# 医用一次性防护服

# Medical disposable protective suit

丹东大爱服装有限公司
Dandong Devote Garment Co., Ltd.

# 营业执照

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.gsxt.gov.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

# BUSINESS LICENSE

**Uniform Social Credit Code**

912106005909082615

**Business License**

**(Duplicate)**

**(Duplicate No.: 1-1)**

To scan the QR code to log onto the "State Publicity System of Enterprise Credit Information" to learn more information on registration, filing, licensing and regulation.

| | | | |
|---|---|---|---|
| **Name** | Dandong Devote Garment Co., Ltd. | **Registered Capital** | RMB Ten Million Yuan Only |
| **Type** | Limited liability company | **Date of Establishment** | March 6, 2012 |
| **Legal Representative** | Zhao Longzhe | **Term of Business** | From March 6, 2012 to March 5, 2032 |
| **Business Scope** | Production and sales of clothing as well as medical apparatus and instruments; import and export of goods and technologies; general road transportation of goods. (With respect to the items subject to approval in accordance with the law, the operating activities shall not be carried out until the approval has been received from the competent authority.) | **Address** | No. 83 Tongxing Road, Tongxing Town, Zhen'an District, Dandong |

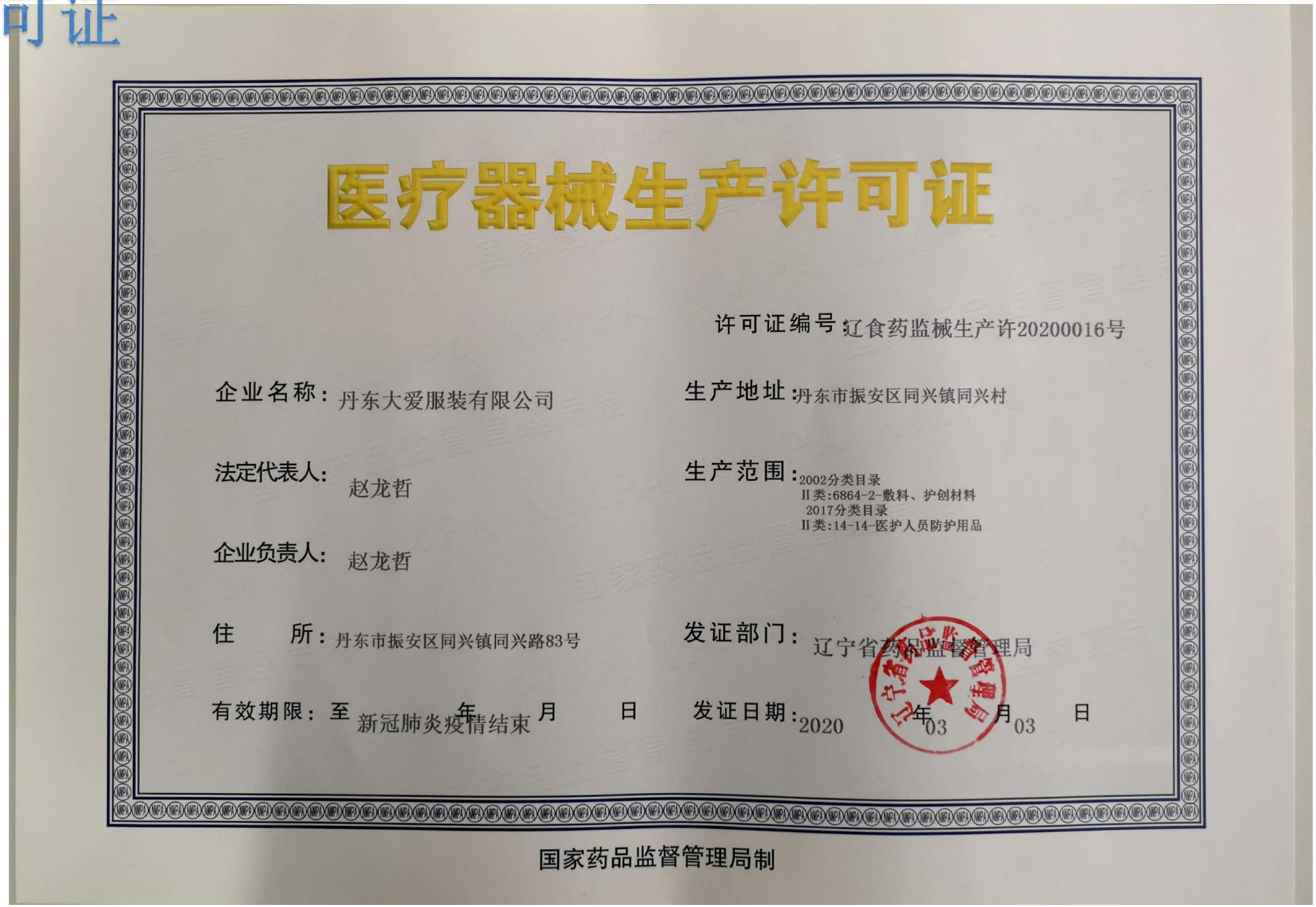
**Registration Authority**: Dandong Municipal Administration for Market Regulation (Seal)

February 14, 2020

Website of State Publicity System of Enterprise Credit Information: http://www.gsxt.gov.cn Prepared under the supervision of State Administration for Market Regulation

The market subject is required to submit and make public the annual report through the State Publicity System of Enterprise Credit Information between Jan. 1 and Jun. 30 every year.

# 生产许可证



# 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

# Permit for Production of Medical Apparatus and Instruments

Serial No. of License: L. S. Y. J. X. S. C. X. No. 20200016

Enterprise Name: Dandong Devote Garment Co., Ltd.

Production Address: Tongxing Village, Tongxing Town, Zhen'an District, Dandong

Legal Representative: Zhao Longzhe

Production Scope: 2020 Classification Catalogue
Class II: 6864-2- dressing, wound protection materials
2017 Classification Catalogue
Class II: 14-14- protective equipment of medical care personnel

Head of Enterprise: Zhao Longzhe

Certificate Issuing Authority: Liaoning Provincial Medial Products Administration

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

Liaoning Provincial Medical Products Administration (Seal)

Valid until: the end of the COVID-19 outbreak

Permit Issuing Date: March 3, 2020

**Under the Supervision of the National Medical Products Administration**

# FDA 证书

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: 100[redacted]**

| 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

# CE 证书

OCT OUCHENG TESTING

## Certificate of Conformity

**Certification No:** OCT20200[redacted]

**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

OUCHENG TESTING

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

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 | | | | | |
| OEA | | | | | |
| 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



## 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

# 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)

| 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<br>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<br>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<br>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<br>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)**<br>Class \| Hydrostatic pressure at which the material passes the test<br>6 \| 20 kPa<br>5 \| 14 kPa<br>4 \| 7 kPa<br>3 \| 3,5 kPa<br>2 \| 1,75 kPa<br>1 \| 0 kPa [a]<br>[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.<br>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**<br>**Class** \| **Breakthrough time, *t* min**<br>6 \| $t > 75$<br>5 \| $60 < t \leq 75$<br>4 \| $45 < t \leq 60$<br>3 \| $30 < t \leq 45$<br>2 \| $15 < t \leq 30$<br>1 \| ≤ 15 min | | |
| | 4.1.4.3 Resistance to penetration by contaminated | | P |

