



企业生产产品资质认证

第一类医疗器械生产备案凭证

备案编号：鲁德食药监械生产备 20200006 号

企业名称	德州美洛服装设计有限公司			
住 所	山东省德州市德城区天衢街道办事处天衢工业园德州金田高新技术创业发展有限公司 8 号厂房 2 层			
生产地址	山东省德州市德城区天衢街道办事处天衢工业园德州金田高新技术创业发展有限公司 8 号厂房 2 层			
法定代表人	李国敬	企业负责人	李国敬	
生产范围				
新生产范围	I 类：14 注输、护理和防护器械			
生产产品列表				
序号	产品名称	产品备案号	是否受托生产	备注
1	隔离衣	鲁 德 械 备 20200029 号		

备案部门（公章）

备案日期：2020 年 02 月 25 日





Certificate

No. ICR Polska/P6301907



Name and address of certificate owner: Meiluo Fashion Design Co., Ltd
Building 8, jintian entrepreneurship center, decheng district, dezhou city, shandong province

Name and address of manufacturer: Meiluo Fashion Design Co., Ltd
Building 8, jintian entrepreneurship center, decheng district, dezhou city, shandong province

Product name: insulating clothing

Product types: ML-XL

Product trademark: n/a

This certificate confirms that the product meets the requirements of the following standards and within limits of its standards gives presumption of conformity with essential requirements of Regulation 2016/425

EN 14126:2003 +AC:2004

The certification process has been carried out in accordance with the program PC-P-07-07. Evaluation has been carried out in accordance with test reports made by SHENZHEN POCE TECHNOLOGY SERVICE CO., LTD.

No. of test reports: 4
The test reports have been carried out in accordance with the test methods specified in the certificate.

Expiration date: 2020-3109.
The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-3109.

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-3109.

This certificate applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standard.

Director: Rafał Kalinowski

Warsaw, 25. 03. 2020

ICR Polska Co. Ltd.
ul. Plac Przymierza 6, 03-944 Warszawa
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产品检测报告

产品风险分析报告

依据 YY/T 0316-2016 医疗器械——风险管理对医疗器械的应用

单位名称：德州美洛服装设计有限公司

产品名称：一次性隔离衣

申报日期：2020年02月18日

隔离衣产品检验报告

产品名称	隔离衣	产品型号	165	产品批次	2020.02.18
抽检时间	2020.02.18	检验数量	20	批次产量	100

检验标准：一次性隔离衣产品技术要求

检验项目	技术要求	检验结果	单项结论
2.1.1	外观干燥、清洁、无霉斑，表面不允许有粘连、裂缝、孔洞等缺陷	合格	符合
2.1.2	连接部位应平整、密封，无气泡。	合格	符合
2.2	身高169胸围125袖长86袖口18脚口24单位cm	身高169胸围125袖长86袖口18脚口24单位cm合格	符合

检验结论：经检验，产品符合技术要求，合格。

检验人： 陈淑英 复核人： 李娟 批准人： 李娟

日期： 2020.02.18 2020.02.18 2020.02.18



医疗器械产品技术要求编号:

隔离衣

1. 产品型号/规格及其划分说明

1.1 隔离衣采用非织造布为主要原料,经裁剪、缝纫制成。非无菌提供,一次性使用。

1.2 隔离衣尺寸见下表

表1 连身式型号规格 (cm)

型号	身長	胸围	袖长	袖口	脚口
165	169	125	86	18	24
170	173	130	90	18	24
175	178	135	93	18	24
180	181	140	96	18	24
185	188	145	99	18	24
偏差	±2	±2	±2	±2	±2

2. 1. 外观

2.1.1 隔离衣应干燥、清洁、无霉斑,表面不允许有粘连、裂缝、孔洞等缺陷。

2.1.2 隔离衣连接部位应平整、密封,无气泡。

2. 2 尺寸

隔离衣尺寸符合表1和表2规定。

3. 检验方法

3. 1 外观

3.1.1 采用目测方式,应符合2.1.1要求。

3.1.2 采用目测方式,应符合2.1.2要求。

3. 2. 尺寸

使用通用量具测量,应符合2.2要求



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检测
TESTING
CNAS L7072

TEST REPORT

No. : SH200500002C01E

Report Date: 2020/05/06

Applicant : Meiluo Fashion Design Co.,Ltd
Address : Building 8,jintian entrepreneurship center decheng district dezhou city,shandong province

