

File No: SL52025257498501TX



**EC Declaration of Conformity**



**Regarding Medical Device Regulation 93/42/EEC**

**Manufacturer:**

Name: ZHEJIANG UGLY DUCK INDUSTRY CO., LTD

Address: NO.2 SOUTH DONGFANG ROAD, OUHAI DISTRICT, WENZHOU, CHINA

**European Authorized Representative :**

Name: SUNGO Europe B.v

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands.

**Product:**

Name: Isolation gown (Non Sterile)

**Classification: I**

Rule: According to Rule 1, Annex VII, Chapter III of EU Medical Device Regulation 93 / 42 EEC.

**Conformity Assessment Route:**

Annex II&III in Medical Device Regulation (93 / 42 EEC)

We confirm our product can meet the requirement of Medical Device Regulation and the following harmonized standards:

EN 14126:2003/AC:2004

EN ISO 12947-2:2016

EN ISO 7854:1997

EN ISO 9073-4:1997

EN ISO 13934-1:2013

EN ISO 13935-2:2014

EN 863:1995

Signature:

Date: 2020 . July 25

Position:



中国认可  
国际互认  
检测  
TESTING  
CNAS L0599

Test Report SL52025257498501TX  
ZHEJIANG UGLY DUCK INDUSTRY CO.,LTD  
NO.2 SOUTH DONGFANG ROAD OUHAI

Date: May 20, 2020

Page 1 of 4

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

Sample Description : (A) Isolation gown(8pcs)  
Sample Color : (A) white  
Manufacturer : Ugly duck  
Proposed Care Instruction : -  
Test Performed : Selected test(s) as requested by applicant  
Sample Receiving Date : May 14, 2020  
Testing Period : May 14, 2020 - May 20, 2020  
Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of  
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)



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Test Result

**Personal Protective Equipment - Protective Clothing - Performance Requirements and Tests Methods for Protective Clothing against Infective Agents**

EN 14126:2003/AC:2004

**Clause 4.1.2 Mechanical and Flammability Requirements**

The materials shall be tested and classified in accordance with the test methods and performance classification system specified in the relevant clauses of EN 14325.

**EN 14325:2018 Clause 4.4 Abrasion Resistance**

(EN ISO 12947-2:2016; Martindale Abrasion & Pilling Tester, Pressure: 9kPa, Grit 240 abrasion paper.)

(A)

As Received	No. 1	No. 2	No. 3	No. 4	Minimum
The quoted result(Rubs)	20	28	28	30	20

Recommended Class: 1

Remark:

1. Visual examination is used for damage assessment after abrasion. If the assessment is performed through visual inspection, the maximum classification that can be claimed is a Class 3.
2. Classification of abrasion resistance: Class 1 >10rubs; Class 2 >40rubs; Class 3 >100rubs; Class 4 >400rubs; Class 5 >1000rubs; Class 6 >2000rubs.

**EN 14325:2018 Clause 4.5 Compression-Folding (Schildknecht) Flex Cracking Resistance**

(EN ISO 7854:1997, Method B;)

(A)

As Received	No. 1	No. 2	No. 3	Minimum
Warp/Lengthwise(Cycles)	>50000	>50000	>50000	>50000
Weft/Widthwise(Cycles)	>50000	>50000	>50000	>50000

Recommended Class: 6

Remark:

- 1) Visual examination is used for damage assessment after flex cracking. Visual inspection shall not be used for the performance classification of Type 1 through Type 3(EN 943-1, EN 943-2, EN 14605)
- 2) Classification of leak tightness after compression-folding(Schildknecht) flex cracking resistance: Class 1 >500cycles; Class 2 >1250cycles; Class 3 >3000cycles; Class 4 >8000cycles; Class 5 >20000cycles; Class 6 >50000cycles.



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**EN 14325:2018 Clause 4.6 Compression-Folding (Schildknecht) Flex Cracking Resistance at -30°C**

(EN ISO 7854:1997, Method B;)

(A) As Received	No. 1	No. 2	No. 3	Minimum
Warp/Lengthwise(Cycles)	>4000	>4000	>4000	>4000
Weft/Widthwise(Cycles)	>4000	>4000	>4000	>4000

Recommended Class: 6

Remark:

- Visual examination is used for damage assessment after flex cracking. Visual inspection shall not be used for the performance classification of Type 1 through Type 3(EN 943-1, EN 943-2, EN 14605)
- Classification of compression-folding(Schildknecht) flex cracking resistance at low temperatures: Class 1 >100cycles; Class 2 >200cycles; Class 3 >500cycles; Class 4 >1000cycles; Class 5 >2000cycles; Class 6 >4000cycles.