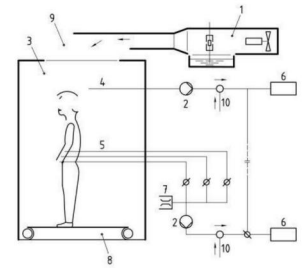
| EN 14126:2003+AC:2004 | | | |
|---|---|---|---|
| **Clause** | **Requirement-Test** | **Result-Remark** | **Verdict** |
| | liquid aerosols<br>When tested in accordance with ISO/DIS 22611 the material shall be classified according to the levels of performance given in Table 3. | | |
| | **Table 3 — Classification of resistance to penetration by contaminated liquid aerosols**<br>Class 3: log > 5<br>Class 2: 3 < log ≤ 5<br>Class 1: 1 < log ≤ 3 | | |
| | 4.1.4.4 Resistance to penetration by contaminated solid particles.<br>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**<br>Class 3: ≤ 1<br>Class 2: 1 < log cfu ≤ 2<br>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 |

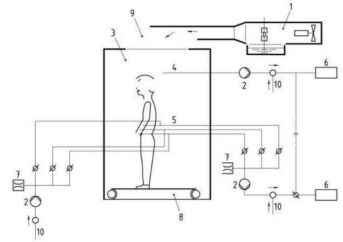


| EN 14126:2003+AC:2004 | | | |
|---|---|---|---|
| **Clause** | **Requirement-Test** | **Result-Remark** | **Verdict** |
| | **Table 5 — Types of protective clothing against infective agents**<br>type 1a, 1b, 1c, 2: EN 943-1 (EN 943-2 for ET suits)<br>type 3: EN 466<br>type 4: EN 465<br>type 5: prEN ISO 13982-1<br>type 6: prEN 13034<br>partial body protection: EN 467 | | P |
| 5 | Marking | | P |
| | 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 |
| 6 | 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:<br>application and limitations of use (temperature range, etc.);<br>if relevant, checks to be carried out by the wearer before use;<br>fitting and adjustments, and any accessories needed to provide the claimed level of protection;<br>use;<br>maintenance, cleaning and disinfection;<br>storage;<br>if relevant, a warning against problems likely to be encountered; | | P |

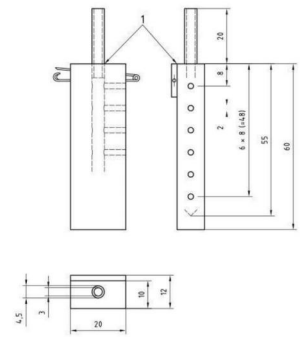
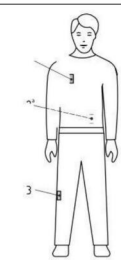
| EN 14126:2003+AC:2004 | | | |
|---|---|---|---|
| **Clause** | **Requirement-Test** | **Result-Remark** | **Verdict** |
| | if relevant, illustrations, part numbers and marking of spare parts, etc.<br>disposal after use. | | |



| | | | |
|---|---|---|---|
| 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.<br>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 |
| |  <br>**Key**<br>1 atomizer<br>2 pump<br>3 chamber<br>4 challenge sample<br>5 air lines to and from the suit (both sampling and feeding lines)<br>6 photometer<br>7 flow meter<br>8 treadmill<br>9 ducting and baffle<br>10 addition of dry, clean air<br>**Figure 1 — Test arrangement (schematic)** | | -- |

| | | | |
|---|---|---|---|
| |  **Figure 2 — Modified test arrangement for feeding additional dry, clean air into tubes close to the sampling probes (schematic)** | | -- |
| 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.<br>Each probe is fitted onto a length of suitable transparent plastic tube with an internal diameter of 4,0 mm. | | P |



| | | | |
|---|---|---|---|
| | Dimensions in millimetres<br>  **Figure 3 — Sampling probe** | | -- |
| | 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 |
| |  **Figure 4 — Positions of the three sampling probes on body of test subject** | | -- |
| | 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.<br>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.<br>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.<br>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.<br>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.<br>The size of the suit shall be selected in accordance with the test subject's body dimensions and according to the manufacturer's instructions.<br>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 | | -- |



| | | | |
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| | At least five test subjects shall test at least two suits per person, i.e., at least ten suits shall be tested.<br>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 |

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| | 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.<br>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.<br>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 | | -- |

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| | The following test sequence shall be followed for each suit.<br>-- 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.<br>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.<br>-- 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.<br>-- 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 |



| | | | |
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| | challenge concentration in the chamber takes more than 1 min, the suit shall be ventilated to avoid penetration of particles into it. --<br>Measure the concentrations at the following sampling positions (see also Figure 4):<br>-- knee (lateral),<br>-- waist (back),<br>-- chest (right);<br>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:<br>1) standing still,<br>2) walking at 5 km/h,<br>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.<br>Allow for a 3 min rest (standing still) between the walking and the squatting exercises.<br>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.<br>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.<br>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.<br>-- 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 |

| | | | |
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| | each of the test subjects (i) (at least five test subjects) in accordance with Equation (1): | | |
| | $L_{ijmn} = \frac{C_{ijmn} \times 100\%}{C}$<br>where<br>$C$ is the challenge concentration;<br>$C_{ijmn}$ is the concentration for sampling position $n$ for exercise $m$ for suit $j$ for test subject $i$.<br>All percentage inward leakage values shall be reported. | | -- |
| 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):<br>$L_{S,j} = \frac{1}{mn}\sum_{m}\sum_{n} L_{ijmn}$<br>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)<br>$L_{H,i} = \frac{1}{jmn}\sum_{j}\sum_{m}\sum_{n} L_{ijmn}$<br>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):<br>$L_{E,m} = \frac{1}{jn}\sum_{j}\sum_{n} L_{ijmn}$<br>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):<br>$L_{P,n} = \frac{1}{jm}\sum_{j}\sum_{m} L_{ijmn}$<br>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):<br>$L_{EP,mn} = \frac{1}{j}\sum_{j} L_{ijmn}$<br>The data reported pertain to 10 suits (or more). | | P |
| 7.2.6 | The mean total inward leakage<br>The average, L of all total inward leakage measurements shall then be calculated in | | P |

