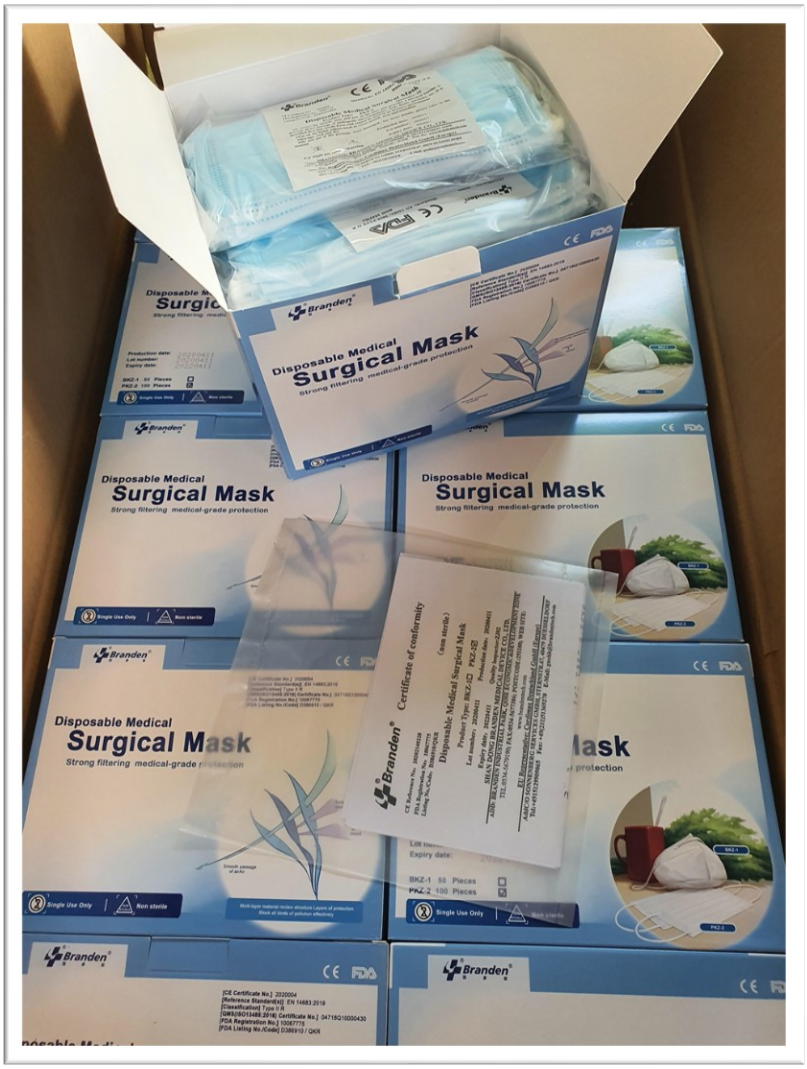
RIENTECH Branden™
Type IIR Disposable Medical Face Mask



- Type IIR Disposable Medical Surgical Face Mask
- 10 packs of 10 masks per box
- Protection for mouth, nose and jaw against pathogenic micro-organism, body fluids and particles.
- Ear-loop elastic straps
- Bacterial efficiency >=98%
- Non-oily particle filtration efficiency >=30%
- Penetration tested at 2mL synthetic blood at 16.0kPa
- This product is provided non-sterile.
- FDA Approved (10067775)
- CE Certified (2020004)
- Manufactured to ISO13485-2016 (04718Q10000430)
- EN14683: 2019

www.o3group.uk

USER'S MANUAL

[Product Name] Disposable Medical Surgical Mask
[Product Type] BKZ-1,PKZ-2
[Standards] EN 14683: 2019 TYPE II R
[CE Certificate No.] 2020004
[CE Reference No.]20202140228
[FDA Registration No.] 10067775
[Listing No./Code] D386910/QKR

[Application]

It covers the mouth, nose and jaw of the user and provides a physical barrier to prevent direct passage of pathogenic microorganisms, body fluids, particles, etc. The product is provided in a non-sterile form and cannot be used in an invasive environment.

[Product Components]

The product is composed of a cup body, earloop straps and a nosepiece. The inner and outer layers of the cup body are polypropylene non-woven fabric, the middle layer is polypropylene melt-blown cloth, the earloop strap is the composite materials of polyester spandex and cotton, and the nosepiece is made of polyethylene.

[Product Performance]

This product meets the requirements of EU standards "EN 14683:2019 TYPE II R" . The main performance indicators are as follows:

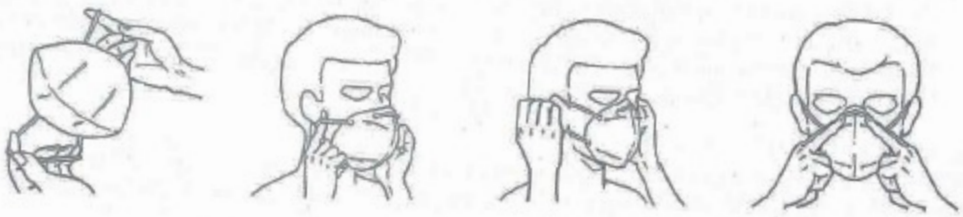
i. Bacterial filtration efficiency (BFE) ≥98%;
ii. Non-oily particles filtration efficiency ≥ 30%;
iii. The inside surface of the mask should not be penetrated, after 2mL of synthetic blood is sprayed on the outside surface of the mask at a pressure of 16.0kPa (120mmHg)

This product is provided non-sterile.

