



BOSIS HEALING
博辉瑞进

Medical Protective Coverall-BH800 TYPE 3

EN14605/466 EN14126



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



Professionelle Produktion

- Renommierter Hersteller für PSA
- Modernste Produktionsanlagen und Sicherheit
- Speziell für den EU-Markt entwickeltes Qualitätsmanagement
- <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>





Medical Protective Coverall-BH800 FDA Registration



U.S. Department of Health & Human Services

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Establishment Registration & Device Listing

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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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U.S. Department of Health & Human Services

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Establishment Registration & Device Listing

• FDA Home • Medical Devices • Databases

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



Medical Protective Coverall-BH800 Conformity and CE



BIOSIS HEALING
博辉瑞进



Certificate

No. Q5 101395 0001 Rev. 00



Product Service

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:



100-001

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 Laparoscopic trocar, Large Endotracheal Intubation Cutter Stapler and Reloads, Disposable Hemorrhoidal Ligator, Veress needle, Scalp Silicon gel, Chitosan Gel, Clip Amplifiers and Removers, Band-aid, Ligating 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
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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.

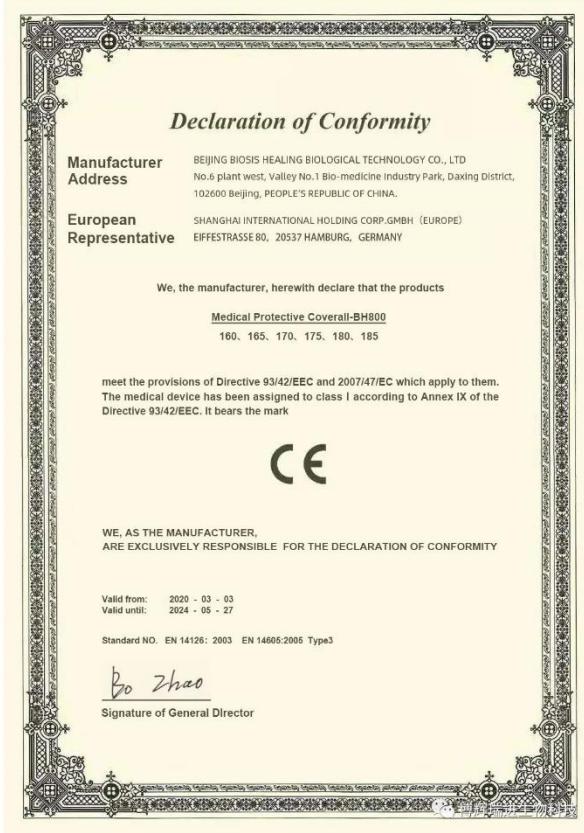
Report No.: BJ1B23301

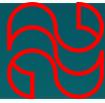
Valid from: 2019-04-15
Valid until: 2022-04-14

Date 2019-04-15

J. Purnip

Stefan Preiß





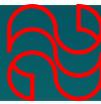
Medial Protective Coverall-BH800 Standard



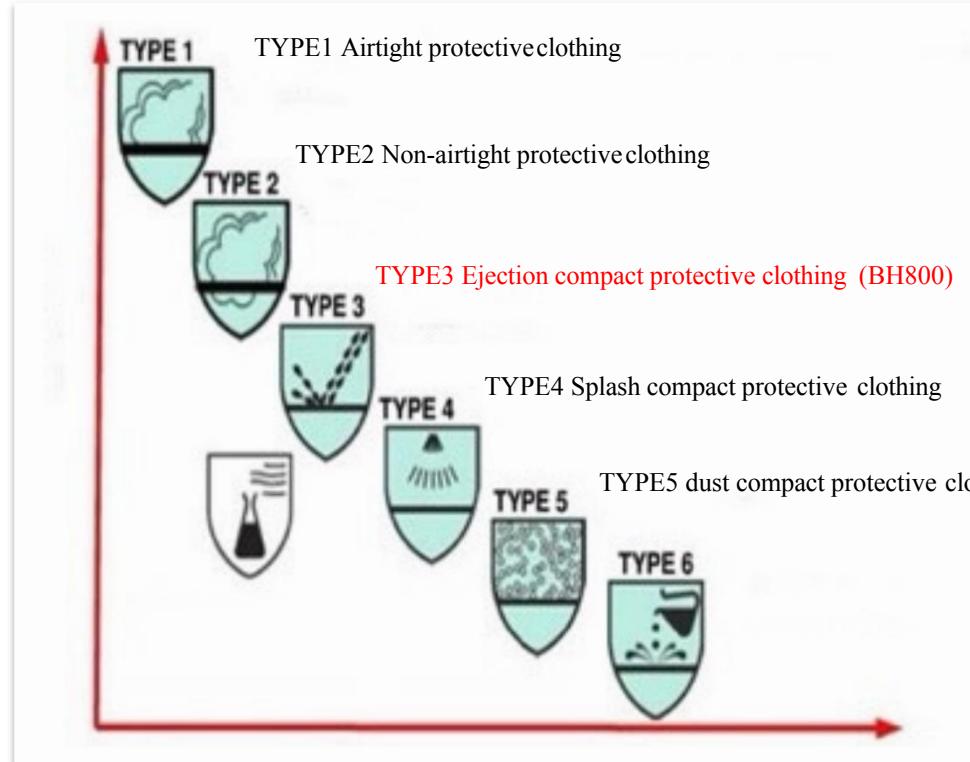
Model	Standard CN	Standard EU	Standard US	Key Features
BH800	GB 19082-2009	<ul style="list-style-type: none">• EN14126• EN14605/466 Ejection Compact Coverall Type3	<ul style="list-style-type: none">• ASTM F1670-98• ASTM F1671-97A• ASTM F903-1999• AAMI PB-70 Medical Protective Coverall	<ul style="list-style-type: 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



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



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.



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.



【Features】

- Meet 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 tensile, 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



Product English Label



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

Authorised Representative In The European Community

Name: Beijing Bosis 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.bosishealing.com

Name: Shanghai International Holding Corp.GmbH(Europe)
Address: Eiffestrasse 80,20537 Hamburg,Germany
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)
	Medical Protective Coverall-BH800	S M L XL	25	480x450x415mm	9.86



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THANK YOU



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