| | | | |
|---|---|---|---|
| | accordance with<br>Equation (7) and reported:<br>$\bar{L} = \frac{1}{j}\sum_{j} L_{S,j} = \frac{1}{i}\sum_{i} L_{H,i} = \frac{1}{m}\sum_{m} L_{E,m} = \frac{1}{n}\sum_{n} L_{P,n}$ | | |
| 8 | Test report | | -- |
| | The test report shall contain the following information:<br>a) reference to this International Standard (i.e., ISO 13982-2:2004);<br>b) identity of the manufacturer of the suit;<br>c) size of the suits tested and the body measurements of the test subjects, in accordance with the provisions of EN 340;<br>d) description of the underwear worn by test subjects;<br>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;<br>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;<br>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;<br>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;<br>i) all inward leakage results, presented in the form of data tables:<br>-- 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),<br>-- table giving total inward leakage values for all test subjects and test suits (modelled on Table 3),<br>-- table giving total inward leakage values per test subject (modelled on Table 4);<br>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 | chest | standing still |
| | | — | waist back | knee | |
| | | — | chest | waist back | |
| 2 | waiting for stabilization and measuring the test agent concentration inside chamber | — | — | — | |
| 3 | measuring the test agent concentration inside suit | 3 | knee | chest | standing still |
| | | 3 | waist back | knee | |
| | | 3 | chest | waist back | |
| | | 3 | knee | chest | walking |
| | | 3 | waist back | knee | |
| | | 3 | chest | waist back | |
| 4 | stabilization between walking and squatting | 1 | knee | chest | standing still |
| | | 1 | waist back | knee | |
| | | 1 | chest | waist back | |
| 5 | measuring the test agent concentration inside suit | 3 | knee | chest | squatting |
| | | 3 | waist back | knee | |
| | | 3 | chest | waist back | |
| 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 | $L_{ij11}$ | $L_{ij12}$ | $L_{ij13}$ | $L_{E1ij}$ |
| walking | $L_{ij21}$ | $L_{ij22}$ | $L_{ij23}$ | $L_{E2ij}$ |
| squatting | $L_{ij31}$ | $L_{ij32}$ | $L_{ij33}$ | $L_{E3ij}$ |
| average per sampling position | $L_{P1ij}$ | $L_{P2ij}$ | $L_{P3ij}$ | $L_{Sij}$ |

**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 | $L_{EP11}$ | $L_{EP12}$ | $L_{EP13}$ | $L_{E1}$ |
| walking | $L_{EP21}$ | $L_{EP22}$ | $L_{EP23}$ | $L_{E2}$ |
| squatting | $L_{EP31}$ | $L_{EP32}$ | $L_{EP33}$ | $L_{E3}$ |
| average per sampling position | $L_{P1}$ | $L_{P2}$ | $L_{P3}$ | $\overline{L}$ |

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

| Test subject | Total inward leakage per suit, $L_{Sj}$ | Total inward leakage per human test subject, $L_{Hi}$ |
|---|---|---|
| 1 | $L_{S1}$, $L_{S2}$ | $L_{H1}$ |
| 2 | $L_{S3}$, $L_{S4}$ | $L_{H2}$ |
| ...i... | $L_{S2i-1}$, $L_{S2i}$ | $L_{Hi}$ |
| average | $\overline{L}$ | $\overline{L}$ |

- End of Review Report -

## Annex：Technical Information

### (1) Product Photos

A.1

QG07

# 中华人民共和国海关
# 报关单位注册登记证书

海关注册编码：2106961403

组织机构代码：590908261

企 业 名 称：丹东大爱服装有限公司

企 业 住 所：丹东市振安区同兴镇同兴路83号

企业经营类别：进出口货物收发货人

注册登记日期：2012年5月30日

法定代表人：赵龙哲

有 效 期：长期

注册海关：丹东海关

核发日期：2017年4月17日

## 重 要 提 示

报关单位应当在每年6月30日前向海关提交《报关单位注册信息年度报告》，不再另行通知。

中华人民共和国海关总署监制

# 开户许可证

核准号: J2260002372304

编 号: 2210- 02488511

经审核，丹东大爱服装有限公司 符合开户条件，准予开立基本存款账户。

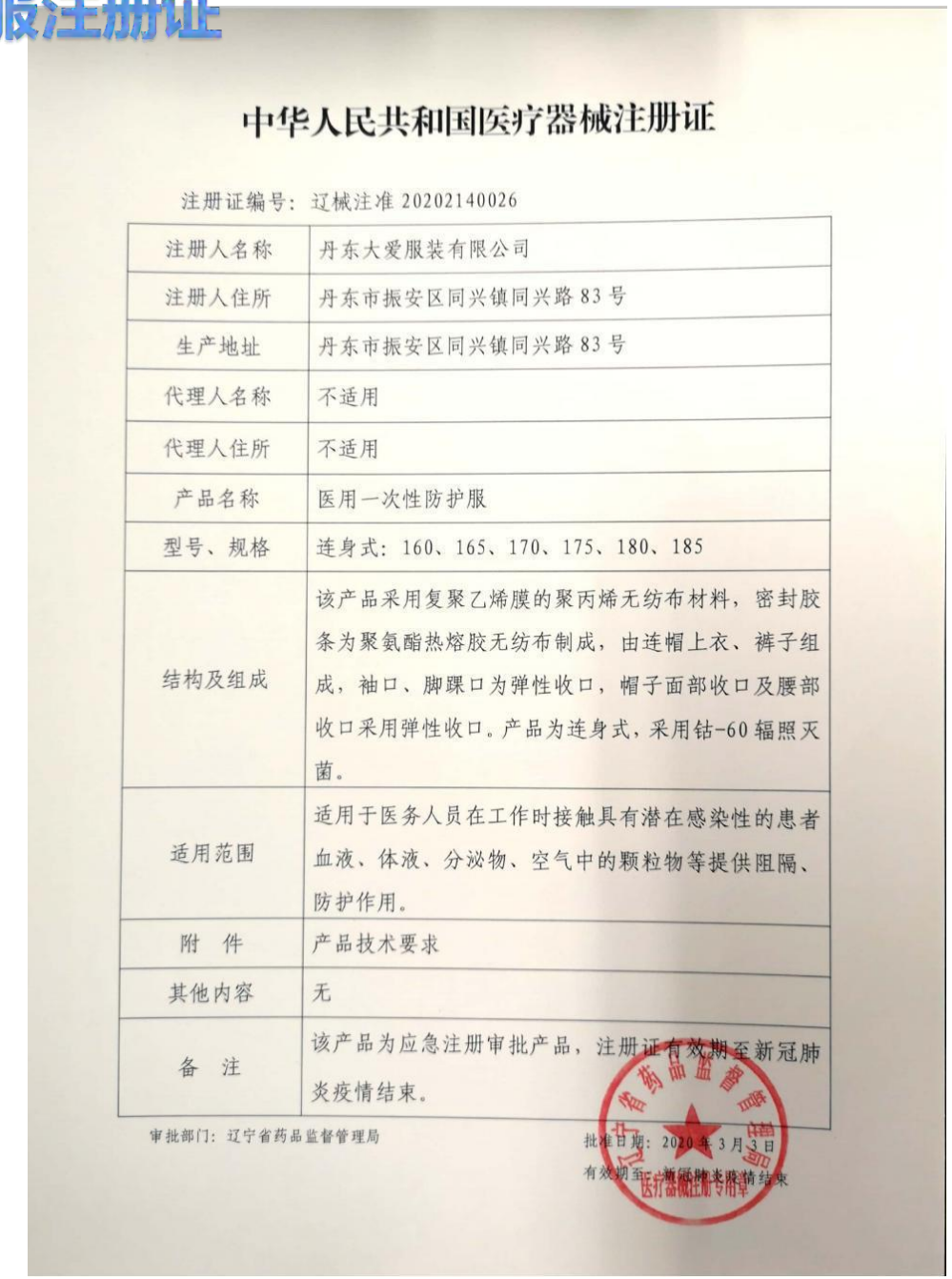
法定代表人（单位负责人） 赵龙哲 开户银行 中国光大银行丹东支行营业部

账 号 75700188000108134

发证机关（盖章）

2021 年 02 月 01 日

# 防护服注册证



## 中华人民共和国医疗器械注册证

注册证编号：辽械注准 20202140026

| | |
|---|---|
| 注册人名称 | 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路 83 号 |
| 代理人名称 | 不适用 |
| 代理人住所 | 不适用 |
| 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 |
| 结构及组成 | 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。 |
| 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。 |
| 附　件 | 产品技术要求 |
| 其他内容 | 无 |
| 备　注 | 该产品为应急注册审批产品，注册证有效期至新冠肺炎疫情结束。 |