[Product specifications and tolerances]

BKZ-1 : Maximum length horizontal 11.0 ± 1cm, width vertical 16.5 ± 1cm;
PKZ-2: Maximum length horizontal 17.5±1cm, width vertical 9.5±1cm .

[Fitting Instructions]
BKZ-1



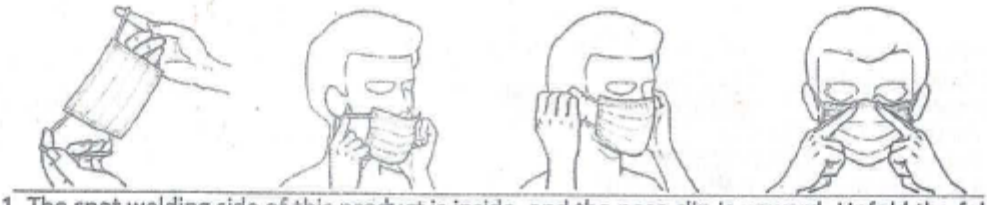
1. With nosepiece facing away from you, hold the earloop strap in each hand with the nosepiece up.
2. Position the mask under the chin.
3. Pull each strap over the ear. Adjust the straps as comfortable as possible.
4. Place the fingertips of both hands at the top of the metal nosepiece. Mold the nosepiece to the shape of the nose bridge by pushing inwards while moving your fingertips down both sides of the nosepiece. Pinching the mask nosepiece using only one hand may result in less effective mask fit.
5. The seal of the mask on the face should be checked by the wearer prior to entering the work area.

a) Cover the front of the mask with both hands, being careful not to disturb the position of the mask.

b) Inhale sharply. If air leaks around the nose bridge, readjust the nosepiece as described in step 4. If air leaks at the mask edges, work the straps back along the side of your hand. If you cannot achieve proper fit, repeat steps 1-4.

c) If no leakage is detected, then work may proceed.

PKZ-2



1. The spot welding side of this product is inside, and the nose clip is upward. Unfold the folds.
2. Cover the chin with the mask and secure the mask with the earloop strap.
3. Pull the bottom of the mask to the mandible to ensure a large area of protection;
4. Use index fingers to shape the nose clip, starting from the middle of the nose clip and moving it to the sides while pressing down.

It is very important to press the nosepiece firmly to the nose bridge to form a good seal.

[Caution、Warning and Advice]

1. Do not modify or abuse
2. This product cannot be used in an anoxic environment, for it cannot produce oxygen
3. Do not use this product when facial beards, hair or other conditions can affect the adhesion between the face and the mask
4. This product is provided as non-sterile, not suitable for medical environments requiring protective isolation or special purification, and not suitable for aseptic operations. The best continuous use time is about 4 hours
5. This product is a one-time use product and do not reuse again
6. Do not user if the package is broken, use it as soon as possible after package is opened
7. Avoid touching the inside of the mask when wearing the mask, and avoid touching the outside of the mask when removing the mask.
8. Keep fire away
9. Do not use in special environments such as harmful dust and gas
10. Please note that the earloop strap will be break if you pull it too strongly
11. Please stop using it if itching, earache and other symptoms appear
12. If you have wound on your mouth, nose, or ears, please treat it before you use this mask
13. Please refer to the instructions before you use
14. When non-medical professional use the mask in a medical environment, if the user has no fever, cough and other symptoms, put the waste mask into a "harmful garbage" bucket after use; if the user has fever, cough and other symptoms, use boiling water (or hot water temperature above 56 °C) soak the mask for 30 minutes, or sterilize with alcohol spray, and then dispose into a "harmful garbage" bucket

[Storage Condition]

Stored in a well-ventilated, cool and dry warehouse, within temperature range from 0°C to 40 °C and less than 80% relative humidity. Avoid direct sunlight or strong artificial light with high UV content, no corrosive gas.

