



BIOSIS HEALING  
博辉瑞进

# Isolation Gowns-BH100

EN13982-1: 2004



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 Sic
- Speziell für den EU-Markt entwickeltes
- <http://en.biosishealing.com>





GMMIT GmbH, Langen , Deutschland



BIOSIS HEALING  
博辉瑞进

## Zertifizierter Vertriebspartner

15 Jahre Erfahrung im Handel zwischen Deutschland und China

Vertriebsbüros in Beijing , Shanghai und Hongkong

Eignes Lager und Logistik

<https://www.gmmi.com>



Büro in Beijing



### POWER OF ATTORNEY

HERE OUR COMPANY 北京博辉瑞进生物科技有限公司 BEIJING BIOSIS HEALING BIOLOGICAL TECHNOLOGY Co, Ltd AUTHORISES GMMIT GmbH, LOCATED IN WIESENSGTR. 5, 63225 LANGEN, GERMANY, AS BEIJING BIOSIS HEALING BIOLOGICAL TECHNOLOGY Co, Ltd AUTHORIZED DISTRIBUTOR TO CARRY OUT SALES/DISTRIBUTION OF THE PRODUCTS MEDICAL PROTECTIVE COVERALL-BH800 MEDICAL, PROTECTIVE COVERALL-BH500, MEDICAL SURGICAL MASK, MEDICAL FACE MASK, PROTECTIVE MASK KN95 (FFP2) IN EUROPE, NORTH AMERICA, AFRICA, MIDDLE EAST AND KOREA.

ALL PRODUCTS SOLD TO ABOVE COUNTRIES WHICH WILL BE SUPPLIED BY GMMIT GmbH . WE PROMISE TO SUPPLY PRODUCTS SAFETY, HYGIENE, LEGAL AND BEST SERVICE. ANY OTHER COMPANIES (OR ANY AGENTS) WHO SELL OUR PRODUCTS IN ABOVE COUNTRIES WITHOUT OUR LETTER OF AUTHORIZATION (OR EXPIRED ONES) , WILL NOT BE GUARANTEED THE PRODUCT THAT IS A GENUINE AND LEGITIMATE.

THIS AUTHORIZATION IS VALID FROM 30<sup>th</sup> March 2020 TO 30<sup>th</sup> March 2023.

AUTHORIZED BY: 北京博辉瑞进生物科技有限公司  
BEIJING BIOSIS HEALING BIOLOGICAL TECHNOLOGY Co, Ltd

Principal SIGNATURE:

Company Seal: *Bo Zhao*

Place: Beijing

DATE: 30<sup>th</sup> March. 2020

• 专注再生医学 植入健康信赖 • Biosishealing Implant Trust



# Isolation Gowns-BH100 FDA Registration



BIOSIS HEALING  
博辉瑞进

U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

Follow FDA | En Español

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

## Establishment Registration & Device Listing

FDA Home Medical Devices Databases

1 result found for **Establishment Registration**  
or Business Trade Name : *beijing biosis*

New Search

Establishment Name	Registration Number	Current Registration Yr
<a href="#">BEIJING BIOSIS HEALING BIOLOGICAL TECHNOLOGY CO., LTD</a> CHINA	3016668451	2020
Non-Surgical Isolation Gown - Isolation Gowns: Medical Protective Clothing		Manufacturer
Accessory: Surgical Apparel - Medical Face Shield: Medical Goggle: Protective Goggle		Manufacturer
Face Mask (Except N95 Respirator) For General Public/Healthcare Personnel Per Lie Guidance - Medical Face Mask		Manufacturer
Cover: Shoe: Operating-Room - Medical Shoe Cover		Manufacturer

Can't find what you're looking for? [Try a new search](#)