审批部门：辽宁省药品监督管理局

批准日期：2020 年 3 月 3 日

有效期至：新冠肺炎疫情结束

辽宁省药品监督管理局 医疗器械注册专用章

## Registration Certificate of Medical Apparatus and Instruments of the People's Republic of China

Serial No. of Registration Certificate: L. X. Z. Z. 20202140026

| | |
|---|---|
| Registrant Name | Dandong Devote Garment Co., Ltd. |
| Registrant Address | No. 83 Tongxing Road, Tongxing Town, Zhen'an District, Dandong |
| Production Address | No. 83 Tongxing Road, Tongxing Town, Zhen'an District, Dandong |
| Agent Name | Not applicable |
| Agent Address | Not applicable |
| Product Name | Medical disposable protective clothing |
| Model and Specifications | One-piece: 160, 165, 170, 175, 180, 185 |
| Structure and Composition | The product uses the polypropylene non-woven fabric with polyethylene film as its materials. The sealing rubber strip is made of rubber-lined non-woven fabric. It consists of a hooded jacket and pants, and there are elastic closing up designs on the cuffs and foot openings. The elastic closing up design is applied in the hoodie face and waist. The product is in the type of one-piece, and uses cobalt-60 radiation sterilization. |
| Scope of Application | It is suitable for playing a role of barrier and protection for clinical medical staff who may be in contact with the blood, body fluids, secretions, etc. of potentially infectious patients during the work as well as the particles in air. |
| Annex | Technical Requirements of Product |
| Other Contents | N/A |
| Remarks | This product is an emergency product with temporary approval during the COVID-19 outbreak, and the registration certificate is valid for 30 days. |

Approval Authority: Liaoning Provincial Medical Products Administration

Approval date: February 21, 2020

Valid until:the end of the COVID-19 outbreak

Special Seal for Filing of Medical Apparatus and Instruments of Dandong Municipal Administration for Market Regulation (Seal)

# 医疗器械生产产品登记表

| | |
|---|---|
| 企业名称 | 丹东大爱服装有限公司 |
| 许可证编号 | 辽食药监械生产许 20200016 号 |
| 许可证有效期限 | 新冠肺炎疫情结束 |
| 生产范围 | 2002 分类目录Ⅱ类: 6864-2-敷料、护创材料<br>2017 分类目录Ⅱ类:14-14-医护人员防护用品 |

生产产品列表

| 序号 | 产品名称 | 注册号 | 登载日期 | 备注 |
|---|---|---|---|---|
| 1 | 医用一次性防护服 | 辽械注准 20202140026 | 2020-03-03 | |
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发证部门（公章）：辽宁省药品监督管理局

辽宁省药品监督管理局

2020 年 03 月 03 日

## Registration Form of Medical Apparatus and Instruments Produced

| | | | | |
|---|---|---|---|---|
| Enterprise Name | Dandong Devote Garment Co., Ltd. | | | |
| License No. | L. S. Y. J. X. S. C. X. No. 20200016 | | | |
| License Validity | Until the end of the COVID-19 outbreak | | | |
| Production Scope | 2002 Classification Catalogue Class II: 6864-2- Dressing and Wound Protection Materials<br>2017 Classification Catalogue Class I: 14-14- Protective Equipment for Medical Staff | | | |
| List of Production Products | | | | |
| No. | Product Name | Registration No. | Date of Entry | Remarks |
| 1 | Medical disposable protective suit | L. X. Z. Z. 20202140026 | March 3, 2020 | |
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| | | | | |
| | | | | |
| | | | | |
| | | | | |
| License Issuing Authority (Common Seal): Liaoning Provincial Medical Products Administration<br>Liaoning Provincial Medical Products Administration (Seal)<br>March 3, 2020 | | | | |

# 检 验 检 测 报 告

# Test Report

防伪查询

STFWT20200826



| | | | |
|---|---|---|---|
| 产品名称 Product Name | 医用一次性防护服材料 | 规格型号 Specification Type | —— |
| | | 商 标 Trademark | 恬然 / TR |
| 委托单位 Trust Unit | 江苏恬然环保科技发展有限公司 | 电 话 Tel | 15900688890 |
| 生产单位 Manufacturer | 江苏恬然环保科技发展有限公司 | 样品等级 Sample Grade | —— |
| 样品数量 Sample Quantity | 3 m | 送样日期 Sample Receiving Date | 2020-02-14 |
| 检验检测类别 Test Category | 委托送样检验 | 批号/货号 Serial Number | —— |
| 样品状态 Samples Conditions | 符合检测要求 | | |
| 检验检测及判定依据 Document and Decide Accordance | GB 19082-2009 《医用一次性防护服技术要求》 | | |
| 检验检测结论 Test Conclusion | 样品经检验，所检项目符合 GB 19082-2009 标准规定的要求。<br>签发日期：2020-02-17<br>SignaturimDate | | |
| 备 注 Remarks | 本报告检验结论仅对所检项目得出，不代表未经检验的项目或功能符合要求。<br>本报告仅对来样负责。 | | |

批 准：Approver 陈敏 审 核：Examiner 吴高高 主 检：Majortester 卞素兰


# 检 验 检 测 报 告

# Test Report

防伪查询

STFWT20200826

共 2 页 第 1 页
Page 1 of 2

| | | | |
|---|---|---|---|
| 产品名称 Product Name | 医用一次性防护服材料 | 规格型号 Specification Type | —— |
| | | 商 标 Trademark | 恬然 / TR |
| 委托单位 Trust Unit | 江苏恬然环保科技发展有限公司 | 电 话 Tel | 15900688890 |
| 生产单位 Manufacturer | 江苏恬然环保科技发展有限公司 | 样品等级 Sample Grade | —— |
| 样品数量 Sample Quantity | 3 m | 送样日期 Sample Receiving Date | 2020-02-14 |
| 检验检测类别 Test Category | 委托送样检验 | 批号/货号 Serial Number | —— |
| 样品状态 Samples Conditions | 符合检测要求 | | |
| 检验检测及判定依据 Document and Decide Accordance | GB 19082-2009 《医用一次性防护服技术要求》 | | |
| 检验检测结论 Test Conclusion | 样品经检验，所检项目符合 GB 19082-2009 标准规定的要求。<br>签发日期：2020-02-17<br>SignaturimDate | | |
| 备 注 Remarks | 本报告检验结论仅对所检项目得出，不代表未经检验的项目或功能符合要求。<br>本报告仅对来样负责。 | | |