[Registrant Name] Shandong Branden Medical Device Co., LTD
[Registrant Address] Branden Industrial Park, QIHE Economic &, Development Zone, 251100 QIHE, Shandong Province, P.R.China
[Post Code]: 251100
[Tel Number] +86 534 5676662
[Fax Number]:+86 534 5677386

[Manufacturer] Shandong Branden Medical Device Co., LTD
[Manufactory Address] Branden Industrial Park, QIHE Economic &, Development Zone, 251100 QIHE, Shandong Province, P.R.China
[Tel Number] +86 534 5676662
[Fax Number]:+86 534 5677386

[Period of Validity] 2 Years
[Date of Manufacture] See product package

Made in China

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

MANUFACTURER:
NAME: **SHANDONG BRANDEN MEDICAL DEVICE CO., LTD**
ADDRESS: BRANDEN INDUSTRIAL PARK, QIHE ECONOMIC& DEVELOPMENT ZONE, 251100, SHANDONG PROVINCE, CHINA,
TEL.: +86-534-5676662 FAX: +86-534-5677386
E-MAIL: CEO@BRANDENTECH.COM

MEDICAL DEVICES:

NAME OF DEVICES	TYPE(S) AND BATCH QUANTITY	LOT No.
Disposable Medical Surgical Mask	*PKZ-2 , 200019*	20200411

REFERENCE STANDARDS: EN 14683-2019 TYPE II R

WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY

EC REP
EUROPEAN REPRESENTATIVE:
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C/O SONNENBERG SERVICES GMBH STERNSTR.67,
40479 DUESSELDORF
TEL: +4915129909065; FAX: +49(211)51369278

DATE OF DECLARATION: 2020.4.11

SIGNATURE:

NAME: HAIJUN ZHANG
POSITION: CEO OF THE MANUFACTURER

FDA

Fiscal Year 2020

CERTIFICATION OF REGISTRATION

This certifies that:

Name: SHANDONG RIENTECH MEDICAL TECHNOLOGY CO., LTD.

Add: Economic Development Zone, Qihe County, Dezhou, Shandong, China

has completed the FDA Establishment Registration (as manufacturer and foreign exporter) and Device Listing with the US Food & Drug Administration, through

The Owner/ Operator Number for this Registration is : 10063096

Listing No	Code	Device Name
D375314	OEA	Isolation Gown, Protective Clothing
D375316	BYG	Medical Face Shield,
D375313	HOY	Medical Safety Goggles
D375312	KEA	Disposable Medical Surgical Mask

ABmed will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. ABmed makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate - holder's device or establishment by the U.S Food and Drug Administration.

ABmed assumes no liability to any person or entity in connection with foregoing.

Date of verification: Mar. 17, 2020

Date of expiration: Dec. 31, 2020

SH OFFICE

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ABMED SERVICE INC.

36 Soyth 18th Avenue, Suite A Brighton,CO USA 80601

TEL:213-375-3998 FAX:213-375-3998 info@abmed.com.cn

REGISTRATION NO. 04717Q10000266

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

Shandong Rientech Medical Technology Co., Ltd.

Registered Address: Brander Industrial Park, Qihe Economic &, Development Zone, 251100 Qihe, Shandong Province, P.R. China

Manufacturing Address: Brander Industrial Park, Qihe Economic &, Development Zone, 251100 Qihe, Shandong Province, P.R. China

Has been assessed and conformed to the following standard(s)

YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

Design, Development, Production and Service of Sirolimus-eluting Coronary Stent System,Medic al Face Shield, Medical Safety Goggles.

Date of issue: July 14,2017

Date of expiry: July 13,2020

Date of change: March 23,2020

General Manager:

BEIJING HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.

Note: This certificate will not be valid until the organization has been approved in the annual audits. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (www.cnca.gov.cn) or the website of CMD (www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No.jia88, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62351993

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

MANUFACTURER:
NAME: **SHANDONG RIENTECH MEDICAL TECH CO., LTD**
ADDRESS: BRANDEN INDUSTRIAL PARK, QIHE ECONOMIC& DEVELOPMENT ZONE, 251100, SHANDONG PROVINCE, CHINA,
TEL.: +86-534-5676662 FAX: +86-534-5677386
E-MAIL: CEO@BRANDENTECH.COM

MEDICAL DEVICES:

NAME OF DEVICES	*TYPE(S) AND BATCH QUANTITY*	LOT No.
Medical Face Shield	*L32 , 200,000 PCS*	20200402

WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.
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DATE OF DECLARATION: 2020.4.02

SIGNATURE:

NAME: HAIJUN ZHANG
POSITION: CEO OF THE MANUFACTURER

PRODUCT TEST REPORT OF

SHANDONG RIENTECH MEDICAL TECHNOLOGY CO., LTD.

Product Name			Medical Face Shield	Tested Department	Production department	
Product Model			L32	Test basis	Technical requirements for Medical face shield	
Product Batch Number			20200402	Sampling Mode	Random sampling	
Product Quantity			200,000 PCS	Sampling Date	20200402	
Sampling Quantity			8 PCS	Testing Date	20200402	
NO	Test Item(s)		Test Requested	Test Results	Conclusion	Remarks
1	size	L1	32.0±1.5cm	31.7-32.2cm	Qualified	\
		L2	22.0±1.5cm	21.8-22.3cm	Qualified	\
		L3	32.0±1.5cm	31.7-32.2cm	Qualified	\
		L4	28.0±1.5cm	27.8-28.3cm	Qualified	\
2	Appearance		Medical Face Shield shall be free from projections, sharp edges or other features which could cause discomfort.	Meet the requirements	Qualified	\
Conclusion(s): The tested products meet the technical requirements of medical face shield.						

Inspector: Cong Cong Liu Auditor: Anyun Approved: Wenying Huo