**EN 14325:2018 Clause 4.7 Trapezoidal Tear Resistance**

(EN ISO 9073-4:1997;)

(A) As Received	No. 1	No. 2	No. 3	No. 4	No. 5	Minimum
Warp/Length Yarns Torn(N)	63	70	64	69	68	63
Weft/Width Yarns Torn(N)	30	28	27	35	30	27

Recommended Class: 2

Remark:

- Classification of trapezoidal tear resistance: Class 1 >10N; Class 2 >20N; Class 3 >40N; Class 4 >60N; Class 5 >100N; Class 6 >150N.

**EN 14325:2018 Clause 4.9 Tensile Strength**

(EN ISO 13934-1:2013;CRE - 2" Strip)

(A) As Received	No. 1	No. 2	No. 3	No. 4	No. 5	Minimum
Warp/Length(N)	110	120	110	120	110	110
Weft/Width(N)	62	61	64	63	60	60

Recommended Class: 1

Remark:

- Classification of tensile strength: Class 1 >30N; Class 2 >60N; Class 3 >100N; Class 4 >250N; Class 5 >500N; Class 6 >1000N.



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**EN 14325:2018 Clause 4.10 Puncture Resistance**

(EN 863:1995;)

(A)

As Received	No. 1	No. 2	No. 3	No. 4	No. 5	Minimum
Puncture Force(N)	9	8	9	8	9	8

Recommended Class: 1

Remark:

Classification of puncture resistance: Class 1 >5N; Class 2 >10N; Class 3 >50N; Class 4 >100N; Class 5 >150N; Class 6 >250N.

**Clause 4.2 Performance Requirements for Seams, Joins and Assemblages**

**EN 14325:2018 Clause 5.5 Seam Strength**

(EN ISO 13935-2:2014)

	# 1	# 2	# 3	Average
Side Seam (N)	95(F.R.)	123(F.R.)	104(F.R.)	108(F.R.)
Sleeve seam (N)	151(F.R.)	135(F.R.)	141(F.R.)	142(F.R.)
In-side seam (N)	96(F.R.)	93(F.R.)	105(F.R.)	98(F.R.)
Back rise Seam (N)	95(F.R.)	93(F.R.)	91(F.R.)	93(F.R.)

Recommended Class      3

Notes      F.R. = Fabric Rupture;

Remark:

Classification of seam strength: Class 1 >30N; Class 2 >50N; Class 3 >75N; Class 4 >125N; Class 5 >300N; Class 6 >500N.

Sample Photo



The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

\*\*\*End of Report\*\*\*



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CNAS L0599

Test Report **SL52025244914401TX**  
ZHEJIANG UGLY DUCK INDUSTRY CO.,LTD  
NO.2 SOUTH DONGFANG ROAD OUHAI

Date: May 12, 2020

Page 1 of 5

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

Sample Description : (A) Isolation gown  
Sample Color : (A) white  
Manufacturer : Ugly duck  
Proposed Care Instruction : -  
Test Performed : Selected test(s) as requested by applicant  
Sample Receiving Date : Apr 15, 2020  
Testing Period : Apr 30, 2020 - May 12, 2020  
Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of  
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)



SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd  
Testing Center

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Test Report

SL52025244914401TX

Date: May 12, 2020

Page 2 of 5

Test Result

**Personal Protective Equipment - Protective Clothing against Liquid Chemicals – Liquid Tight (Type 3) or Spray Tight (Type 4)**

EN 14605:2005+A1:2009

**Clause 4.1 Materials**

Chemical protective clothing materials shall be tested and classified in accordance with the provisions of EN 14325:2018 for the following properties:

**EN 14325:2018 Clause 4.4 Abrasion Resistance**

(EN ISO 12947-2:2016; Martindale Abrasion & Pilling Tester, Pressure: 9kPa, Grit 240 abrasion paper.)

As Received

(A)	No. 1	No. 2	No. 3	No. 4	Minimum
The quoted result(Rubs)	30	30	60	80	30

Recommended Class: 1

Remark:

1. Visual examination is used for damage assessment after abrasion. If the assessment is performed through visual inspection, the maximum classification that can be claimed is a Class 3.
2. Classification of abrasion resistance: Class 1 >10rubs; Class 2 >40rubs; Class 3 >100rubs; Class 4 >400rubs; Class 5 >1000rubs; Class 6 >2000rubs.