The following sample(s) was/were submitted and identified by/on behalf of the applicant as:

Sample Name : Isolation clothing (disposable civilian)
Model : JAL-GLYC-TYPE-S
Materials : Single layer ,100% non-woven
Description : Implementation Standards GB/T 20097-2006 Guidance Standards for general requirements for protective clothing
Receiving Date : 2020/05/04
Testing Period : 2020/05/04-2020/05/06
Test Requested : To determine the Pb,Cd, Hg,Cr(VI),PBBs&PBDEs, DBP, BBP, DEHP and DIBP content of the submitted sample.
Test Method : Please refer to next page(s).
Test Results : Please refer to next page(s).
Conclusion : Based on the analysis on the submitted sample, the results **do comply with** the requirement of RoHS Directive (EU)2015/863.



Approve

Huihui Li

Reviewed by Huihui Li

Page 1 of 4

Ying Liu

Redact by Ying Liu

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优联(上海)检测有限公司

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TEST REPORT

No. : SH200500002C01E

Report Date: 2020/05/06

TEST RESULTS:

RoHS2.0

No.	Test Items	Methods	MDL (mg/kg)	Results (mg/kg)	Limited Value* (mg/kg)
1	Pb	M1	2	N.D.	1000
2	Cd		2	N.D.	100
3	Hg	M2	2	N.D.	1000
4	Cr (VI)	M3	2	N.D.	1000
5	Monobromobiphenyl (MonoBB)	M4	5	N.D.	---
	Dibromobiphenyl (DiBB)		5	N.D.	---
	Tribromobiphenyl (TriBB)		5	N.D.	---
	Tetrabromobiphenyl (TetraBB)		5	N.D.	---
	Pentabromobiphenyl (PentaBB)		5	N.D.	---
	Hexabromobiphenyl (HexaBB)		5	N.D.	---
	Heptabromobiphenyl (HeptaBB)		5	N.D.	---
	Octabromobiphenyl (OctaBB)		5	N.D.	---
	Nonabromobiphenyl (NonaBB)		5	N.D.	---
	Decabromobiphenyl (DecaBB)		5	N.D.	---
	Total PBBs / sum of above		---	N.D.	1000
6	Monobromodiphenyl ether (MonoBDE)	M4	5	N.D.	---
	Dibromodiphenyl ether (DiBDE)		5	N.D.	---
	Tribromodiphenyl ether (TriBDE)		5	N.D.	---
	Tetrabromodiphenyl ether (TetraBDE)		5	N.D.	---
	Pentabromodiphenyl ether (PentaBDE)		5	N.D.	---
	Hexabromodiphenyl ether (HexaBDE)		5	N.D.	---
	Heptabromodiphenyl ether (HeptaBDE)		5	N.D.	---
	Octabromodiphenyl ether (OctaBDE)		5	N.D.	---
	Nonabromodiphenyl ether (NonaBDE)		5	N.D.	---
	Decabromodiphenyl ether (DecaBDE)		5	N.D.	---
	Total PBDEs / sum of above		---	N.D.	1000
7	Dibutyl Phthalate(DBP)	M5	50	N.D.	1000
8	Benzylbutyl Phthalate(BBP)		50	N.D.	1000
9	Di-(2-ethylhexyl)Phthalate(DEHP)		50	62	1000
10	Diisobutyl phthalate(DIBP)		50	N.D.	1000

Remark : *The Limited value is based on the RoHS Directive (EU)2015/863.



