Your Health United Kingdom

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YHUK Product Certificate Document

Type 5 Medical Protective Coveralls

Date: 2020/04/25

检验报告 TEST REPORT

(No.): BA20000277

Applicant	Beijing Biosis Healing Biological TechnologyCo.,Ltd	Test Type	Requested Examination
Manufacture	Beijing Biosis Healing Biological TechnologyCo.,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 Baojun (Director)

（检验检测专用章）
Stamp

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.

中纺标检验认证股份有限公司
中国商业联合会轻纺消费品质量监督检测中心
进出口商品检验鉴定机构
国家纺织制品质量监督检验中心

Chinatesta Textile Testing & Certification Services Tel：010-65002813 400-086-0486
Add：No.3 Yanjingli Middle Street, Chaoyang District, Beijing 10025, China Fax：010-65076599
地址：北京市朝阳区延静里中街 3 号 100025

博泮瑞进生物科技

(No.): BA20000277

Items	Requirement (Class1)	Results	Judgement	Test Methods
Adrasion 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
Azo Dyes(24) mg/kg	Not detected	Not detected	Pass	EN 14362-1:2017

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

国家纺织制品质量监督检验中心 检验检测专用章

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

博辉瑞进生物科技

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

Product Service

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 trocar, Disposable Endoscopic Linear Cutter Stapler and Reloads, Disposable Hemorrhoid Ligator, Veress needle, Scar Silicon gel, Chitosan Gel, Clip Appliers 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

Stefan Preiß

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD
A4 / 07.17
博辉瑞进生物科技