Medical disposable protective Coveralls

1) Brand : Biosis Healing

2) Product Name: Medical Protective Coverall BH800

3) Model: S/M/L/XL

4) Information:

(1) Type: sterility, non-sterility

(2) Standard CN: GB19082-2009

(3) Standard EU: EN14126, EN14605/466,ejection compact, Coverall Type3

(4) Standard US: ASTM F1670-98 ASTM F1671-97A ASTM F903-1999 AAMI PB-70 Medical Protective Clothing

(5) Futures: water-proof, blood-proof, blocking bacteria, blocking virus, anti-static, water vapour penetrable, full-body protective

(6) Usage: protect from blood,humor, secreta of the potentially infectious patient

(7) Material: SF NON-woven frabic

(8) Package: 25 suits/Box

(9) Dimension: 480x450x415mm

(10) Net wight: 9.8kg

(11) CE certificate: Passed

5) Performance Introduction

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.

(1) Feature

- Meets the technical requirements for CE &FDA
- High gram-weigth 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 from 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.

(2) Specifications

- This protective clothing includes a hooded top and trousers

(3) 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.

(4) Working principle

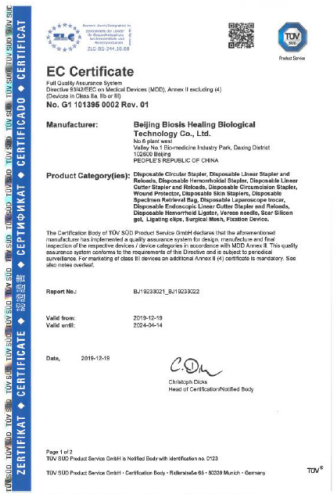
- The coverall is made from a high gram-weight composite nonwoven material, through cutting and sewing. Self-adhesive sipper from the front to chin placket protection. Seams are covered with special heat sealing tape for protective clothing. Helps isolate virus and protect against hazardous dusts and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

(5) 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

6) Certifcate & CE Declarition of conformity

ISO 和 CE一致性声明 (ISO & CE Declarition of Conformity)



EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 101396 0002 Rev. 01

Manufacturer: Beijing Biosis Healing Biological Technology Co., Ltd.
No.6 plant west
Valley No.1 Biomedicine Industry Park, Daxing District
102600 Beijing
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): 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, Disposable Endoscopic Linear Cutter Stapler and Reloads, Disposable Hemorrhoid Ligator, Veress needle, Scar Silicon gel, Ligating clips, Surgical Mask, Fixation Device.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of the Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: BJ1923021_BJ1923022

Valid from: 2019-12-19
Valid until: 2024-04-14

Date, 2019-12-19

Christoph Dicks
Head of Certification/Notified Body

Page 1 of 2
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH · Certification Body · Ridlerstraße 65 · 80339 Munich · Germany

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) EFFESTRASSE 80, 20537 HAMBURG, GERMANY

We, the manufacturer, herewith declare that the products

Medical Protective Coverall-BH800
160、165、170、175、180、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 - 02
Valid until: 2024 - 03 - 27

Standard NO.: EN 14126: 2003 EN 14605:2005 Type3

Bo Zhao
Signature of General Director

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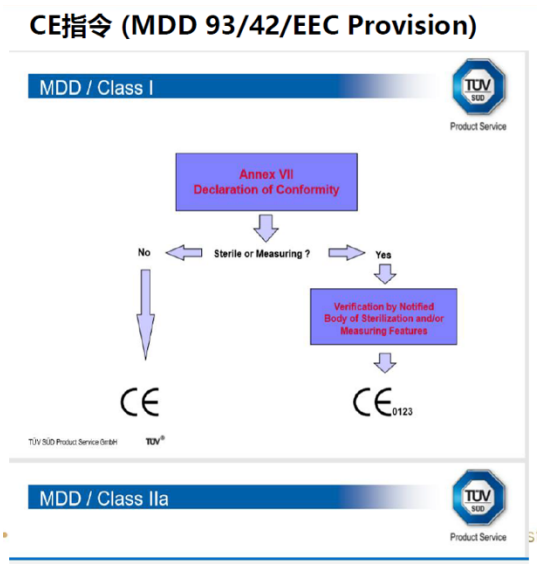

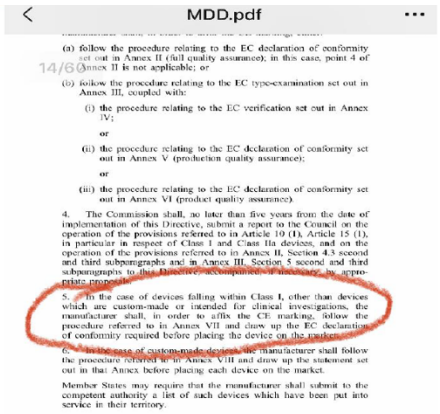

结论Conclusion:
非无菌的一类医疗产品，有CE一致性声明即符合欧盟上市的规定
As Class I products, non-sterile protective are ready to enter market with EC declaration

7) Test report

BH800防护服中国标准GB19082-2009检测报告 GB19082-2009 test report for Protective Coveralls - BH800

BN800 防护服EN14605检测报告 EN14605 Test report for Protective Coveralls-BH800