



BOSIS HEALING
博辉瑞进

Isolation Gowns-BH100

EN13982-1: 2004



GMMIT GmbH Wiesenstr.5 , 63225 Langen, info@gmmit.com, www.gmmit.com



Professionelle Produktion

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





Zertifizierter Vertriebspartner

15 Jahre Erfahrung im Handel zwischen Deutschland und China

Vertriebsbüros in Beijing , Shanghai und Hongkong

Eigene Lager und Logistik

<https://www.gmmit.com>





Isolation Gowns-BH100 FDA Registration



U.S. Department of Health & Human Services

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Establishment Registration & Device Listing

• FDA Home • Medical Devices • Databases

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

Establishment Name	Registration Number	Current Registration Yr
BEIJING BIOSIS HEALING BIOLOGICAL TECHNOLOGY CO., LTD CHINA	3016668451	2020

- Non-Surgical Isolation Gown - Isolation Gowns, Medical Protective Clothing
- Accessory, Surgical Apparel - Medical Face Shield, Medical Goggle, Protective Goggle
- Face Mask (Except N95 Respirator) For General Public/Healthcare Personnel Per Iie
- Cover, Shoe, Operating-Room - Medical Shoe Cover

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Establishment Registration & Device Listing

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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



Isolation Gowns-BH100 Conformity and CE



ISO 9001
ISO 13485
EN ISO 13485
CE
FDA
TUV SUD
DAkkS
ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書



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:



Scope of Certificate:
Design, Development, Production, Distribution and Sales of
Disposable Circular Stapler, Disposable Linear Stapler and Reloads,
Disposable Hemorrhoid Stapler, Disposable Linear Cutter Stapler
and Reloads, Disposable Circumcision Stapler, Wound Protector,
Disposable Skin Staplers, Disposable Specimen Retrieval Bag,
Disposable Hemorrhoid Ligator, Disposable Hemorrhoid Stapler
and Reloads, Disposable Hemorrhoid Ligator, Veress
needle, Scar Silicon gel, Chitosan Gel, Clip Applicators and Removers,
Band-aid, Lighting 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 TUV SUD 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 Preiß

Page 1 of 1
TUV SUD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich, Germany
TUV 博辉瑞进生物科技





Isolation Gowns-BH100 EN13982 Test Report



CTC 检验报告
TEST REPORT

No.: BA20000612-25

IMA
CMA
CNAS

LA
CNAS

ISO17025
CNAS

ISO17025
CNAS

ISO17025
CNAS

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Applicant	Beijing Biosis Healing Biological Technology Co., Ltd				
Manufacturer	—				
Submitted Sample Description	Trade Marks: — Sample Name: Single-use isolation gowns for medical Color: — 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/tnl.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 Ranjun (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.

中国纺织产品监督检验中心
中国纺织工业联合会质量监督检验检测中心
中国纺织产品监督检验中心
中国纺织产品监督检验中心

Chinatex Textile Testing & Certification Services Tel: +86-10-63036311 400-086-0486
Add: No.3 Yuxingjie, Modu Street, Chaoyang District, Beijing 100028, China. Fax: +86-10-63036399
Email: bj.cttc@cttc.org

www.cttc.org.cn

CTTC 检验报告
TEST REPORT

No.: BA20000612-25

中国合格评定国家认可委员会
CNAS-CC01:2016
CNAS-CL01:2016

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Requirement	Results	Judgement	
Abrasion resistance (cycles) EN 530-2010	> 30	>2000	Pass
Tear resistance [N] ISO 9073-4:1997			Pass
Longitudinal	> 30	> 10	
Crosswise	> 30	> 10	
Specimen is torn abnormally			
Seam strength(N) EN ISO 18935-2:2014			Pass
	> 30	47	
pH value EN 1413:1998	3.5-9.5	6.6	Pass
Colour fastness to perspiration[Grade] ISO 105-E04:2013			Pass
Change colour	≥4	4-5	
Azo Dyes(mg/kg) EN ISO 14362-1:2017	Not detected	Not detected	Pass
The low limit is 5mg/kg, the result is reported as "not detected" if it's below the limit.			

End of report.

中国合格评定认可有限公司
中国纺织纤维检验中心
法定纤维检验机构
法定纤维检验机构
法定纤维检验机构

China Textile Testing & Certification Services
Add: No.3 Yerjiao Middle Street, Chaoyang District, Beijing 100125, China Tel: +86-10-58262122/400-886-2488
邮编: 100125
法定纤维检验机构
法定纤维检验机构
法定纤维检验机构

00000000000000000000000000000000

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Model	Standard EU	Product Standard Compliance	Scope of application
BH100	EN13982-1:2004 With No Puncture Resistance	•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

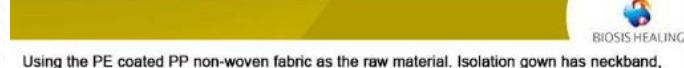


BIOSIS HEALING

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.



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.



【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



5
PCS

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



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.

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

[Size] 120cm(length)/140cm (bust)

[Color] blue or yellow.

[Material] Non-woven fabric.

[Working principle] By effectively filtering and blocking the penetration of dust particles, bacteria and other harmful substances in the air.

[The use of the product] Protection for 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] Do not use if the gown is damaged.

[Instructions]

[Take on the gown]

1. Hold the gown 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. Fix the waistband in the front, using 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 edges 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. Lift the gown neckband.
3. Put right hand inside left sleeve and pull down it.
4. Hold the outside of the right sleeve with right hand, while it is still covered by sleeve.
5. Cross the edges of the sleeves 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 contact with other gowns when taking off.

[Features]

1. The material is 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.

[Usage]

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]

EC REP Authorized representative **Lot** Batch code **Manufacturer** **CE** marketing of conformity **Warning** **Keep away from sunlight**

Do not re-use **Production Date** **CE**

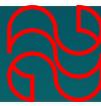
Keep dry **Consult instructions for use**

EC REP European Representative

Manufacturer:

Beijing Biosis Healing Biological Technology Co.,Ltd
Address: No.6 plant west, Valley No.1 Bio-medicine Industry Park, Daxing District, 102600 Beijing, China.
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Name: Shanghai International Holding Corp. GmbH (Europe)
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Post Code: 20537
Tel: +49-40-2513175
Fax: +49-40-255726



- ✓ Tray volume: 95x95x187cm (total height, excluding blue chassis);
- ✓ Carton size: 480x450x415mm, aviation weight of 15kg, each carton size is 0.09m³, 16 cartons are a tray, total 1.44m³;
- ✓ 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
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THANK YOU



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