



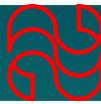
BOSIS HEALING  
博辉瑞进

# 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.bosishealing.com>





## Zertifizierter Vertriebspartner

15 Jahre Erfahrung im Handel zwischen Deutschland und China

Vertriebsbüros in Beijing , Shanghai und Hongkong

Eigene Lager und Logistik

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U.S. Department of Health & Human Services

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## Establishment Registration & Device Listing

① FDA Home ② Medical Devices ③ 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

④ Non-Surgical Isolation Gown - Isolation Gowns; Medical Protective Clothing  
④ Accessory, Surgical Apparel - Medical Face Shield; Medical Goggle; Protective Goggle  
④ Face Mask (Except N95 Respirator) For General Public/Healthcare Personnel Per ie Guidance - Medical Face Mask  
④ Cover, Shoe, Operating-Room - Medical Shoe Cover

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## Establishment Registration & Device Listing

① FDA Home ② Medical Devices ③ 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:	8784040
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)



# Medical Protective Coverall-BH500 Conformity and CE



DAKKS  
Deutsche  
Akkreditierungsstelle  
D-ZM-11321-01-00

TÜV SÜD  
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich, Germany  
TUV SÜD 博辉瑞进

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT



Product Service

## Certificate

No. Q6 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 Endotracheal Tube, Disposable Endotracheal Cutter Stapler and Reloads, Disposable Hemorrhoid Ligator, Veress needle, Scar Silicon gel, Chitosan Gel, Clip Appliers and Removers, Band-aid, Lighting 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.

**Report No.:** BJ1823301

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

**Date:** 2019-04-15

Stefan Preiß

*I. Preiß*

Page 1 of 1

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# Medical Protective Coverall-BH500 EN13982 Test Report



BIOSIS HEALING  
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CTC 检验报告  
TEST REPORT



(No.): BA20000277

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-Part1: Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates. (Type 5 clothing)		



Approved by

Wang Jianjun (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.

中国检验检疫科学研究院  
中国医药保健品进出口商会质量检验检测中心  
进口医疗器械质量检测中心  
进口医疗器械质量检测中心

China Inspection & Testing Certification Services Tel: 010-65002813 400-096-0486  
Add: No.3 Yantai Middle Street, Chaoyang District, Beijing 100025, China Fax: 010-65075599  
E-mail: 3087778611@qq.com Web: www.cti.org.cn

www.cti.org.cn

CTC 检验报告  
TEST REPORT



(No.): BA20000277

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: 2Δ	4-5	Pass	EN ISO105-E04:2013
Azo Dyes(24) mg/kg	Not detected	Not detected	Pass	EN 34362-1:2017

Notes: 1. The extracting solution is KCl solution  
2. The low limit is 5mg/kg, the result is reported as "not detected" if it is below the limit.

End of report



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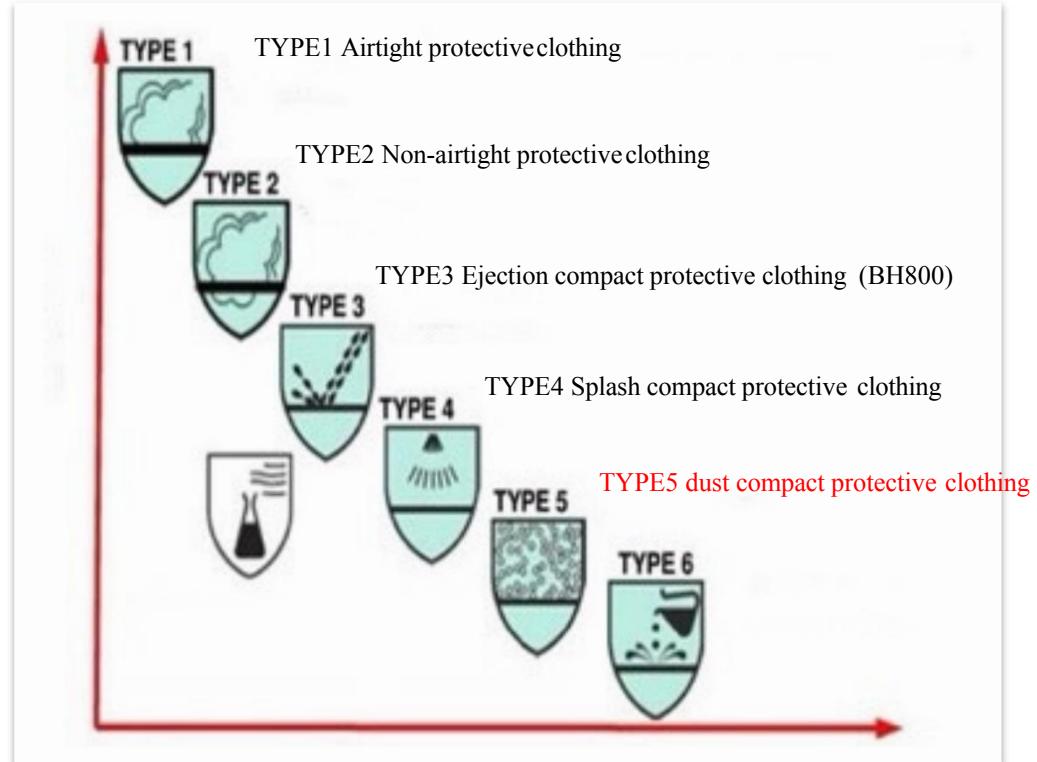
Model	Standard EU	Standard US	Key Features
<b>BH500</b>	<ul style="list-style-type: none"><li>• EN14126</li><li>• EN13982 ISO13982-1 <b>Coverall Type5</b></li></ul>	<ul style="list-style-type: none"><li>• AAMI PB-70 <b>Medical Protective Coverall</b></li></ul>	<p><b>Used for general isolation in</b></p> <ul style="list-style-type: none"><li>• out-patient</li><li>• ward</li><li>• laboratory of medical institution</li></ul>

**Please noted specifications for some other countries :**

**1. Passed the test equivalent to EN14126、EN13982、EN13034-1&2 protection standard**



# European Classification Standard of Medical Protective



**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



## 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/m<sup>2</sup>
- ※ 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.



### 【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 tensility, 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



■ manufacturer

■ batch number

□ Refer to the operating instructions △ warning

High-end PE coated spunbond non-woven materials;



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



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THANK YOU



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