



BIOSIS HEALING
博辉瑞进

Medical Protective Coverall-BH500 TYPE 5

EN14126 / EN13982 ISO13982-1



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

Professionelle Produktion

- Renommierter Hersteller für PSA
- Modernste Produktionsanlagen und Sicherheitskonzepte
- Speziell für den EU-Markt entwickeltes Qualitätsprodukt
- <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 30th March 2020 TO 30th 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: 30th March. 2020

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

Medical Protective Coverall-BH500 FDA Registration



U.S. Department of Health & Human Services

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FDA U.S. FOOD & DRUG ADMINISTRATION

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
BEIJING BIOSIS HEALING BIOLOGICAL TECHNOLOGY CO., LTD 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 IIE Guidance - Medical Face Mask		Manufacturer
Cover - Shoe - Operating-Room - Medical Shoe Cover		Manufacturer

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U.S. Department of Health & Human Services

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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: [QEA](#)

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



Medical Protective Coverall-BH500 Conformity and CE



BIOSIS HEALING
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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 Trecar, Disposable Endoscopic Linear Cutter Stapler and Reloads, Disposable Hemorrhoid Ligator, Veress 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.: BJ1823301
Valid from: 2019-04-15
Valid until: 2022-04-14

Date, 2019-04-15

S. Prell
Stefan Prell

Page 1 of 1

TÜV SÜD Product Service GmbH • Certification Body • Ridderstraße 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)
EIFFESTRASSE 80, 20537 HAMBURG, GERMANY

We, the manufacturer, herewith declare that the products

Medical Protective Coverall-BH500
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 - 03 - 03
Valid until: 2024 - 05 - 27

Standard NO. EN 14126: 2003 EN 13982-1 & 2 : 2011 Type5

Bo Zhao
Signature of General Director



Medical Protective Coverall-BH500 EN13982 Test Report



BIOSIS HEALING
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cttc 检验报告
TEST REPORT



(No.): BA20000277



Page 1 of 2

Applicant	Beijing Biosis Healing Biological Technology Co., Ltd	Test Type	Requested Examination
Manufacturer	Beijing Biosis Healing Biological Technology Co., Ltd	Client	Ting Jiang
Sample Name	Medical Protective Coverall-BH500	Date received	2020-03-12
Submitted Sample Description	White nonwoven fabric, Type 5	Date issued	2020-03-17
Performance Standard	ISO 13982-1:2011 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

王辉

Wang Huijun (Director)



Notes

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.
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.

中国博辉瑞进生物技术有限公司
中国检验认证集团北京检测认证中心
北京市通州区台湖镇亦庄经济开发区
国家质检总局北京检测认证中心

China Testing Center for Textiles & Clothing Services Tel: 010-65002813 400-086-0486
Add: No.3 Yanqinli Middle Street, Chaoyang District, Beijing 100025, China Fax: 010-65002899
地址: 北京市朝阳区安立路3号 100025

www.cttc.net.cn

cttc 检验报告
TEST REPORT



(No.): BA20000277



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Items	Requirement (Class1)	Results	Judgement	Test Methods
Adhesion property(cycles)	>10	>2000	Pass	EN 530-2010*
Tearing strength(N)	Longitudinal >10	>48	Pass	ISO 9073-4:1997
	Crosswise >10	>24		
Piercing force(N)	>5	8.9	Pass	EN 863:1995*
Seam strength(N)	>30	110	Pass	EN ISO 13935-2:2014
pH value	3.5-9.5	9.5	Pass	EN 1413:1998
Colour fastness to perspiration(Grade)	Change colour: ≥4	4-5	Pass	EN ISO105-E04:2013
Aze Dye(24) mg/kg	Not detected	Not detected	Pass	EN 14362-1:2017

Notes: 1. The extracting solution is RCI solution.

2. The low limit is 5mg/kg, the result is reported as "not detected" if it is below the limit.

End of report



中国检验认证集团北京检测认证中心
中国检验认证集团北京检测认证中心
北京市通州区台湖镇亦庄经济开发区
国家质检总局北京检测认证中心

China Testing Center for Textiles & Clothing Services Tel: 010-65002813 400-086-0486
Add: No.3 Yanqinli Middle Street, Chaoyang District, Beijing 100025, China Fax: 010-65002899
地址: 北京市朝阳区安立路3号 100025

