
DISPOSABLE MEDICAL
PROTECTIVE SUIT
医用
一次性防护服
抗静电
阻隔细菌
阻隔血液

产品信息

精细裁剪 专业防护

产品详情

产品名称：医用一次性防护服
型号规格：连身式：160□、165□、170□、
175□、180□、185□
生产日期：
生产批号：
灭菌日期：
灭菌批号：
灭菌方法：钴-60辐照灭菌
使用期限：自灭菌日期后一个月
医疗器械注册证编号：辽械注准 20202140026
产品技术要求编号：辽械注准 20202140026
生产许可证编号：辽食药监械生产许 20200016号
注册人/生产企业：丹东大爱服装有限公司
注册人住所：丹东市振安区同兴镇同兴路83号
生产地址：丹东市振安区同兴镇同兴村

一次性使用，用后销毁，包装破损，禁止使用。

其他内容详见说明书

STERILE R
经钴-60辐照灭菌

如包装破损
切勿使用

一次性使用

产 品 实 拍

产品细节图


品质保证

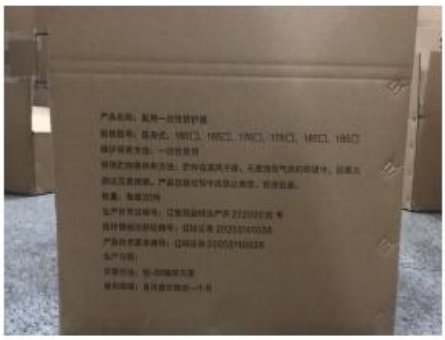

仓库现货


24小时加班供应

外箱包装


怕晒
向上
怕雨


DA
医用一次性防护服
生产企业名称：丹东大爱服装有限公司
生产地址：丹东市振安区同兴镇同兴村



医用一次性防护服使用说明书

【产品名称】医用一次性防护服
【规格型号】连身式：160□、165□、170□、175□、180□、185□
【结构组成】
该产品采用复聚乙烯膜的聚丙烯无纺布材料，密封胶条为聚氨酯热熔胶无纺布制成，由连帽上衣、裤子组成，袖口、脚踝口为弹性收口，帽子面部收口及腰部收口采用弹性收口。产品为连身式，采用钴-60 辐照灭菌。
【主要性能】
1、产品无菌;
2、主要性能指标符合 GB 19082-2009 标准规定。
【适用范围】
适用于医务人员在工作时接触具有潜在感染性的患者血液、体液、分泌物、空气中的颗粒物等提供阻隔、防护作用。
【禁忌症、注意事项、警示以及提示性内容】
1、本产品仅限一次性使用，禁止重复使用。
2、使用前请阅读使用方法，确保正确穿戴。
3、使用前检查包装是否完好，并对包装标志、生产日期、灭菌有效期进行确认，并在有效期内使用。
4、使用后请按医疗卫生机构医疗废物管理办法要求进行处理，不得随意丢弃。
5、本品经钴-60辐照灭菌，包装破损严禁使用。
6、对非织造布过敏者、心脏病患者及其他穿戴后身体不适者请在医生指导下慎用。
【使用说明】
1、使用前检查包装是否完好，并对包装标志、生产日期、使用期限进行确认，并在有效期内使用。
2、穿连身式防护服
将拉链拉至合适位置，左右手握住左右袖口的同时，抓住医用防护服腰部拉链的开口处，先穿下肢，再穿上肢，然后将拉链拉至胸部，套上医用防护服连体帽，最后将拉链拉至顶端 并系好领口。
3、脱连身式医用一次性防护服
3.1、先将医用防护服拉链拉到底，如图①;
3.2 、向上提拉帽子，使帽子脱离头部，如图②;
3.3、双手抓住医用防护服两侧肩部，将防护服褪至肩部以下图③;
3.4、先用左手捏住右手医用手套污染面（外面）的边缘将手套（里面朝外）脱下，并握在手中。然后右手进入左手手套内面，将医用手套脱下（里面朝外）。两手从袖子中脱出。如图④;
3.5、双手抓住医用防护服的内面，由里向外、从上到下边脱边卷，直至全部脱下，将医用防护服及包裹其中的外层手套卷好放入医疗废物袋内。如图⑤

脱连身式医用一次性防护服图示:

① ② ③ ④ ⑤

【标签、包装标识样图】

经钴-60辐照灭菌　　如包装破损切勿使用　　一次性使用

【维护保养方法】一次性使用
【特殊贮存条件和方法】贮存在通风干燥、无腐蚀性气体的环境中。远离火源以及易燃物。产品运输过程中应防止潮湿、封闭包装。
【灭菌方法】钴-60辐照灭菌
【包装以及其他】本品采用PE袋封闭包装，每袋一件，每箱20件。

【注册人/生产企业名称】丹东大爱服装有限公司
【注册人住所】丹东市振安区同兴镇同兴路83号
【生产地址】丹东市振安区同兴镇同兴村
【联系电话】0415-6136677
【售后服务单位】丹东大爱服装有限公司
【生产许可证编号】辽食药监械生产许 20200016 号
【医疗器械注册证编号】辽械注准 20202140026
【产品技术要求编号】辽械注准 20202140026
【说明书编制日期】2020年03月03日
【生产日期】详见产品标签
【使用期限】自灭菌日期后一个月

OUCHENG TESTING

Certificate of Conformity

Certification No:	**OCT20200318118P**
Applicant:	**Dandong Devote Garment Co., Ltd.**
Address:	No. 83 Tongxing Road, Tongxing Town, Zhen’an District, Dandong
Manufacturer:	**Dandong Devote Garment Co., Ltd.**
Address:	No. 83 Tongxing Road, Tongxing Town, Zhen’an District, Dandong
Certification Marking:	**CE-PPE**
Product Description:	**Medical Disposable Protective Suit**
Model:	170/175/180/185

Sufficient samples of the product have been tested and found to be in conformity with

Test Standards	:	**EN 14126:2003+AC:2004, EN ISO 13982-1:2004+A1:2010**

When tested as specified, the submitted sample complies with Personal Protective Equipment (PPE) – Regulation (EU) 2016/425

The certificate is based on a single evaluation of one sample of above-mentioned products. It does not imply an assessment of the whole production and does not permit the use of the test laboratory logo.

CE

Authorized Signer: _____

Manager

March 17, 2020

Oct Technology Testing Co., Ltd.

637,No. 56, zhongyun Road,Panyu District,Guangzhou,Guangdong Province,China

TEL:020-89015652,888@oucetesting.com,www.oucetesting.com

Fiscal Year 2020

CERTIFICATION OF REGISTRATION

This certifies that:

Dandong Devote Garment Co., Ltd.

No.83 Tongxing Road,Tongxing Town,Zhen'an District,Dandong, Liaoning, 118000, CHINA

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through Shenzhen Huide Medical Device Certification Service Co., Ltd.

Owner/Operator Number: 10063478

Listing Number:	Product Code:	Device Name:
D376548	OEA	Disposable Isolation Gown
D376549	LYU	Disposable Protective Coverall

Shenzhen Huide Medical Device Certification Service Co., Ltd. will confirm that such registration remains effective upon request and presentation of this certificate until end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. Shenzhen Huide Medical Device Certification Service Co., Ltd. makes no other representations or warranties, nor does this certificate make any representation or warranties to any person or entity other than the named certificate holder, for those sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Shenzhen Huide Medical Device Certification Service Co., Ltd. assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, ''Registratio n of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding.''

The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, Shenzhen Huide Medical Device Certification Service Co., Ltd. is not affiliated with the U.S. Food and Drug Administration.

Shenzhen Huide Medical Device
Certification Service Co., Ltd.
16C, Building 1, Sunshine Green,

Issue Date: March 20, 2020

Expiration Date: 31 December, 2020

EN 14126:2003+AC:2004			
Clause	Requirement-Test	Result-Remark	Verdict
1	Scope		P
	This European Standard specifies requirements and test methods for re-usable and limited use protective clothing providing protection against infective agents. Clothing worn by surgical teams or drapes laid on patients to prevent cross-contamination during surgical interventions are not covered by the scope of this standard.		P
2	Normative references		P
	This European standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).		P
3	Terms and definitions		P
	For the purposes of this European Standard, the terms and definitions of prCEN ISO/TR 11610:2003 and the following terms and definitions apply.		P
4	Requirements		P
4.1	Materials requirements		P
	4.1.1 General If the care instructions indicate that the clothing can be cleaned and reprocessed at least five times, protective clothing materials shall be submitted to five cleaning and reprocessing cycles according to the manufacturer's care instructions before testing. If the care instructions specify a lower number of cleaning/reprocessing cycles, then materials shall be submitted to the number of cleaning/reprocessing cycles indicated. Unless otherwise stated in the relevant test procedure, the specimens shall be conditioned for at least 24 h in an atmosphere of (20 ±2) °C and (65 ±5) % relative humidity before testing. Tests shall be carried out in the same atmosphere or within 5 min of removing the sample from the conditioning atmosphere.		P
	4.1.2 Mechanical and flammability requirements The materials shall be tested and classified in		P