TEST REPORT

No. : SH200500002C01E

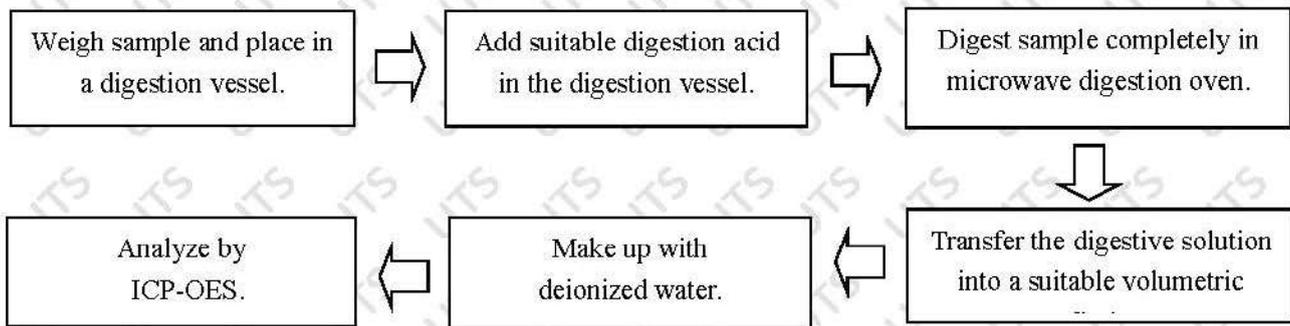
Report Date: 2020/05/06

- Note :
- 1) “---” = Not Regulated.
 - 2) MDL = Method Detection Limit.
 - 3) N.D. = Not detected, less than MDL.
 - 4) M1: With reference to IEC 62321-5: 2013, analysis was performed by ICP-OES.
 - 5) M2: With reference to IEC 62321-4:2013+AMD1:2017 CSV, analysis was performed by ICP-OES.
 - 6) M3: With reference to IEC 62321-7-2:2017, analysis was performed by UV-Vis.
 - 7) M4: With reference to IEC 62321-6: 2015, analysis was performed by GC-MS.
 - 8) M5: With reference to IEC 62321-8: 2017, analysis was performed by GC-MS.
 - 9) The data in this report can be used for scientific research, teaching, internal quality control and product development.

TEST PART DESCRIPTION: Isolation clothing (disposable civilian)

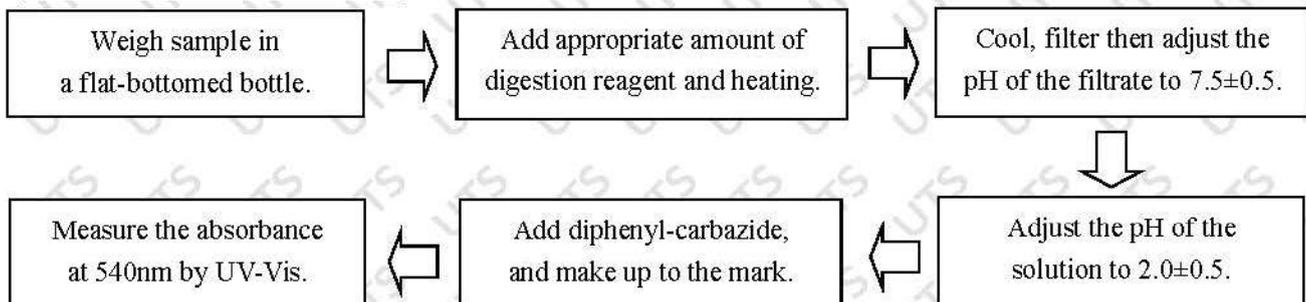
FLOW CHART

1. Test for Pb, Hg, Cd Content



Sample Material	Digestion Acid
Glass	HNO ₃ /HF
Plastic	H ₂ SO ₄ , H ₂ O ₂ , HNO ₃ , HCl
Others	Any acid to total digestion.

