtration both meet relevant standards

### 【Intended usage】

These face masks, designed for medical personnel to wear over the face, prevent dandruff and respiratory microbes from spreading to open surgical wounds and stop the body fluids of patients from spreading to medical personnel thus to play a two-way biological protection role.

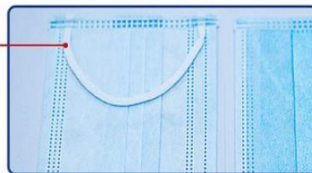
### 【Structure and components】

The Medical Surgical Mask is composed of ear loops, nose clip and tie-band , made of non-woven fiber fabric. Plays the role of isolation and protection through filtration, the fixed nose clip enhance the protection of the mouth and nose. The ear-loops medical surgical mask is more convenient to wear and remove.

Isolation and protection through filtration



The ear-loops medical surgical mask is more convenient to wear and remove



### 【Features and standard】

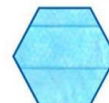
- ※ Tie-bands with sufficient strength to fix the mask. The breaking strength of the connection point between each tie-band and the mask is not less than 10N;
- ※ The PFE ( particle filtration efficiency ) is no less than 30%, and the BFE ( Bacterial filtration efficiency ) is no less than 95%;
- ※ Pressure difference between the two sides of the mask for air exchange  $\Delta P \leq 49$  Pa;
- ※ Synthetic blood was sprayed on the mask sample at a pressure of 120mmHg, and there was no penetration through the mask;
- ※ Ethylene oxide residual does not exceed 10ug/g.

### 【Applicable people】

Medical staff in a medical environment.

### 【Application method】

1. Take the mask out and the nose-clip should be positioned at the top;
2. Fully unfold the pleats of the mask;
3. Place the mask on the face and make sure to cover the nose and face, fix the mask with the tie-bands or ear loops, form the nose-clip over the bridge of the nose and press the nose-clip with the middle fingers of both hands;
4. Pull the mask from the top to bottom to cover the end of jaw to cover face and the protection;
5. Check adhesion after putting on the mask: cover the mask with both hands, breath out. If there is leakage air from the nose-clip, adjust the nose-clip. If the adhesion cannot be achieved, do not wear the mask into the dangerous area.



Two-way biological protection, prevent scurf, respiratory microorganisms from spreading to open surgical wounds ;



The ear-loops medical surgical mask is more convenient to wear and remove



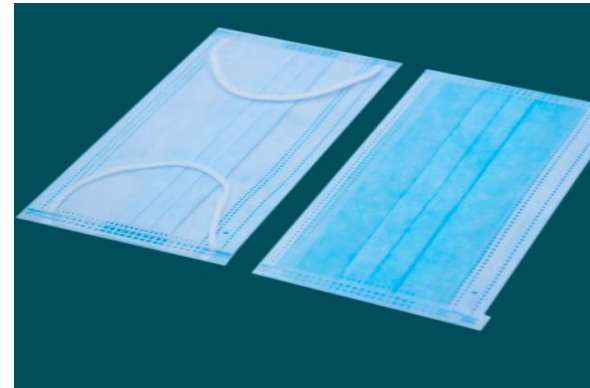
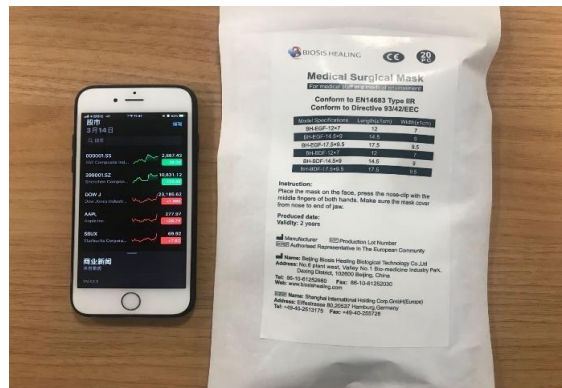
BIOSIS HEALING




# Product Packaging Information



BIOSIS HEALING  
博辉瑞进



Product Name	Product Name	Model	Carton volume (pcs/box)	Carton Dimension (mm)	Carton N.W (kg)
	Surgical Mask	BH-EGF-17.5x9.5	2000 (20pcs/pack)	485x450x415mm	8.5



## Product Packaging Information



BIOSIS HEALING  
博辉瑞进



### ✓ Carton size:

480 x 450 x 415mm, each carton volume is 0.09m<sup>3</sup>, aviation weight of 15kg.

### ✓ Tray volume :

95 x 95 x 187cm, total volume is 1.44m<sup>3</sup>. 16 cartons are a tray, total aviation weight of 240kg. (total height and weight, excluding blue chassis)

### ✓ Container:

20 feet container, can hold 310 Cartons, 40 feet container can hold 610 Cartons.



BIOSIS HEALING  
博辉瑞进

THANK YOU



GMMIT GmbH Wiesenstr.5 , 63225 Langen, Germany. Email: [info@gmmit.com](mailto:info@gmmit.com)