U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

Follow FDA | En Español

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary

## Establishment Registration & Device Listing

FDA Home Medical Devices Databases

New Search Back To Search Results

Proprietary Name: Isolation Gowns: Medical Protective clothing  
Classification Name: NON-SURGICAL ISOLATION GOWN  
Product Code: OEA  
Device Class: 1  
Regulation Number: [878.4040](#)  
Medical Specialty: General & Plastic Surgery  
Registered Establishment Name: [BEIJING BIOSIS HEALING BIOLOGICAL TECHNOLOGY CO., LTD](#)  
Registered Establishment Number: 3016668451  
Owner/Operator: [Beijing Biosis Healing Biological Technology Co., Ltd](#)  
Owner/Operator Number: 10062854  
Establishment Operations: Manufacturer

All information can. be double-checked from this official web: [www.accessdata.fda.gov](http://www.accessdata.fda.gov)

• 专注再生医学 植入健康信赖 • Biosishealing Implant Trust





# Isolation Gowns-BH100 Conformity and CE



BIOSIS HEALING  
博辉瑞进

DAkkS  
Deutsche  
Akademie  
für  
Normung  
DIN 1321-01-02

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:

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, Verres needle, Scar Silicon gel, Chitosan Gel, Clip Applicators and Removers, Band-aid, Ligating clips, 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.

Report No.: BJ1923301

Valid from: 2019-04-15  
Valid until: 2022-04-14

Date: 2019-04-15

Stefan Prell

Page 1 of 1  
TÜV SÜD Product Service GmbH - Certification Body - Ridenstraße 65 • 80339 Munich • Germany

博辉瑞进生物科技

Declaration of Conformity

Manufacturer Address: 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.

European Representative: SHANGHAI INTERNATIONAL HOLDING CORP.GMBH (EUROPE)  
EFFSTRASSE 80, 20537 HAMBURG, GERMANY

We, the manufacturer, herewith declare that the products

Isolation Gowns  
S-160, M-165, L-170, XL-175, XXL-180, XXXL-185

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

CE

WE, AS THE MANUFACTURER,  
ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY

Valid from: 2020 - 04 - 22  
Valid until: 2024 - 04 - 21

Bo Zhao  
Signature of General Director



# Isolation Gowns-BH100 EN13982 Test Report



BIOSIS HEALING  
博辉瑞进

**CHTC 检验报告 TEST REPORT**

No.: BA20000612-25 Page 1 of 2

Applicant: Beijing Biosis Healing Biological Technology Co., Ltd.

Manufacturer: —

Trade Marks: —

Sample Name: Single-use isolation gowns for medical

Color: —

Submitted Sample Description: Quantity: 1, Description: type 5 Yellow protective clothing

Sample Grade: —, Safety Category: —

Style No.: —

Test Type: Requested Examination Date Received: 2020-04-22 Date Issued: 2020-04-30

Performance Standard: ISO 13982-1:2004/AmD 1:2010 Protective clothing for use against solid particulates-Part 1 performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates (type 5 clothing)



Approved by:   
Wang Baojun (Director)

This report is valid only for the samples delivered by clients.  
If there is any objection concerning the report, it is required that the objection should be put forth to the center within 15 days from the reception date of the report.

Notes: Measurement uncertainty is not considered on the results and conformity assessment in the report unless required by the customer.  
\*The test isn't requested for confirmation temporarily.

China Test & Certification Services Co., Ltd.  
Address: No. 3 Yongqiang Middle Street, Chaoyang District, Beijing 100175, China Tel: +86-400-0088888  
Fax: +86-400-0088888

**CHTC 检验报告 TEST REPORT**

No.: BA20000612-25 Page 2 of 2

Requirement	Results	Judgement
Abrasion resistance (cycles) EN 530-2080	>30 >2000	Pass
Tear resistance (N) ISO 9079-4:1997	>10 >10	Pass
Longitudinal Crosswise Specimen is torn abnormally	>10 >10	
Seam strength(N) EN ISO 13935-2:2014	>30 47	Pass
pH value EN 1413:1996	3.5-9.5 6.6	Pass
Colour fastness to perspiration(Grade) ISO 105-E04:2013	2-4 4-5	Pass
Change colour Azo Dyes(mg/kg) EN ISO 14362-1:2017	Not detected Not detected	Pass

The low limit is mg/kg, the result is reported as "not detected" if it is below the limit.