**EN 14325:2018 Clause 4.5 Compression-Folding (Schildknecht) Flex Cracking Resistance**

(EN ISO 7854:1997, Method B;)

As Received

(A)	No. 1	No. 2	No. 3	Minimum
Warp/Lengthwise(Cycles)	>50000	>50000	>50000	>50000
Weft/Widthwise(Cycles)	>50000	>50000	>50000	>50000

Recommended Class: 6

Remark:

- 1) Visual examination is used for damage assessment after flex cracking. Visual inspection shall not be used for the performance classification of Type 1 through Type 3(EN 943-1, EN 943-2, EN 14605)
- 2) Classification of leak tightness after compression-folding(Schildknecht) flex cracking resistance: Class 1 >500cycles; Class 2 >1250cycles; Class 3 >3000cycles; Class 4 >8000cycles; Class 5 >20000cycles; Class 6 >50000cycles.



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**EN 14325:2018 Clause 4.6 Compression-Folding (Schildknecht) Flex Cracking Resistance at -30°C**

(EN ISO 7854:1997, Method B;)

As Received

(A)	No. 1	No. 2	No. 3	Minimum
Warp/Lengthwise(Cycles)	>4000	>4000	>4000	>4000
Weft/Widthwise(Cycles)	>4000	>4000	>4000	>4000

Recommended Class: 6

Remark:

- 1) Visual examination is used for damage assessment after flex cracking. Visual inspection shall not be used for the performance classification of Type 1 through Type 3(EN 943-1, EN 943-2, EN 14605)
- 2) Classification of compression-folding(Schildknecht) flex cracking resistance at low temperatures: Class 1 >100cycles; Class 2 >200cycles; Class 3 >500cycles; Class 4 >1000cycles; Class 5 >2000cycles; Class 6 >4000cycles.

**EN 14325:2018 Clause 4.7 Trapezoidal Tear Resistance**

(EN ISO 9073-4:1997;)

As Received

(A)	No. 1	No. 2	No. 3	No. 4	No. 5	Minimum
Warp/Length Yarns Tom(N)	59	64	56	64	57	56
Weft/Width Yarns Tom(N)	29	28	27	31	28	27

Recommended Class: 2

Remark:

Classification of trapezoidal tear resistance: Class 1 >10N; Class 2 >20N; Class 3 >40N; Class 4 >60N; Class 5 >100N; Class 6 >150N.

**EN 14325:2018 Clause 4.9 Tensile Strength**

(EN ISO 13934-1:2013;CRE - 2" Strip)

As Received

(A)	No. 1	No. 2	No. 3	No. 4	No. 5	Minimum
Warp/Length(N)	110	120	120	110	120	110
Weft/Width(N)	54	60	57	58	59	54

Recommended Class: 3

Remark:

Classification of tensile strength: Class 1 >30N; Class 2 >60N; Class 3 >100N; Class 4 >250N; Class 5 >500N; Class 6 >1000N.



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Test Report

SL52025244914401TX

Date: May 12, 2020

Page 4 of 5

**EN 14325:2018 Clause 4.10 Puncture Resistance**

(EN 863:1995);

As Received

(A)	No. 1	No. 2	No. 3	No. 4	No. 5	Minimum
Puncture Force(N)	8	10	9	8	9	8

Recommended Class: 1

Remark:

Classification of puncture resistance: Class 1 >5N; Class 2 >10N; Class 3 >50N; Class 4 >100N; Class 5 >150N; Class 6 >250N.

**Clause 4.2 Seams, Joins and Assemblages**

**Seam Strength**

(EN ISO 13935-2:2014)

	# 1	# 2	# 3	Average
Sleeve seam(N)	141(F.R.)	139(F.R.)	143(F.R.)	141(F.R.)
In-side seam(N)	66(F.R.)	78(F.R.)	90(F.R.)	78(F.R.)
Back rise seam(N)	68(F.R.)	98(F.R.)	79(F.R.)	82(F.R.)

Recommended Class 3

Notes F.R. = Fabric Rupture;

Remark:

Classification of seam strength: Class 1 >30N; Class 2 >50N; Class 3 >75N; Class 4 >125N; Class 5 >300N; Class 6 >500N.



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**Test Report** SL52025244915101TX  
ZHEJIANG UGLY DUCK INDUSTRY CO,LTD  
NO.2 SOUTH DONGFANG ROAD OUHAI

Date: June 05, 2020

Page 1 of 4

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

Sample Description : (A) Isolation Gown  
Sample Color : (A) white  
Manufacturer : Ugly duck  
Proposed Care Instruction : -  
Test Performed : Selected test(s) as requested by applicant  
Sample Receiving Date : Apr 14, 2020  
Testing Period : May 07, 2020 - Jun 05, 2020  
Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

**Comment**

	<b>EN 14605:2005+A1:2009 (Type 4)</b>
Whole Suits Testing	Pass

Remark: Pass = Meet Relative Standard Requirement

Signed for and on behalf of  
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

*Sara Guo*

Sara Guo (Account Executive)