www.cttc.net.cn



Medial Protective Coverall-BH500 Standard



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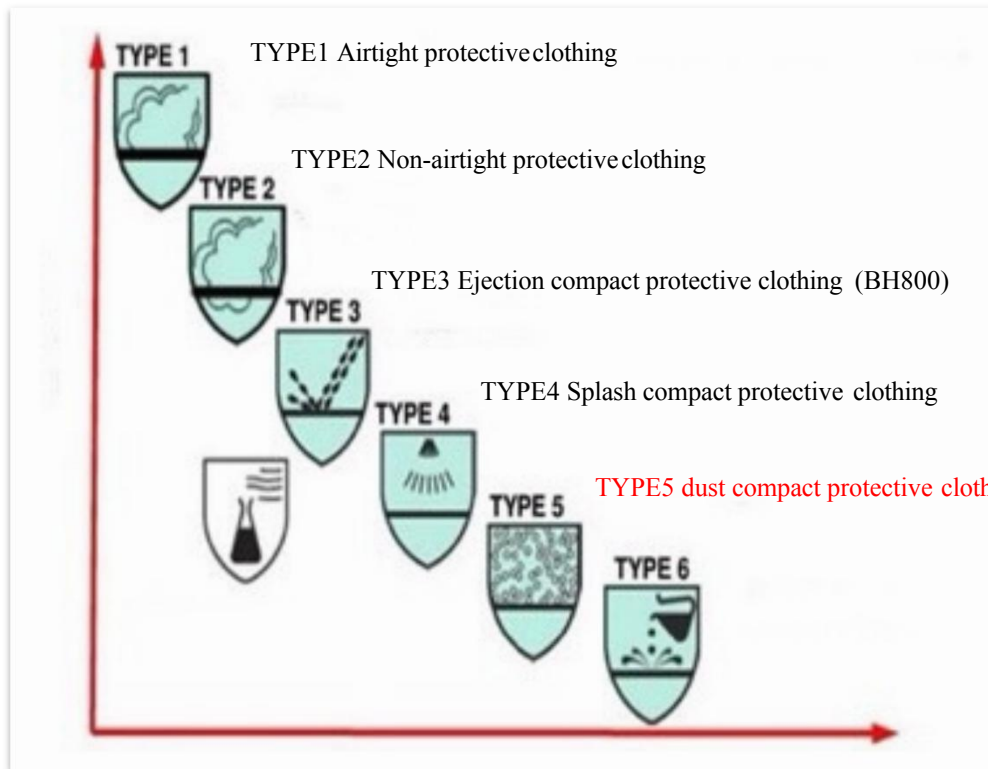
Model	Standard EU	Standard US	Key Features
BH500	<ul style="list-style-type: none">• EN14126• EN13982 ISO13982-1 Coverall Type5	<ul style="list-style-type: none">• AAMI PB-70 Medical Protective Coverall	<p>Used for general isolation in</p> <ul style="list-style-type: none">• out-patient• ward• laboratory of medical institution
<p>Please noted specifications for some other countries :</p> <p>1. Passed the test equivalent to EN14126、EN13982、EN13034-1&2 protection standard</p>			



European Classification Standard of Medical Protective



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Application: Type4 Level and above Level Medical Protective Coverall can be used in the places with higher levels of protection (e.g: ICU Isolation Approach).

European Standard : Type3 and Type4 accord with EN14126、EN14605、EN13982、EN13034-1&2.

Application: Type5 Level and Type6 Level Medical Protective Coverall can be used in the places with relatively low levels of protection (e.g: Fever Clinics, General Isolation Approach) .

European Standard :
Type5 accord with EN14126、EN13982、EN13034-1&2;
Type6 accord with EN14126、EN13034-1&2



Performance Introduction of Medical Protective Coverall-BH500



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Medical Protective Coverall-BH500

Protect against particulates infiltration and barrier to infective agents

- ※ Type 5 and type 6 protection
- ※ Elasticated wrists, ankles and face, hooded coverall
- ※ High-density and high gram-weight spunbond non-woven of 68g/m²
- ※ Self-adhesive zipper is to prevent direct penetration of fluid into the clothing

High-end PE coated spunbond non-woven materials, through cutting and sewing into thickened hooded bodysuits, leaving openings around the face, wrists and ankles, no waist tightening so that doctors can move freely

【Working principle】

The material is subjected to secondary coating treatment on the surface of high-density polymer long-fiber heat-sealed non-woven fabric to form a high-strength, thickened, moisture-resistant, and penetration isolation protective layer.



It effectively filters and blocks the penetration of dusts, bacteria and other harmful substances in the air



【Features】

- Meets the technical requirements for CE&FDA
- Enhanced water resistance, synthetic blood penetration resistance, surface moisture resistance, to prevent particles effectively.
- Class 5 protection and class 6 protection (limited liquid splashing).
- PE coating enhances resistance to liquid penetration, and is moisture-proof, breathable, flexible, non-combustible, easy to decompose, non-toxic and nonirritating, etc.
- High elasticity offers free movement.
- High strength and tenacity, durable and tear resistance.
- Antistatic treatment, reduce the adsorption of harmful substances.
- There is elastic at facial part, wrist and ankles, 30% more protective area than ordinary isolation clothing.
- High-density sewing and front zipper protection to enhance isolation protection.



【Package】

Independent packing, 48pcs/carton.

【Application】

Used as a general isolation for doctors in medical institutions, wards, examination rooms, etc.

【Specifications and sizes】

Model	Height (cm)	Chest size(cm)
S-160	165	120
M-165	169	125
L-170	173	130
XL-175	178	135
XXL-180	181	140
XXXL-185	188	145



Face / wrists / ankles with elastic closures, 30% more protection



Self-adhesive zipper is to prevent direct penetration of fluid into the clothing



High-end PE coated spunbond non-woven materials.

manufacture

batch number

Refer to the operating instructions

warning




Product packaging information



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- ✓ 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)
	Medical Protective Coverall-BH500	S M L XL	25	480x450x415mm	9.86



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THANK YOU



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