批 准：Approver 陈敏 审 核：Examiner 吴高高 主 检：Majortester 卞素兰

# 检 验 检 测 结 果
# Testing Results

STFWT20200826



| 序号 Serial | 检验检测项目 Test Items | 单位 Unit | 技术要求 Requirement | 检验检测结果 Results | 单项评价 Individual Judgment |
|---|---|---|---|---|---|
| 1 | 抗渗水性（液体阻隔功能） | kPa ($17cmH_2O$) | ≥1.67 | >2.0 | 合 格 |
| 2 | 透湿量（液体阻隔功能） | $g/(m^2 \cdot d)$ | ≥2500 | $4.32\times10^3$ | 合 格 |
| 3 | 抗合成血液穿透性（液体阻隔功能） | —— | 试样在 1.75kPa 压力下，保持 5min 后，可视面观察无液体穿透。 | 试样在 20kPa 压力下，保持 5min 后，可视面观察无液体穿透，样品抗合成血液穿透性 6 级 | 合 格 |
| 4 | 表面抗湿性/级（液体阻隔功能） | —— | 沾水等级 ≥3 | 沾水等级 4-5、4-5、4-5 | 合 格 |
| 5 | 断裂强力 | N | ≥45 | 经向：190<br>纬向：114 | 合 格 |
| 6 | 断裂伸长率/% | —— | ≥15 | 经向：100<br>纬向：96 | 合 格 |
| 7 | 过滤效率/%（流量 85L/min） | —— | ≥70 | 面料：<br>1#100.0 2#100.0<br>3#100.0<br>接缝：<br>1#100.0 2#100.0<br>3#100.0 | 合 格 |

## 样 品 图 片

测试样品

——以下空白——

# 注 意 事 项

1、检验检测报告无“检验检测报告专用章”或检验检测单位公章无效。

2、复制检验检测报告未重新加盖“检验检测报告专用章”或检验检测单位公章无效。

3、检验检测报告无主检、审核、批准人签字无效。

4、检验检测报告涂改无效。

## Points For Attention

1. This Report Is Invalid If Without “The Text Report Special Seal” Or The Official Seal Of The Institute.
2. The Reproduction Is Invalid If Without Being Confirmed By “The Text Report Special Seal” Or The Official Seal Of The Institute.
3. This Report Is Invalid If Without Signature Of The Major Tester And The Examiner And The Approver.
4. This Report Is Invalid If In Any Form By Any Means Altered.

检验检测机构地址：江苏省泰州市高港区临港经济园临港大道166号
The Institute Add: Lingang Road 166, Lingang Economic Park , Gaogang, Taizhou.Jiangsu
检验检测机构监督电话：0523-86989901
The Institute Complain Tel:0523-86989901
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# 检验报告 1

# 检　验　报　告

辽检（医械）字（2020）第 180 号

受检单位 丹东大爱服装有限公司

样品名称 医用一次性防护服

型号规格 连身式/170

检验类别 应急检验

辽宁省医疗器械检验检测院

辽宁省医疗器械检验检测院

## 检　验　报　告

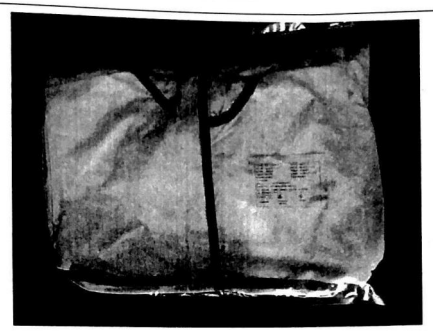
报告编号：辽检（医械）字（2020）第 180 号　　共 3 页　第 1 页

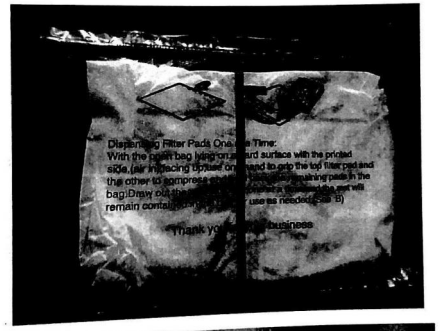
| | | | |
|---|---|---|---|
| 样品名称 | 医用一次性防护服 | 型号规格 | 连身式/170 |
| 委托单位 | 丹东大爱服装有限公司 | 商　标 | —— |
| 客户地址 | 丹东市振安区同兴镇同兴路 83 号 | 检验类别 | 应急检验 |
| 受检单位 | 丹东大爱服装有限公司 | 生产日期 | 2020 年 02 月 13 日 |
| 生产单位 | 丹东大爱服装有限公司 | 抽样日期 | —— |
| 送样单位 | 丹东大爱服装有限公司 | 到样日期 | 2020 年 02 月 17 日 |
| 抽样地点 | —— | 抽样单编号 | —— |
| 检验地点 | 本院试验室 | 抽样基数 | —— |
| 检验日期 | 2020.02.18～2020.02.23 | 样品数量 | 50 件 |
| 检验项目 | 抗渗水性等 | 样品批号 | L20200201 |
| 检验依据 | GB 19082-2009 医用一次性防护服技术要求 | | |
| 检验结论 | **受检项目符合 GB 19082-2009 标准要求**<br>检验检测专用章<br>（检验检测专用章） | | |
| 备注 | 1）报告中的“——”表示此项不适用或此项空白。<br>2）判定中 P 为检验结果符合要求、F 为检验结果不符合要求、N 为要求不适用于该产品。<br>3）本报告为应急注册检验，未取得医疗器械注册证和生产许可证之前，本报告不得用于产品的销售、宣传。 | | |

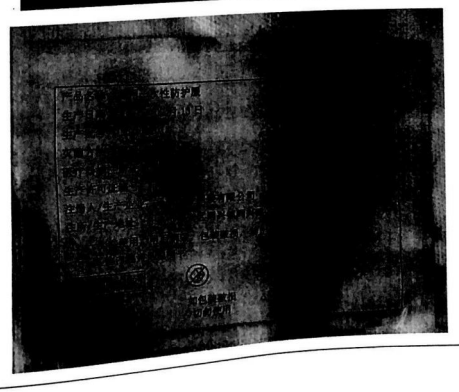
批准：　　职务：副院长　　日期：2020.2.23

审核：　　检验：

照片和说明









| 准条款 | 要　求 | 检验结果 | 判定 | | |
|---|---|---|---|---|---|
| | | | P | F | N |
| 4.4.1 | 抗渗水性<br>防护服关键部位静水压应不低于 1.67kPa（17cm $H_2O$） | 符合要求 | √ | | |
| 4.4.3 | 抗合成血液穿透性<br>防护服抗合成血液穿透性应不低于表 3 中 2 级的要求 | 符合要求 | √ | | |
| 4.5 | 断裂强力<br>防护服关键部位材料的断裂强力应不小于 45N | 纵向：110N<br>横向：73N | √ | | |
| 4.7 | 过滤效率<br>防护服关键部位材料及接缝处对非油性颗粒的过滤效率应不小于 70% | 最小值为：99.8% | √ | | |