EN 14126:2003+AC:2004			
Clause	Requirement-Test	Result-Remark	Verdict
	accordance with the test methods and performance classification system specified in the relevant clauses of prEN 14325.		
	4.1.3 Chemical requirements If protection against chemicals is claimed, the materials shall be tested and classified in accordance with the test methods and performance classification system specified in the relevant clauses of prEN 14325.		P
	4.1.4 Performance requirements against penetration by infective agents 4.1.4.1 Resistance to penetration by contaminated liquids under hydrostatic pressure When tested in accordance with ISO/FDIS 16603 and ISO/FDIS 16604 the material shall be classified according to the levels of performance given in Table 1, as obtained in the bacteriophage test (ISO/FDIS 16604).		P

Table 1 — Classification of resistance to penetration by contaminated liquids under hydrostatic pressure (ISO/FDIS 16604)

Class	Hydrostatic pressure at which the material passes the test
6	20 kPa
5	14 kPa
4	7 kPa
3	3,5 kPa
2	1,75 kPa
1	0 kPa [a]

[a] this means that the material is only exposed to the hydrostatic pressure of the liquid in the test cell

	4.1.4.2 Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids. When tested in accordance with Annex A the material shall be classified according to the levels of performance given in Table 2.		P

Table 2 — Classification of resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids

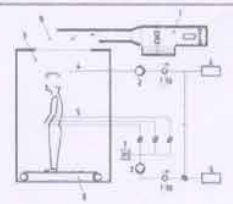
Class	Breakthrough time, t min
6	$t > 75$
5	$60 < t \leq 75$
4	$45 < t \leq 60$
3	$30 < t \leq 45$
2	$15 < t \leq 30$
1	≤ 15 min

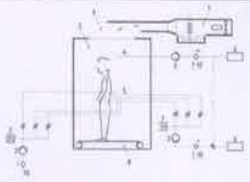
	4.1.4.3 Resistance to penetration by contaminated		P

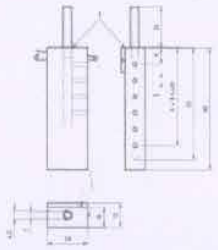
EN 14126:2003+AC:2004			
Clause	Requirement-Test	Result-Remark	Verdict
	liquid aerosols When tested in accordance with ISO/DIS 22611 the material shall be classified according to the levels of performance given in Table 3.		
	Table 3 — Classification of resistance to penetration by contaminated liquid aerosols Class 3: Penetration ratio (log) log > 5 Class 2: 3 < log ≤ 5 Class 1: 1 < log ≤ 3		
	4.1.4.4 Resistance to penetration by contaminated solid particles. When tested in accordance with ISO/DIS 22612 the material shall be classified according to the levels of performance given in Table 4.		P
	Table 4 — Classification of resistance to penetration by contaminated solid particles Class 3: Penetration (log cfu) ≤ 1 Class 2: 1 < log cfu ≤ 2 Class 1: 2 < log cfu ≤ 3		
4.2	Performance requirements for seams, joins and assemblages		P
	Seams, joins and assemblages of protective clothing against infective agents shall fulfil the requirements specified in the relevant clauses of prEN 14325 Seam strength shall be classified according to 5.5 of prEN 14325:2001.		P
4.3	Whole suit requirements		P
	Protective clothing against infective agents shall fulfil the relevant requirements of EN 340 and the whole suit requirements specified in the relevant standard for chemical protective clothing (see Table 5). The materials and design used shall not cause skin irritation nor have any adverse effect to health.		P

