



BIOSIS HEALING
博辉瑞进

Medical Protective Coverall-BH800 TYPE 3

EN14605/466 EN14126



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

Professionelle Produktion

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





GMMIT GmbH, Langen , Deutschland



BIOSIS HEALING
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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

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Medical Protective Coverall-BH800 FDA Registration



U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

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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*

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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Establishment Registration & Device Listing

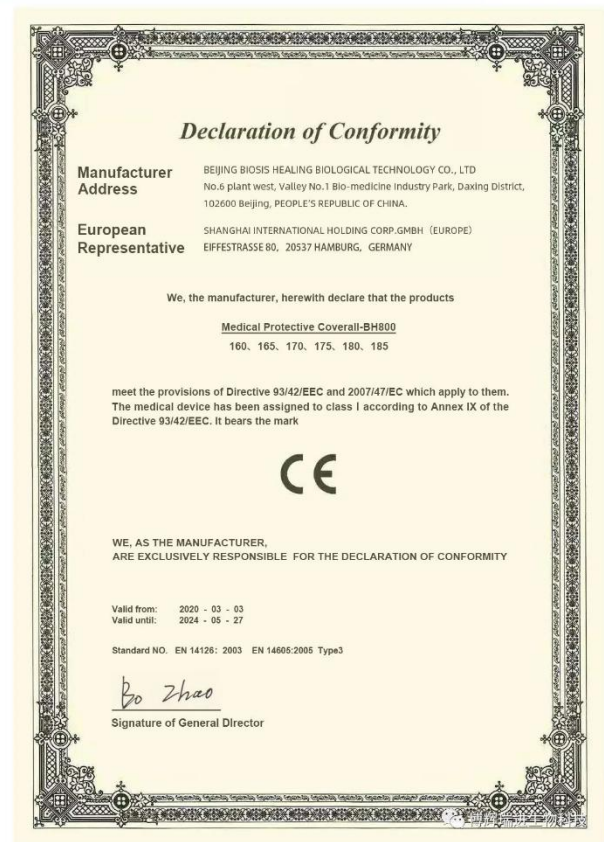
FDA Home Medical Devices Databases

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

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SGS

Remark(s) : M=Meet Client's Requirement

Sara Guo
Sara Guo (Account Executive)



Member of the SGS Group (SGS SA)

SGS

End of Report



Member of the SGS Group (SGS SA)



Medial Protective Coverall-BH800 Standard



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Model	Standard CN	Standard EU	Standard US	Key Features
BH800	GB 19082-2009	<ul style="list-style-type: none">• EN14126• EN14605/466 Ejection Compact Coverall Type3	<ul style="list-style-type: none">• ASTM F1670-98• ASTM F1671-97A• ASTM F903-1999• AAMI PB-70 Medical Protective Coverall	<ul style="list-style-type: none">• Elasticated wrists, ankles and face, hooded coverall.• ICU protective clothing, longer zipper extends to nose for complete protection.• High gram-weight composite nonwovens (SMS) of 78g/m2, soft, lightweight and good air permeability.

Please noted specifications for some other countries :

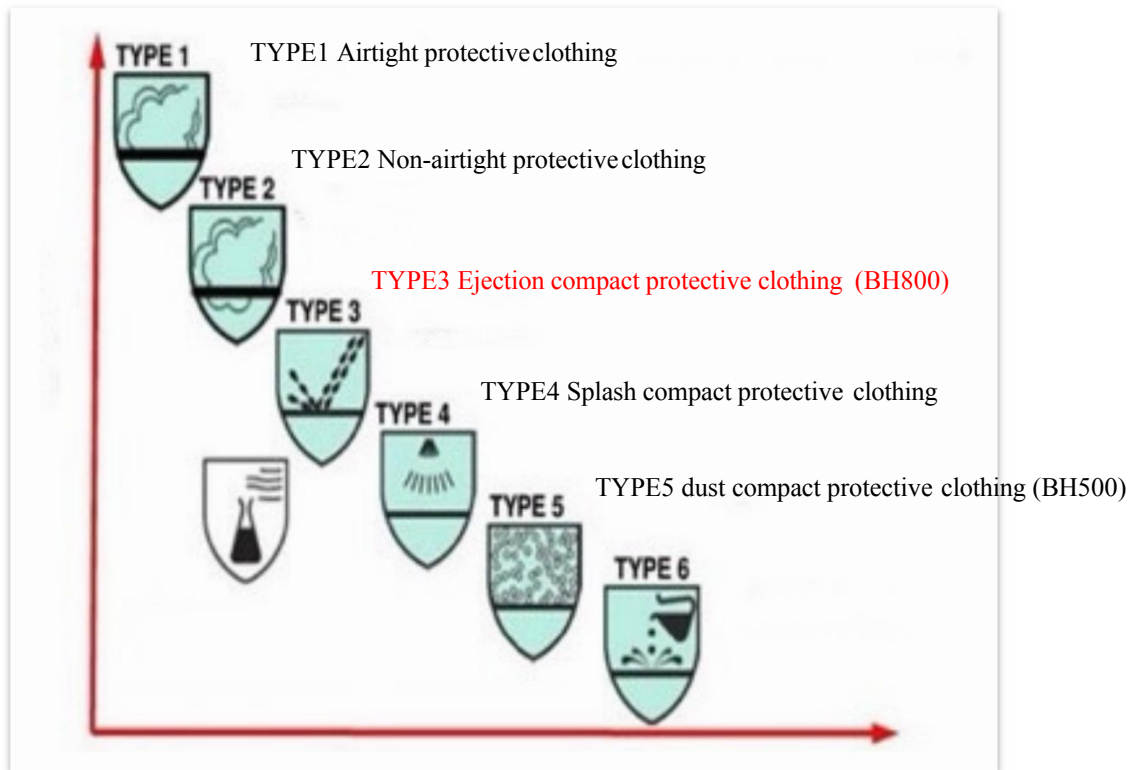
1. Passed the test equivalent to EN14126 protection standard
2. Passed the test equivalent to EN14605、EN13982、EN13034-1&2 protection standard