# 声　明

1、报告未加盖检验检测专用章或检验检测单位公章无效。

2、复制报告必须全文复制，未经检验检测单位批准不得部分复制，且复制的报告未重新加盖检验检测专用章或检验检测单位公章无效。

3、报告无检验/检测、审核、批准人签字无效。

4、报告涂改无效。

5、对报告若有异议，请于收到报告之日起十五日内以书面方式向检验检测单位提出，逾期不予受理。

6、报告结果仅适用于收到的样品。

7、对委托送样的样品及信息的真实性，由委托单位负责。

8、非检验检测单位抽取的样品（如样品由客户提供），检验检测单位不对抽样的真实性负责。

地　　址：沈阳市浑南区麦子屯 600-1 号
电　　话：（024）83780222　（024）83780223
传　　真：（024）83780221
邮政编码：110171
网　　址：http://www.lmti.cn

# Test Report 1

**Test Report**

L. J. (Y. X.) (2020) No. 180

Entity under Test: Dandong Devote Garment Co., Ltd.

Sample Name: Medical disposable protective suit

Model and Specifications: One-piece / 170

Test Category: Emergency test

Special Seal for Test of Liaoning Medical Device Test Institute (Cross-Page Seal)

Liaoning Medical Device Test Institute

Special Seal for Test of Liaoning Medical Device Test Institute (Seal)

Liaoning Medical Device Test Institute

**Test Report**

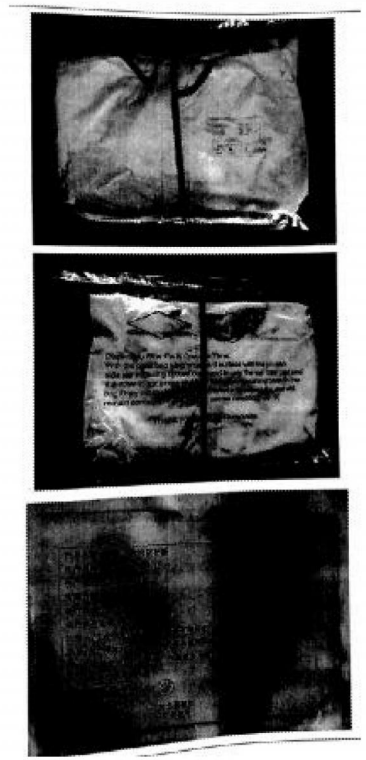


| | | | |
|---|---|---|---|
| Sample Name | Medical disposable protective suit | Model and Specifications | One-piece / 170 |
| Entrusting Entity | Dandong Da Ai Clothing Co., Ltd. | Trademark | --- |
| Customer Address | No. 83 Tongxing Road, Tongxing Town, Zhen'an District, Dandong City | Test Category | Emergency test |
| Entity under Test | Dandong Da Ai Clothing Co., Ltd. | Production Date | February 13, 2020 |
| Production Entity | Dandong Da Ai Clothing Co., Ltd. | Sampling Date | --- |
| Sampling Entity | Dandong Da Ai Clothing Co., Ltd. | Sample Arrival Date | February 17, 2020 |
| Sampling Location | --- | Sampling Order No. | --- |
| Test Location | Laboratory of the Institute | Sampling Base | --- |
| Test Date | Feb. 18, 2020 ~ Feb. 23, 2020 | Number of Samples | 50 pieces |
| Test Item | Impermeability, etc. | Sample Lot No. | L20200201 |
| Test Basis | GB 19082-2009 technical requirements for medical disposable protective suit | | |
| Test Conclusion | The tested item meets the requirements of the GB19082-2009 Standard<br>Special Seal for Test of Liaoning Medical Device Test Institute<br>(Special Seal for Test) | | |
| Remarks | 1) The "----" in the report indicates that this item is not applicable or this item is blank.<br>2) In the determination, P means that the test results meet the requirements F means that the test results do not meet the requirements, and N means that the requirements are not applicable to the product.<br>3) This report is an emergency registration test. Before the medical device registration certificate and production license have been obtained, this report shall not be used for product sales and promotion. | | |

Special Seal for Test of Liaoning Medical Device Test Institute (Cross-Page Seal)

Approved by: Jian Yu Title: Deputy Director Date: February 23, 2020
(Signature)
Tested by: Feng Yan
(Signature)
Checked by: Du Chunmiao
(Signature)

Photos and Description



Special Seal for Test of Liaoning Medical Device Test Institute (Cross-Page Seal)



| Standard Clause | Requirements | Test Result | Determination | | |
|---|---|---|---|---|---|
| | | | P | F | N |
| 4.4.1 | Impermeability<br>The hydrostatic pressure of key parts of protective suit shall not be lower than 1.67kPa (17cmH2O.) | In compliance with the requirements | √ | | |
| 4.4.3 | Resistance to synthetic blood penetration<br>The protective suit's resistance to synthetic blood penetration shall not be lower than the requirements of Level 2 as set out in Table 3. | In compliance with the requirements | √ | | |
| 4.5 | Breaking strength<br>The breaking strength of the key parts of the protective suit shall not be lower than 45N | Longitudinal: 110N<br>Horizontal: 73N | √ | | |
| 4.7 | Filtration efficiency<br>The filtering efficiency of non-oily particles in the key parts of the protective suit and the seam crossing shall not be lower than 70% | The minimum value is 99.8% | √ | | |

---

Special Seal for Test of Liaoning Medical Device Test Institute (Cross-Page Seal)

Statement

1. The report without the special seal for test or the common seal of testing entity affixed hereto shall be invalid.
2. The report may be reproduced in its entirety only. Partial copy shall not be made without the approval of the testing entity, and the copy of report without the special seal for test or the common seal of testing entity further affixed hereto shall be invalid.
3. The report without the signatures of the inspection / testing, review and approval personnel shall be invalid.
4. The alteration of the report will make it invalid.
5. In case of any objection to the report, please submit the same in written to the testing entity within 15 days from the date of receipt of the report. The overdue objection will not be accepted.
6. The report results are only applicable to the samples received.
7. The entrusting entity shall be responsible for the authenticity of the samples entrusted for submission and the information thereof.
8. For samples taken by entities other than the testing entity (such as the samples provided by the customer), the testing entity shall not be responsible for the authenticity of the samples.