EN 14126:2003+AC:2004			
Clause	Requirement-Test	Result-Remark	Verdict
	Table 5 — Types of protective clothing against infective agents type 1a, 1b, 1c, 2: EN 943-1 (EN 943-2 for ET suits) type 3: EN 466 type 4: EN 465 type 5: prEN ISO 13982-1 type 6: prEN 13034 partial body protection: EN 467		P
5	Marking		P
6	The clothing shall be marked in accordance with the applicable requirements of the relevant standard for chemical protective clothing. The marking of protective clothing against infective agents shall contain the following additional information: a) the number of this European Standard; b) the type of protective clothing, as specified in Table 5, with the suffix "-B", e.g. type 3-B; c) the pictogram "protection against biological hazard"		P
	Information supplied by the manufacturer		P
	The information for the user shall be worded clearly and unambiguously and be understandable by a trained person. The information for the user of protective clothing against infective agents shall contain all the information required by EN 340 and by the relevant standard for that specific type of chemical protective clothing. In addition it shall contain the following information: a) the number of this European Standard; b) the type designation, e.g. type 3-B; c) the biological agents against which the protective clothing has been tested. This information shall be expressed as performance levels, as specified in 4.1.4.1 to 4.1.4.4 for the relevant types of biological challenge; d) all other relevant information on performance levels, preferably as a Table; e) the information necessary for trained persons about: application and limitations of use (temperature range, etc.); if relevant, checks to be carried out by the wearer before use; fitting and adjustments, and any accessories needed to provide the claimed level of protection, use; maintenance, cleaning and disinfection; storage; if relevant, a warning against problems likely to be encountered;		P

EN 14126:2003+AC:2004			
Clause	Requirement-Test	Result-Remark	Verdict
	if relevant, illustrations, part numbers and marking of spare parts, etc. disposal after use.		

4	Principle		--
	A standard aerosol of sodium chloride particles is generated inside a test chamber in which a test subject, wearing the protective suit under test, carries out a predetermined sequence of test exercises. The inward leakage at each sampling position inside the suit is measured by means of flame photometry. The percentage inward leakage at each sampling position (L ijmn), the total inward leakage per suit (L S) and per test subject (L H), the total inward leakage per exercise (L E) and per sampling position (L P) and the mean total inward leakage (L) are calculated.		P
5	Apparatus		--
5.1	Aerosol generator, flame photometer(s), one or two, and a test chamber, as described in EN 136.		P
5.2	Level treadmill, capable of operating at (5 ? 0,5) km/h, which is installed inside the chamber. The test arrangement used for the determination of inward leakage is shown schematically in Figures 1 and 2.		P
			--

			--
5.3	Sodium chloride aerosol test agent, with a particlesize distribution, mean test-agent concentration and distribution inside the chamber as described in EN 136.		P
5.4	Adjustable pump and air lines, used for sampling air from the suit under test.		P
	This pump is adjusted to deliver a sampling flow rate from inside the suit in the range of (2 ? 0,5) l/min. The flow shall be kept constant within ? 0,2 l/min. Depending on the type of photometer, it may be necessary to dilute the sample air with clean air. There shall be no condensation in tubes during testing. Condensation in the tubes can be avoided by feeding dry, clean air directly into the tubes upstream of where condensation occurs (see Figure 2), by heating of the tubes or by any other suitable means. One should take the dilution into account when calculating the concentration at the sampling point.		P
5.5	Sampling probes, four, constructed as shown in Figure 3, one which shall be used to measure the challenge concentration and three, the concentration inside the suit. Each probe is fitted onto a length of suitable transparent plastic tube with an internal diameter of 4,0 mm.		P

			--
	The three probes for measuring the concentration inside the suit shall be positioned close to the body of the test subject, at the following positions as shown in Figure 4:		P
			--
	Especially in the case of two-piece suits and coveralls equipped with an elastic waistband or a belt worn over the suit, the positions of the sampling points should be carefully chosen. Sampling probes shall not be positioned directly onto the skin, but shall be fixed onto the underwear. The sampling lines to and from the sampling probes inside the suit shall be fixed close to the body of the test subject and shall pass through the material of the suit between 5 cm and 15 cm above one of the arm-cuffs in an airtight manner. The fixings of the sampling lines and the		P