2. Test for Chromium(VI) Content

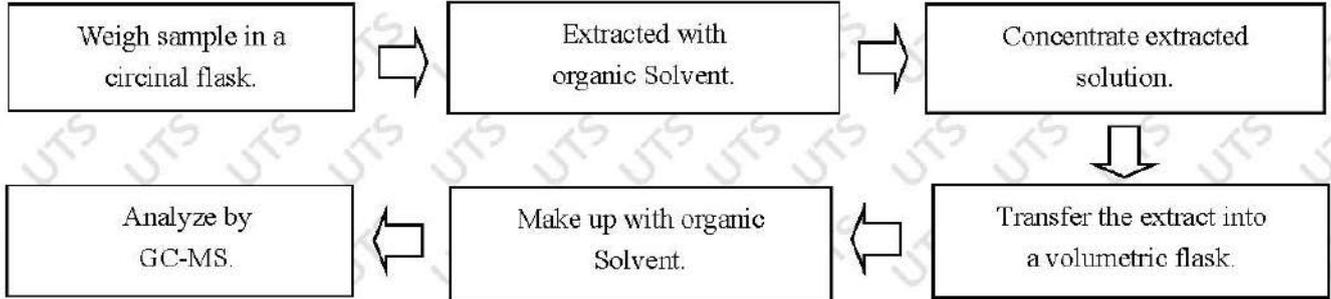


TEST REPORT

No. : SH200500002C01E

Report Date: 2020/05/06

3. Test for PBBs&PBDEs and Phthalates



SAMPLE PHOTO



..... End of Report.....



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检测
TESTING
CNAS L7072

TEST REPORT

No: SH200500501C01E

Report date: 2020/05/08

Applicant : Meiluo Fashion Design Co.,Ltd
Address : Building 8,jintian entrepreneurship center decheng district dezhou city,shandong province

The following sample(s) was/were submitted and identified by/on behalf of the applicant as:

Sample Name : Isolation clothing (disposable civilian)
Model : JAL-GL YC-TYPE-S
Material : Single layer ,100% non-woven
Sample description : Enforcement standards GB/T 20097-2006 general requirements guidance standards for protective clothing.
Receiving Date : 2020/05/04
Testing Period : 2020/05/04-2020/05/08
Test Requested : Please refer to next page(s).
Test Method : Please refer to next page(s).
Test Results : Please refer to next page(s).
Conclusion : Based on the analysis on the submitted sample, the results **do comply with** the customer regulation.



Approved by Salvia Hu

Reviewed by Ying Liu

Redact by Huihui Li

Page 1 of 3

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TEST REPORT

No: SH200500501C01E

Report date: 2020/05/08

TEST RESULTS:

1.Strength and elongation at break

Test Method: With reference to GB/T 3923.1-2013 analysis of Tensile Properties of Fabric Part 1 Sample Method
Velocity 100mm/min

Test Items	Unit	Results	Limited*	
Strength	Warp	MPa	38.0	≥ 30
	Warp	MPa	54.7	≥ 45
Elongation at break	Warp	%	192	≥ 170
	Warp	%	164	≥ 150

Remark : *The limit value is provided by the customer.

2.Color fastness to saliva (GB/T18886-2002)

Pressure: (12.5 ± 0.9) Kpa Room temperature 30 min; 37°C oven to maintain 4 h; multi-fiber cloth DW.

Test Items	Results	Limited*
Discolour	4-5	≥ 4
Colour of the linings		
Vinegar	4-5	≥ 4
Cotton	4-5	≥ 4
Chinlon	4-5	≥ 4
Polyester fibre	4-5	≥ 4
Acrylic fibers	4-5	≥ 4
Wool	4-5	≥ 4

Remark : *The limit value is provided by the customer.

Colour Fastness Rating

- Grade 5 Negligible or no change or staining
- Grade 4 Slightly changed or stained
- Grade 3 Noticeably changed or stained
- Grade 2 Considerably changed or stained
- Grade 1 Much changed or stained

TEST REPORT

No: SH200500501C01E

Report date: 2020/05/08

3. Peculiar smell

Test Method: Refer to the national technical specification for basic safety of textile products GB18401-2010 clause 6.7.

Test Item	Test Result	Limited *
Peculiar smell	No perceptible odour	No perceptible odour

Remark : *The limit value is provided by the customer.

4. Formaldehyde

Test Method: With reference to GB/T 2912.1-2009, analysis was performed by UV-Vis Colorimetry.

Test Item	MDL (mg/kg)	Test Results (mg/kg)
Formaldehyde	20	N.D.

- Note :**
- 1) “---” = Not Regulated.
 - 2) MDL = Method Detection Limit.
 - 3) N.D. = Not detected, less than MDL.
 - 4) The data in this report can be used for scientific research, teaching, internal quality control and product development.

TEST PART DESCRIPTION: Isolation clothing (disposable civilian)

SAMPLE PHOTO



..... End of Report.....



Shipping label with tracking information and recipient details.

Shipping label with tracking information and recipient details.