Special Seal for Test of Liaoning Medical Device Test Institute (Cross-Page Seal)

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Fax: (024) 83780221
Zip Code: 110171
Website: http://www.lmti.cn

# 检验报告2

# 检　验　报　告

辽检（医械）字（2020）第 180(SW)号

受检单位　丹东大爱服装有限公司

样品名称　医用一次性防护服

型号规格　连身式/170

检验类别　应急检验

辽宁省医疗器械检验检测院

辽宁省医疗器械检验检测院

## 检　验　报　告

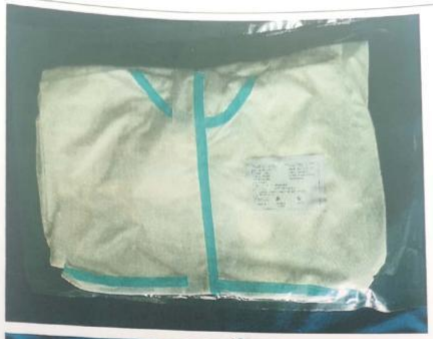
报告编号：辽检（医械）字（2020）第 180(SW)号　　共 3 页　第 1 页

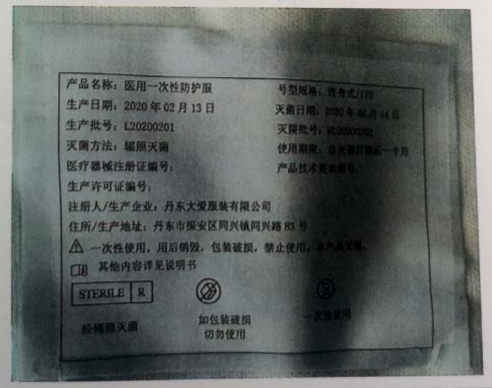
| | | | |
|---|---|---|---|
| 样品名称 | 医用一次性防护服 | 型号规格 | 连身式/170 |
| 委托单位 | 丹东大爱服装有限公司 | 商　标 | —— |
| 客户地址 | 丹东市振安区同兴镇同兴路 83 号 | 检验类别 | 应急检验 |
| 受检单位 | 丹东大爱服装有限公司 | 生产日期 | 2020 年 02 月 13 日 |
| 生产单位 | 丹东大爱服装有限公司 | 抽样日期 | —— |
| 送样单位 | 丹东大爱服装有限公司 | 到样日期 | 2020 年 02 月 17 日 |
| 抽样地点 | —— | 抽样单编号 | —— |
| 检验地点 | 本院试验室 | 抽样基数 | —— |
| 检验日期 | 2020.02.17～2020.03.02 | 样品数量 | 50 件 |
| 检验项目 | 无菌 | 样品批号 | L20200201 |
| 检验依据 | GB 19082-2009 医用一次性防护服技术要求 | | |
| 检验结论 | **受检项目符合 GB 19082-2009 标准要求**<br>（检验检测专用章） | | |
| 备注 | 1）报告中的“——”表示此项不适用或此项空白。<br>2）判定中 P 为检验结果符合要求、F 为检验结果不符合要求、N 为要求不适用于该产品。<br>3）本报告为应急注册检验，未取得医疗器械注册证和生产许可证之前，本报告不得用于产品的销售、宣传。 | | |

批准：　　职务：副院长　　日期：2020.3.2.

审核：　　检验：

照片和说明






| 标准条款 | 要　求 | 检验结果 | 判定 | | |
|---|---|---|---|---|---|
| | | | P | F | N |
| 4.12.2 | 包装上标志有“灭菌”或“无菌”字样或图示的防护服应无菌 | 符合要求 | √ | | |

# Test Report 2

**Test Report**

L. J. (Y. X.) (2020) No. 180 (SW)

Entity under Test: Dandong Devote Garment Co., Ltd.

Sample Name: Medical disposable protective suit

Model and Specifications: One-piece / 170

Test Category: Emergency test

Special Seal for Test of Liaoning Medical Device Test Institute (Cross-Page Seal)

Liaoning Medical Device Test Institute

Special Seal for Test of Liaoning Medical Device Test Institute (Seal)

Liaoning Medical Device Test Institute

**Test Report**

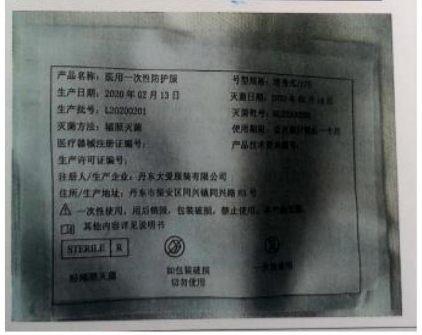


| | | | |
|---|---|---|---|
| Sample Name | Medical disposable protective suit | Model and Specifications | One-piece / 170 |
| Entrusting Entity | Dandong Da Ai Clothing Co., Ltd. | Trademark | --- |
| Customer Address | No. 83 Tongxing Road, Tongxing Town, Zhen'an District, Dandong City | Test Category | Emergency test |
| Entity under Test | Dandong Da Ai Clothing Co., Ltd. | Production Date | February 13, 2020 |
| Production Entity | Dandong Da Ai Clothing Co., Ltd. | Sampling Date | --- |
| Sampling Entity | Dandong Da Ai Clothing Co., Ltd. | Sample Arrival Date | February 17, 2020 |
| Sampling Location | --- | Sampling Order No. | --- |
| Test Location | Laboratory of the Institute | Sampling Base | --- |
| Test Date | Feb. 17, 2020 ~ Mar. 2, 2020 | Number of Samples | 50 pieces |
| Test Item | Impermeability, etc. | Sample Lot No. | L20200201 |
| Test Basis | GB 19082-2009 technical requirements for medical disposable protective suit | | |
| Test Conclusion | The tested item meets the requirements of the GB19082-2009 Standard<br>Special Seal for Test of Liaoning Medical Device Test Institute<br>(Special Seal for Test) | | |
| Remarks | 1) The "----" in the report indicates that this item is not applicable or this item is blank.<br>2) In the determination, P means that the test results meet the requirements F means that the test results do not meet the requirements, and N means that the requirements are not applicable to the product.<br>3) This report is an emergency registration test. Before the medical device registration certificate and production license have been obtained, this report shall not be used for product sales and promotion. | | |

Special Seal for Test of Liaoning Medical Device Test Institute (cross-page seal)

Approved by: Chen Su Title: Deputy Director Date: March 2, 2020 (signature)
Tested by: [Original Unclear] (signature)
Checked by: Yu Yang (signature)

Photos and Description


Special Seal for Test of Liaoning Medical Device Test Institute (Cross-Page Seal)



| Standard Clause | Requirements | Test Result | Determination | | |
|---|---|---|---|---|---|
| | | | P | F | N |
| 4.12.2 | The protective suit with its package marked with the works or graphic description of “sterilization” or “sterile” shall be sterilized. | In compliance with the requirements | √ | | |

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Special Seal for Test of Liaoning Medical Device Test Institute (Cross-Page Seal)

# 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。

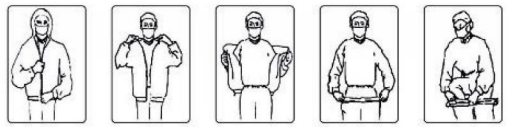
【注册人/生产企业名称】丹东大爱服装有限公司
【注册人住所】丹东市振安区同兴镇同兴路83号
【生产地址】丹东市振安区同兴镇同兴村
【联系电话】0415-6136677
【售后服务单位】丹东大爱服装有限公司
【生产许可证编号】辽食药监械生产许 20200016 号
【医疗器械注册证编号】辽械注准 20202140026
【产品技术要求编号】辽械注准 20202140026
【说明书编制日期】2020年03月03日
【生产日期】详见产品标签
【使用期限】自灭菌日期后一个月