End of report

China Test & Certification Services Co., Ltd.  
Address: No. 3 Yongqiang Middle Street, Chaoyang District, Beijing 100175, China Tel: +86-400-0088888  
Fax: +86-400-0088888



# Isolation Gowns-BH100 Standard



BIOSIS HEALING  
博辉瑞进

Model	Standard EU	Product Standard Compliance	Scope of application
BH100	EN13982-1:2004 <b>With No Puncture Resistance</b>	•京大械备20200065	Used for general isolation in • out-patient • ward • laboratory of medical institution

Please noted specifications for some other countries :

1. Passed the test equivalent to EN13982-1:2004 protection standard.
2. Medical device recordation certificate of Isolation Gowns: Beijing Daxing medical device recordation certificate number No.20200065.



# Performance Introduction of Isolation Gowns-BH100



BIOSIS HEALING  
博辉瑞进



## Isolation gowns

Using the PE coated PP non-woven fabric as the raw material.  
Isolation gown has neckband,  
waistband together with elastic cuff wrist as one piece structure.

- ※ High-density polyethylene composite polypropylene spunbond no
- ※ Elasticated openings around the wrists



Using the PE coated PP non-woven fabric as the raw material. Isolation gown has neckband, waistband together with elastic cuff wrist as one piece structure.

### 【Working principle】

The main raw material of the isolation gown adopts high-density polyethylene (PE) composite polypropylene (PP) non-woven fabric as the main raw material. The PE on the surface of the material greatly improves the properties of moisture resistance, liquid penetration resistance and microbial penetration resistance. The material also has good antistatic properties to prevent the adsorption of microorganisms and solid particles. At the same time, the material has good breathability, ensuring the comfort of medical staff wearing. The gown can effectively prevent the infiltration of dust particles and bacteria and other harmful substances, and protect the health of medical personnel.

Neckband design, firm without falling off

Antistatic treatment to reduce the absorption of harmful substances.

Waistband design to tighten the isolation gown.

Elastic cuffs for tighter protection



Using the PE coated PP non-woven fabric as the raw material.



### 【Features】

- The PE on the surface of the material greatly improves the properties of moisture resistance, liquid penetration resistance and microbial penetration resistance.
- Block viruses, bacteria, microorganisms.
- Isolation protection.
- High strength and toughness, durable and tear resistance.
- Antistatic treatment, reduce the adsorption of harmful substances.
- Neckband design, firm without falling off.
- Antistatic treatment to reduce the absorption of harmful substances.
- Waistband design to tighten the isolation gown.
- Elastic cuffs for tighter protection.



Elastic cuffs for tighter protection



Using the PE coated PP non-woven fabric as the raw material.



Neckband design, firm without falling off

### 【Application】

It is used for general isolation in medical institutions' clinics, wards, and test rooms.

### 【Specifications】

Isolation gown has neckband, waistband together with elastic cuff wrist as one piece structure.

### 【Specifications and sizes】

Model	Length (±5cm)	Unfolded width (±10cm)
S-160	118	150
M-165	120	152
L-170	123	153
XL-175	125	155
XXL-180	127	157
XXXL-185	130	160





# Instruction of Use of Isolation Gowns-BH100



BIOSIS HEALING  
博辉瑞进



BIOSIS HEALING



## Isolation Gowns

Size:120cm(length)/140cm (bust)

**Instructions:** Isolation gown has neckband, waistband together with elastic cuff wrist as one piece structure. Following the general principle in hospital to wear or take off the isolation gown. Replace it immediately if any damage is found.

**Produced date:**

**Validity:** 2 years



Manufacturer



Production Lot Number



Authorised Representative In The European Community



Name: Beijing Biosis Healing Biological Technology Co.,Ltd

Address: No.6 plant west, Valley No.1 Bio-medicine Industry Park,  
Daxing District, 102600 Beijing, China

Tel: 86-10-61252660 Fax: 86-10-61252030

Web: www.biosishealing.com



Name: Shanghai International Holding Corp.GmbH(Europe)

Address: Eiffestrasse 80,20537 Hamburg,Germany

Tel: +49-40-2513175 Fax: +49-40-255726



BIOSIS HEALING

## Isolation Gowns

△ Please read the product instruction for use carefully before use

**[Product name]** Isolation Gowns

**[Expected usage]** It is used for general isolation in medical institutions' clinics, wards, and test rooms.

**[Product mode/specifications]**

Isolation gown has neckband, waistband together with elastic cuff wrist as one piece structure.