	passthrough should have as little influence on the fit of the suit as possible and should not impair the		
	movements of the test subject. To ensure that there is no additional inward leakage into the suit, due to under-pressure created by extraction of the sample air, clean air shall be fed back into the suit at the same rate as sample air is pumped out, i.e. at (2 ? 0,5) l/min. This clean air shall be introduced through one of the other two sampling probes, according to the sequence of sampling given in Table 1. The necessary arrangements should be made to ensure that the air is injected in the right compartment of the suit, in particular in the case of two-piece suits or coveralls including a belt or elastic waistband, where there may be insufficient exchange of air between compartments.		
5.6	Sampling system for the challenge aerosol, separate from that sampling the test concentration in the suit, with a separate flame photometer if possible, in order to avoid contamination of the total inward leakage sampling lines. If a second photometer is not available, it is possible to determine the challenge concentration by a separate sampling system and the same photometer. However, sufficient time will then be required to allow the photometer to return to a stable background signal level before measuring total inward leakage.		P
6	Test procedure		--
6.1	Selection of test subjects		--
	For the test, persons shall be selected who are familiar with the use of this or similar protective equipment and whose medical history is known to be satisfactory. Before performing tests involving human subjects, account shall be taken of any national regulations concerning the medical history, examination or supervision of the test subject. The test subject shall wear close-fitting underwear (e.g. polyester/cotton long trousers and a T-shirt with long sleeves). The underwear shall be changed after each suit tested. The size of the suit shall be selected in accordance with the test subject's body dimensions and according to the manufacturer's instructions. Prior to the test, each suit shall be examined to ensure that it is in good working condition and that it can be used without hazard.		P
6.2	General test conditions		--

	At least five test subjects shall test at least two suits per person, i.e., at least ten suits shall be tested. The test subjects shall be asked to read the manufacturer's instructions and, if necessary, they shall be shown by the test supervisor how to wear the suit properly according to the instructions. The		P
	test subjects shall be informed that if they wish to adjust the suit during the test they may do so. If this is done, however, the relevant section of the test shall be repeated after sufficient time has elapsed for the system to stabilize. After putting on the suit, each test subject shall be asked: "Does the suit fit?" If the answer is "yes", proceed with the test. If the answer is "no", take the subject off the test panel, report the fact and replace the test subject by another. The test subjects shall be given no indication of the results as the test proceeds. If not otherwise specified, all tests shall be carried out at (20 ? 5) °C and a relative humidity inside the test chamber of less than 60 %. The test temperature and relative humidity inside the test chamber prior to the testing of each suit and at the end of all test exercises for each suit shall be recorded and reported.		
6.3	Test sequence		--

	The following test sequence shall be followed for each suit. -- Connect the tubing to the sampling points and dress the test subject in the suit, in accordance with the manufacturer's instructions. Ensure that the pass-through for the sampling tubes is as leaktight as possible. Let the test subject also put on additional equipment, such as boots, gloves, hood, mask, etc., in accordance with the manufacturer's instructions. If the manufacturer's instructions do not specify the need for additional equipment, then these should not be worn. However, the test subject may wear a suitable respiratory protective device, e.g. a filtering facepiece. In addition, if the manufacturer's instructions do not require the suit to be taped to any part of the body of the wearer (such as wrists and ankles) or to any additional item (e.g. gloves or boots) worn by the test subject, then these types of taping should not be done. It is recommended that all additional equipment be supplied by the manufacturer. -- Let the test subject enter the test chamber. -- Measure and report the concentration of the test agent before the generation of the aerosol inside the suit at all three sampling positions to ensure that, in all cases, the background concentration is at least one order of magnitude below the expected concentration during testing. If the background concentration is higher, investigate why and correct the problem. This may require preliminary testing. -- Start generating the test agent and allow the challenge concentration in the chamber to stabilize. Ensure that the test subject is standing still during this period. Measure and report the challenge concentration. If stabilization of		P

	challenge concentration in the chamber takes more than 1 min, the suit shall be ventilated to avoid penetration of particles into it. -- Measure the concentrations at the following sampling positions (see also Figure 4): -- knee (lateral), -- waist (back), -- chest (right); following the sampling sequence and the corresponding sequence of feeding clean air into the suit described in Table 1, whilst the test subject performs the test exercises in the following order: 1) standing still, 2) walking at 5 km/h, 3) continuous squatting at a frequency of five squats per minute, between standing up straight and knees completely bent, while keeping both hands during all squats on a grip at a height of (1 ? 0,05) m above the standing surface. Allow for a 3 min rest (standing still) between the walking and the squatting exercises. During the test sequence 4, "stabilization between walking and squatting", concentrations should be measured but do not need to be reported. The time for each exercise at each sampling position shall be 3 min. The average concentration over the last 100 s of each exercise and at each of the sampling points shall be calculated and reported. Measurement of the average concentration is preferably made using an integrating recorder. Where the same photometer is used to measure both the challenge and the penetrating sodium chloride concentrations, the challenge concentration shall be measured and reported at the completion of the test sequence. The challenge concentration at the end of all test exercises shall be within ? 10% of the initial challenge concentration. If this is not the case, the test results shall be discarded and the problem shall be corrected. -- Stop generating the test agent, disconnect the sample tubes and let the test subject leave the test chamber.		
7	Calculation of test results		
7.1	Calculation of percentage inward leakage		
	The percentage inward leakage, L_{ijmn}, shall be calculated from measurements made over the last 100 s (to avoid carry-over of results from one exercise to the other) for each of the three sampling positions (n) for each of the three exercise periods (m) for each of the suits tested (j) (with at least two suits per test subject) for		P