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Test Result

**Protective Clothing against Liquid Chemicals — Performance Requirements for Clothing with Liquid-Tight (Type 3) or Spray-Tight (Type 4) Connections, including Items Providing Protection to Parts of The Body Only (Types PB [3] and PB [4])**  
(EN 14605:2005+A1:2009)

**Clause 4.3 Performance Requirements for Whole Suits-Type 4**

	Description		
Undergarment:	SMS nonwovens		
Additional equipment:	/		
The physical dimensions of the wearers are shown below			
Tested Subjects	Total Height(cm)	Chest girth(cm)	Suit size
Chen	180	120	XL

**Clause 4.3.4.1 General and Preliminary Testing**

Prior to testing each suit in accordance with EN ISO 17491-3 or EN ISO 17491-4, a practical test shall be carried out by a human test subject. The test shall comprise three repetitions, at moderate speed, of the "seven movement" sequence described in below. If the test subject is not able to perform one or several movements due to the hindrance of the suit or if the movements result in substantial damage to the suit, the suit shall be considered to have failed.

Sequence of movements according to standard

Test sample	Assessment after Movements
1	Pass
2	Pass
3	Pass

Remark:

- Movement 1: Kneel on both knees, lean forward and place both hands on the floor (45 ±5) cm in front of the knees; crawl forward and backwards on hands and knees for a distance of three metres in each direction;
- Movement 2: climb a vertical ladder at least four steps, rungs to be as encountered on a typical ladder;
- Movement 3: position hands at chest level, palms out; reach directly overhead, interlock thumbs, extend arms fully upwards;
- Movement 4: kneel on right knee, place left foot on floor with left knee bent (90±10)°, touch thumb of right hand to toe of left shoe. Repeat movement with alternate posture, i.e. by kneeling on left knee and placing the right foot on the floor with knee bent at 90° ;
- Movement 5: extend arms fully in front of body, lock thumbs together, twist upper body (90±10)° left and right;
- Movement 6: stand with feet shoulder width apart, arms at side; raise arms until they are parallel to the floor in front of the body; squat down as far as possible;
- Movement 7: kneel as in movement 4, left arm hanging loosely at side; raise arm fully overhead. Repeat movement with alternate posture by alternating arms.



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**Clause 4.3.4.2 Resistance to Penetration by Liquids (Spray Test)**

(EN ISO 17491-4:2008 Method B: high-level spray test)

Test room temperature:	23.5
Test liquid composition:	Methyl blue, sodium lauryl ether sulphate, citric acid and water
Test liquid surface tension:	(30±5)X10 <sup>-3</sup> N/m
Pressure of the liquid supplied:	300kPa

Test sample	Calibrated Stain area (cm <sup>2</sup> )	Total stain area on undergarment (cm <sup>2</sup> )	Conclusion
1	3.95	0	Pass
2	3.92	0	Pass
3	3.93	0	Pass

Remark: All suits shall pass the test, i.e. the total area on any one undergarment of each suit shall be less than or equal to three times the total calibrated stain area.

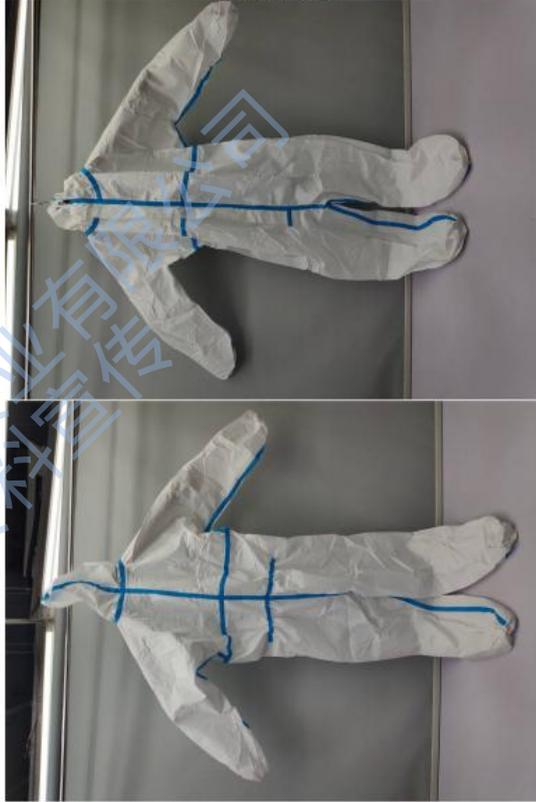
**Comment: The submitted sample complies with the requirements of EN 14605:2005+A1:2009 Clause 4.3 whole Suits Test for Type 4**



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Sample Photo



The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

\*\*\*End of Report\*\*\*



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Sample Photo



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