Size:120cm(length)/140cm (bust).

Color:blue or yellow.

**[Structural composition]** Non-woven fabric.

**[Working principle]**

By effectively filtering and blocking the penetration of dust particles, bacteria and other harmful substances in the air, the product can offer protection for the medical staff.

**[Applicable people]** Medical staff in medical institutions.

**[Contraindications]** Use with caution to those allergic to the ingredients of this product.

Do not use if the gown is damaged.

**[Instructions]**

**Take on the gown:**

1. Hold the collar with right hand, put the left hand into the left sleeve. While pulling the collar upward.

2. Exchange hands to do the same procedure,exposing two hands without touching face.

3. Fasten the neckband in the back.

4. Find two edges of gown by pulling a bit forward.

5. Align the edges of your clothing with your hands behind your back.

6. Fold the edges to one side, hold the fold at one hand, and pull out the belt with another hand.

7. Cross the belt at the back and fasten the belt back to the front.

**Take off the gown:**

1. Open the belt and tie a slipknot at the front. Disinfect the hands.

2. Loosen the neckbands.

3. Put right hand inside left sleeve and pull down it.

4. Hold the outside of the right sleeve with left hand while it is still covered by sleeve.

5. Gradually withdraw from the sleeve and take off the isolation gown.

6. At last, take off the isolation gown, pollution facing inward, roll it into a package, throw it into the clinical waste container or put it into the recycling bin.

**[Precautions]**

1. Read the instructions and precautions before putting on it;

2. When the gown is found to be damaged, it should be replaced in time, and be cautious of contamination when taking off.

**[Features]**

1. The material is soft, comfortable, and has good barrier properties against bacteria and liquids;

2. It can effectively prevent the infiltration of harmful substances and is safe and convenient to use;

3. Mature technology, clear ingredients, no side effects;

4. Meet the requirements for medical staff to use and dress freely.

**[Warnings and instructions]**

1. This product is non-sterile and should not be used in a sterile environment;

2. The waste shall comply with the waste disposal methods prescribed by national or local regulations.

**[Storage and transportation conditions]**

Store at room temperature, dark and cool place

**[Validity]** Two years

**[Graphic/symbol explanation]**



Authorized representative  
in the European Community



Batch code



Manufacturer



Warning



Keep away from sunlight



Do not reuse



Production Date



CE marking of conformity



Keep dry



Consult instructions for use



Manufacturer information

Name: Beijing Biosis Healing Biological Technology Co.,Ltd

Address: No.6 plant west, Valley No.1 Bio-medicine

Industry Park,Daxing District, 102600 Beijing, China,

Post Code: 102600

Tel: 0086-10-61252660

Fax: 0086-10-61252030

Email: info@biosishealing.com



European Representative

Name: Shanghai International Holding Corp.GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Post Code: 20537

Tel: +49-40-2513175

Fax: +49-40-255726




## Product packaging information



BIOSIS HEALING  
博辉瑞进



- ✓ Tray volume: 95x95x187cm (total height, excluding blue chassis);
- ✓ Carton size: 480x450x415mm, aviation weight of 15kg, each carton size is 0.09m<sup>3</sup>, 16 cartons are a tray, total 1.44m<sup>3</sup>;
- ✓ Container: 20 feet container, can hold 310 cartons, 40 feet container can hold 610 cartons.

Picture.	Product Name	Model	Carton Volume (pcs/box)	Carton Dimension (mm)	Carton N.W (kg)
	Isolation Cowns-BH100	S M L XL	100	480x450x415mm	11.5



BIOSIS HEALING  
博辉瑞进

THANK YOU



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