**Instruction Manual for Medical Disposable Protective Suit**

**oduct Name]** Medical disposable protective suit
**lodel and Specifications]** One-piece: One-piece: 160 □, 165 □, 170 □, 175 □, 180 □, 185 □
**ructure Composition]**
e product uses the polypropylene non-woven fabric with polyethylene film as its material
aling rubber strip is made of rubber-lined non-woven fabric. It consists of a hooded jacke
nts, and there are elastic closing up designs on the cuffs and foot openings. The elastic c
design is applied in the hoodie face and waist. The product is in the type of one-piece
es cobalt-60 radiation sterilization.
**lain Performance]**
The product is sterile;
The main performance indicators are in compliance with the provisions of the GB 19082
ndard.
**:ope of Application]**
s suitable for playing a role of barrier and protection for clinical medical staff who may
ntact with the blood, body fluids, secretions, etc. of potentially infectious patients durin
rk as well as the particles in air.
**ontraindications, Precautions, Warnings and Informative Contents]**
This product is provided for single use only, and repeated use is prohibited.
Please read the usage method before using this product so as to ensure the correct wearir
Please check whether the package is intact, and confirm the packaging mark, productior
d sterilization validity period before using this product, and please use it within the va
riod.
After using this product, please dispose of it according to the medical waste manage
easures of medical and health institutions, and do not discard it freely.
This product is sterilized by irradiation with cobalt-60, and its use is strictly prohibited ir
the damaged packaging.
Those who are allergic to non-woven fabrics, have heart disease patients, and have
comforts after wearing it shall use it with caution under the guidance of a physician.
**structions on Use]**
Please check whether the package is intact, and confirm the packaging mark, productior
d service life before using this product, and please use it within the validity period
Wear one-piece protective suit
ll the zipper to the proper position, grasp the opening of the waist zipper of the m
otective suit while holding the left and right cuffs with your left and right hands, wea
ver limbs first and then wear the upper limbs. After that, pull the zipper to the chest, an
the hood of medical protective suit. Finally, pull the zipper to the top and tie up the neckl
Take off the one-piece medical disposable protective suit
. First pull the zipper of medical protective suit to the end, as shown in Figure ①;
. Lift the hood upward to make the hat off the head, as shown in Figure ②;
. Hold the shoulders on both sides of the medical protective suit with both hands, and ta
protective suit to the lower part of the shoulder.
. First hold the edge of the contaminated surface (outer surface) of the right-handed m
ve with your left hand to remove the glove (inside-out), and hold it in your hand. Then

# 防护服说明书
# （按实际出货微调）

the inside of the left-handed glove with your right hand and remove the medical glove (inside-out). Both hands leave the sleeves. As shown in Figure ④;
3.5. Grasp the inner surface of the medical protective suit with both hands, and taking it off from the inside to the outside and from top to bottom while rolling it up until the suite is fully removed. Roll up the medical protective suit and the outer gloves wrapped therein into the medical waste bag. As shown in Figure ⑤
**Graphic description of taking off the medical disposable protective suit**



① ② ③ ④ ⑤

**[Sample Drawing of Label and Packaging Mark]**


Sterilized by irradiation with cobalt-60　Its use is strictly prohibited in case of the damaged packaging.　For single use

**[Maintenance Method]** For single use
**[Special Storage Conditions and Methods]** It shall be stored in a ventilated, dry and non-corrosive gas environment. Keep it away from fire and flammable materials. The product shall be protected from moisture and put in closed package during transportation.
**[Sterilization Method]** Sterilized by irradiation with cobalt-60
**[Package and Others]** This product is packed in PE bags with one piece packaged in a bag and 20 pieces in a carton.
**[Name of Registrant / Manufacturing Enterprise]** Dandong Devote Garment Co., Ltd.
**[Registrant Address]** No. 83 Tongxing Road, Tongxing Town, Zhen'an District, Dandong City
**[Production Address]** Tongxing Village, Tongxing Town, Zhen'an District, Dandong City
[Tel] 0415-6136677
**[After-sales Service Entity]** Dandong Devote Garment Co., Ltd.
**[Production License No.]** L. S. Y. J. X. S. C. X. No. 20200016
**[Registration Certificate No. of Medical Apparatus and Instruments]** L. X. Z. Z. 2020202040026
**[Product Technical Requirement No.]** L. X. Z. Z. 20202140026
**[Preparation Date of Instruction Manual]** March 3, 2020
**[Production Date]** See product label for details
**[Term of Use]** One month after the date of sterilization

# 防护服合格证

## 合格证

产品名称：一次性使用防护服
生产批号：
生产日期：
检验章：合 格

## Certificate of Conformity

Product Name: Disposable protective suit

Production Lot No.:

Production Date:

Inspection Seal: Pass


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
弹性帽檐
防尘
阻隔血液、抗静电
透气
胶条密封防护
防喷溅


医用一次性防护服
连身式
弹性收口
全身包裹
现货秒发
适应于医院、重症监护、
政府机关

# 产 品 实 拍


产品包装

# 产品细节图



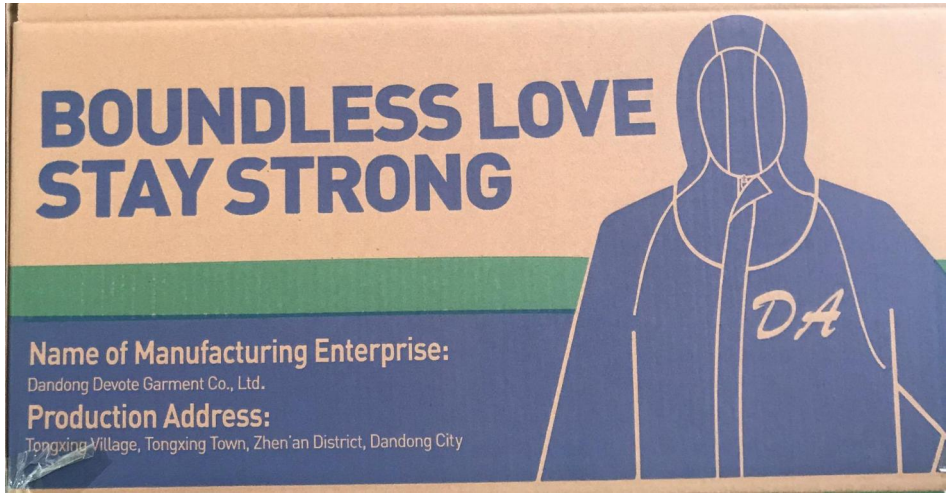


品质保证


仓库现货


24小时加班供应

# 出口外箱包装


尺寸size：60*40*30cm
装箱规格：30件/箱
Qty/Ctn:30pieces/ctn
单件毛重0.3公斤/件
GW./piece: 0.3kg/piece
整箱毛重:9.8公斤
GW./Ctn： 9.8kg/Ctn

# 国内外箱包装


尺寸size：65*42*25cm
装箱规格：20件/箱
Qty/Ctn: 20pieces/ctn
单件毛重：0.2公斤/件
GW./piece: 0.3kg/piece
整箱毛重公斤：6.5公斤/箱
GW./Ctn： 6.5kg/Ctn