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-BH800



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Medical Protective Coverall-BH800

Good moisture resistance and synthetic blood penetration resistance
Effectively blocks viruses, bacteria, and microorganisms

- ※ Elasticated wrists, ankles and face, hooded coverall.
- ※ ICU protective clothing, longer zipper extends to nose for complete protection.
- ※ High gram-weight composite nonwovens of 78g/m², soft, lightweight and good air permeability

High gram-weight composite nonwoven material, through cutting and sewing. Seams are covered with special heat sealing tape for protective clothing. The coating can isolate virus gas sol, virus-containing liquid. When taking off, the outer surface of the protective coverall is not in contact with the human body.

【Typical applications】

Can be used for medical staffs at isolation and observation ward (room), Isolation Ward (room) to stop virus spreading from patients to the medical staffs with air or liquid.

【Working principle】

The coverall is made from a high gram-weight composite nonwoven material, through cutting and sewing. Self-adhesive zipper from the front to chin placket protection. Seams are covered with special heat sealing tape for protective clothing. Helps isolate virus and protect against hazardous dusts and liquid, blood splashes.



Self-adhesive zipper is to protect the mouth and chin



There is elastic at facial part, wrist and ankles to maximize the coverage. Wrist loop design for easy removal of the coverall and gloves prevents secondary contamination.



High gram weight composite

【Features】

- Meets the technical requirements for CE&FDA
- High gram-weight composite nonwovens, soft, light, good air permeability, good moisture resistance and anti-synthetic blood penetration ability.
- Seams are covered by special heat sealing tape for protective clothing, effectively block viruses, bacteria, microorganisms.
- Zipper front protection, double-sided adhesive sealed. Double insurance enhances isolation protection.
- High elasticity offers freedom of movement.
- High strength and tensility, durable and tear resistance.
- Antistatic treatment, reduce the adsorption of harmful substances.

【Application】

Can be used for medical staffs at isolation and observation ward (room), Isolation Ward (room) to stop virus spreading from patients to the medical staffs with air or liquid

【Specifications】

This protective clothing includes a hooded top and trousers

【Specifications and sizes】

Model	Height(cm)	Chest size(cm)	Sleeve Length(cm)	Cuff(cm)	Foot mouth(cm)
160	165+5	120	84	18	24
165	169+5	125	86	18	24
170	173+5	130	90	18	24
175	178+5	135	93	18	24
180	181+5	140	96	18	24
185	188+5	145	99	18	24
devia-tion	±2	±2	±2	±2	±2



Instruction of Use of Medical Protective Coverall-BH800



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Product English label



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Disposable Medical Protective Coverall
Type 3-4 product code: BH-800

For Preventing the medical staffs from virus and other germs in air or liquid.

Conform to EN14126, EN13982, EN14605, EN13034

Conform to Directive 93/42/EEC, 2007/47/EC

Specifications	Length (cm)	Bust (cm)	Sleeve Length (cm)	Cuff Width (cm)	Foot Width (cm)
160	178	120	84	15	24
165	183	125	86	15	24
170	198	130	90	18	24
175	203	135	93	18	24
180	208	140	96	18	24
185	213	145	99	18	24
Deviation	±2	±2	±2	±2	±2

Instructions: Follow general contamination prevention principle in hospital to wear or take off the clothing. Replace it immediately if any leakage or damage is found.

Produced date:

Validity: 2 years



Manufacturer



Production Lot Number



Authorized Representative In The European Community



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




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-BH800	S M L XL	25	480x450x415mm	9.86



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THANK YOU



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