	each of the test subjects (i) (at least five test subjects) in accordance with Equation (1):		
	$L_{ij} = \frac{C_{in}}{C_{out}} \times 100\%$ where C_{in} : ambient challenge concentration; C_{out} : in-mask concentration for sampling position j, full exercise or fit test, for test subject i; L_{ij} percentage inward leakage value of the exercise		--
7.2	Calculation of total inward leakage		--
7.2.1	The total inward leakage, L $S_{,j}$, per suit for suit j, shall be calculated in accordance with Equation (2): $L_{S,j} = \frac{1}{n_i n_j} \sum_{m} \sum_{n} L_{ijmn}$ The data reported shall pertain to 10 results from 10 or more suits.		P
7.2.2	The total inward leakage, L H,i , per human subject for subject i shall be calculated in accordance with Equation (3) $L_{H,i} = \frac{1}{n_j n_m n_n} \sum_{j} \sum_{m} \sum_{n} L_{ijmn}$ The data reported shall pertain to 5 results from 5 or more subjects.		P
7.2.3	The total inward leakage, L E,m , per exercise for exercise m shall be calculated in accordance with Equation (4): $L_{E,m} = \frac{1}{n_i n_j} \sum_{i} \sum_{j} L_{ijmn}$ The data reported shall pertain to 3 results from 3 exercises.		P
7.2.4	The total inward leakage, L P,n , per position for test position n shall be calculated in accordance with Equation (5): $L_{P,n} = \frac{1}{n_i n_j} \sum_{i} \sum_{j} L_{ijmn}$ The data reported pertain to 3 results from 3 sampling positions.		P

7.2.5	The total inward leakage per position and per exercise, L EP , for exercise m and position n shall be calculated in accordance with Equation (6): $L_{EP,mn} = \frac{1}{i} \sum_{i} L_{ijmn}$ The data reported pertain to 10 suits (or more).		P
7.2.6	The mean total inward leakage The average, L of all total inward leakage measurements shall then be calculated in		P

FDA证书
确认信

Help (/help/index.html)

DRLM Home (mainMenu.htm) > Register a New Medical Device Facility

✔ Facility

✔ Products Listing

Registration Confirmation

Facility: DANDONG DEVOTE GARMENT CO., LTD, Dandong, Liaoning, CHINA

You have successfully entered your facility registration and device listing information. You should print a copy of this page for your records. Listing numbers appear below for the products manufactured, developed, or processed at this facility.

As a manufacturer, specification developer, or single-use device reprocessor, you are required to pay an annual fee for medical device facility registration.

You will receive another e-mail providing you with your registration number in approximately 30 to 90 days. Until your registration number is assigned, reference your Owner/Operator number in any correspondence with the Center for Devices and Radiological Health.

Your registration will be valid through Dec 31, 2020. An e-mail will be sent to the Owner/Operator and the Official Correspondent 90 days before the facility is required to re-register for Fiscal Year 2020 with instructions on how and when to re-register.

Note: Registering your device facility and listing your devices does not, in any way, constitute FDA approval of your facility or your devices.

Should you have any questions, please send an e-mail to reglist@cdrh.fda.gov (mailto:reglist@cdrh.fda.gov).

The Owner/Operator Number for this Registration is: 10063478

Facility Information

Registration Number:

Initial Importer:
N

Facility Name:
DANDONG DEVOTE GARMENT CO., LTD

Address:
No.83 Tongxing Road, Tongxing Town, Zhen'an District
Dandong, Liaoning, 118000, CHINA

DUNS Number:
548308210

Foreign Trade Zone:
N

Facility URL:

Other Business Trade Name(s):

Owner/Operator Information

Owner/Operator Number:
10063478

Contact Name:
Zhimei Zheng

Company:
DANDONG DEVOTE GARMENT CO., LTD

Address: No.83 Tongxing Road, Tongxing Town, Zhen'an District
Dandong, LIAONING, 118000, CHINA

Telephone:
86 - 415 - 6136677

Fax:
-

E-mail: 403306994@qq.com

DUNS Number:

Official Correspondent Information

Contact Name:
Zhimei Zheng

Company:
DANDONG DEVOTE GARMENT CO., LTD

Address: No.83 Tongxing Road, Tongxing Town, Zhen'an District
Dandong, LIAONING, 118000, CHINA

Telephone:
86 - 415 - 6136677

Fax:
-

E-mail: 403306994@qq.com

DUNS Number:

FDA证书
确认信

United States Agent Information

Contact Name:
Jerry Doane

Contact Title:
Mr

Business Name:

Address: 15815 SW 11th Court Rd.
Ocala, Florida, 34473, UNITED STATES

Phone:
716 - 7750533

Fax:

DUNS Number:

E-mail: jdoane@usagent-tobias.com

Device Listings

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name (s)	Activities	Importers
		D376548			
		Exempt			
		DEA			
		Non-surgical isolation gown			
				Manufacturer	
		D376549			
		Exempt			
		LYU			
		ACCESSORY, SURGICAL APPAREL			
				Manufacturer	

Date of Initial Registration: Fri Mar 20 18:36:48 EDT 2020

CE认证确认声明

Dandong Devote Garment Co., Ltd.

Declaration of Conformity

Dandong Devote Garment Co., Ltd.
No. 83 Tongxing Road, Tongxing Town, Zhen' an District, Dandong
We declare that the following product :

Medical Disposable Protective Suit

Models No: 170/175/180/185

Described above is in conformity with the following directive (s) :
Personal Protective Equipment 2016/425

Relevant standard (s):

EN 14126:2003+AC:2004, EN ISO 13982-1:2004+A1:2010

The reference of the File identified with the No:
MESTTCF-PPE

And we are aware about the contents and information included in the ModCOM04.06 Regulation that is considered totally accepted.

CE

Date of issue

2020.03.17

Stamp and Signature of authorized personnel

丹东市振兴区德服装有限公司

防护服PPE检测报告

PCTCF0315-PPE

PPE TEST REPORT

For

Dandong Devote Garment Co., Ltd.

Medical disposable protective suit

Model: 170

Prepared For : Dandong Devote Garment Co., Ltd.
No. 83 Tongxing Road, Tongxing Town, Zhen'an District, Dandong

Prepared By : China Ceprei (Sichuan) Laboratory
No.45 Wenming Dong Road Longquanyi District, Chengdu, Sichuan

Report Number: PCTCF0315-PPE
Date of Test: Mar.15, 2020
Date of Report: Mar.15, 2020

PCTCF0315-PPE

TEST REPORT DECLARATION

Applicant	:	Dandong Devote Garment Co., Ltd.
Address	:	No. 83 Tongxing Road, Tongxing Town, Zhen'an District, Dandong
Manufacturer	:	Dandong Devote Garment Co., Ltd.
Address	:	No. 83 Tongxing Road, Tongxing Town, Zhen'an District, Dandong
EUT Description	:	Medical disposable protective suit
Model No.	:	170
Remark	:	N/A

Test Procedure Used:
EN 14126:2003+AC:2004, EN ISO 13982-1:2004+A1:2010

The test results of this report relate only to the tested sample identified in this report.

Date of Test : Mar.15, 2020

Prepared by : (Jack)

Checked by : (Gina)

Approved by : (Johnson)

	accordance with Equation (7) and reported: $\bar{I}_{...} = \frac{1}{i}\sum_{i} I_{P_i} = \frac{1}{j}\sum_{j} I_{P_j} = \frac{1}{m}\sum_{m} I_{P_m} = \frac{1}{n}\sum_{n} I_{P_n}$		
8	Test report		–
	The test report shall contain the following information: a) reference to this International Standard (i.e., ISO 13982-2:2004); b) identity of the manufacturer of the suit; c) size of the suits tested and the body measurements of the test subjects, in accordance with the provisions of EN 340; d) description of the underwear worn by test subjects; e) description of any pre-treatment and/or preconditioning of the suits tested, e.g. mechanical pre-stressing of suits for determining the durability of barrier efficiency; f) description of any additional protective equipment or any accessories worn during the test and if and how the accessories were taped to the suit; g) temperature and relative humidity inside the test chamber prior to the testing of each suit and at the end of all test exercises for each suit; h) concentration of test agent inside the suit at all three sampling positions for each suit prior to testing; concentration of test agent inside the test chamber after stabilizing the test agent concentration and at the end of all test exercises; i) all inward leakage results, presented in the form of data tables: – tables giving the percentage inward leakage values L_{ijmn} and averages per test subject and test suit (i.e., at least 10 tables modelled on Table 2), – table giving total inward leakage values for all test subjects and test suits (modelled on Table 3), – table giving total inward leakage values per test subject (modelled on Table 4); j) any comments considered appropriate by the person who has carried out the tests.		P

Table 1 — Sampling sequence for probes inside the suit during the period when the test subject is present in the chamber and during the sequence of activity

Measuring sequence		Timing min	Sampling through probe at position:	Feeding of clean air through probe at position:	Exercise
Number	Activity				
1	measuring the background inside suit (before generation of the aerosol)	– – –	knee waist back chest	chest knee waist back	standing still
2	waiting for stabilization and measuring the test agent concentration inside chamber	– –	– –	– –	
3	measuring the test agent concentration inside suit	1 1 1 1 1 1	knee waist back chest knee waist back chest	chest knee waist back chest knee waist back	standing still walking
4	stabilization between walking and squatting	1 1 1	knee waist back chest	chest knee waist back	standing still
5	measuring the test agent concentration inside suit	3 3 3	knee waist back chest	chest knee waist back	squatting
6	measuring the test agent concentration inside chamber	–	–	–	standing still

Table 2 — Model for reporting inward leakage values, expressed in percent, of suit *j* worn by test subject *i*

Exercise	Sampling position/Feeding-in position			Average per exercise %
	Knee/Chest	Waist back/Knee	Chest/Waist back	
standing still	I_{j11}	I_{j12}	I_{j13}	I_{ej1}
walking	I_{j21}	I_{j22}	I_{j23}	I_{ej2}
squatting	I_{j31}	I_{j32}	I_{j33}	I_{ej3}
average per sampling position	I_{sj1}	I_{sj2}	I_{sj3}	I_{sj}

Table 3 — Model for reporting total inward leakage values, expressed in percent, per sampling position and per exercise (averaged over all suits)

Exercise	Sampling position/Feeding-in position			Average per exercise %
	Knee/Chest	Waist back/Knee	Chest/Waist back	
standing still	I_{s1}	I_{s12}	I_{s13}	I_{e1}
walking	I_{s21}	I_{s22}	I_{s23}	I_{e2}
squatting	I_{s31}	I_{s32}	I_{s33}	I_{e3}
average per sampling position	I_{s1}	I_{s2}	I_{s3}	$\bar{I}$

Table 4 — Model for reporting total inward leakage values, expressed in percent, per test subject

Test subject	Total inward leakage per suit, I_{sj}	Total inward leakage per human test subject, I_{hi}
1	I_{s1}; I_{s2}	I_{h1}
2	I_{s3}; I_{s4}	I_{h2}
...	$I_{s(2i-1)}$; I_{s2i}	I_{hi}
average	$\bar{I}$	$\bar{I}$

- End of Review Report -

Annex: Technical Information

(1) Product Photos

A.1

统一社会信用代码

91210600590908261 5

营业执照

（副 本）

（副本号：1-1）

扫描二维码登录“国家企业信用信息公示系统”了解更多登记、备案、许可、监管信息。

名　　称　丹东大爱服装有限公司

类　　型　有限责任公司

法定代表人　赵龙哲

经营范围　服装、医疗器械生产及销售；货物及技术进出口；道路普通货物运输。（依法须经批准的项目，经相关部门批准后方可开展经营活动）。

注册资本　人民币壹仟万元整

成立日期　2012年03月06日

营业期限　自2012年03月06日至2032年03月05日

住　　所　丹东市振安区同兴镇同兴路83号

登记机关　丹东市市场监督管理局

2020 年 02 月 14 日

国家企业信用信息公示系统网址：　http://www.gsx[illegible].cn

市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告。

国家市场监督管理总局监制

医疗器械生产许可证

许可证编号：辽食药监械生产许20200016号

企业名称：丹东大爱服装有限公司

生产地址：丹东市振安区同兴镇同兴村

法定代表人：赵龙哲

生产范围：2002分类目录
Ⅱ类:6864-2-敷料、护创材料
2017分类目录
Ⅱ类:14-14-医护人员防护用品

企业负责人：赵龙哲

住　　所：丹东市振安区同兴镇同兴路83号

发证部门：辽宁省药品监督管理局

有效期限：至　新冠肺炎疫情结束　年　月　日

发证日期：2020 年 03 月 03 日

国家药品监督管理局制