

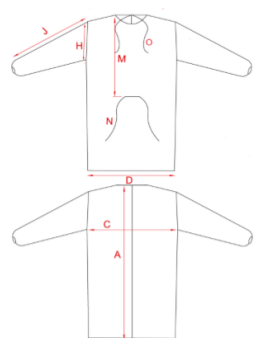
## Medical Isolation Gown

- PRODUCT DESCRIPTION: Medical Isolation Gown (Non-Sterile)
- MPC – (Manufacturers Part Code): 20200035
- UOP – (Unit of Packaging): 10 bags per carton = 100 gowns per carton
- UOI – (Unit of Issue): 10 pieces per bag
- CTN size: 60×27×31 cm
- Weight/carton (gross): 9.1kg
- Colours: White/Blue/Green
- COMPANY NAME: DTS Trading Inc. Ltd
- COMPANY REGISTERED NO: 07499221
- DUNS number: 217093844
- Product expiry date: April 2023
- Lead time: Subject to order volume (more limited production capacity in April)
- Conformity with GB/T24218.1-2009 + BS EN13795:2011 + 2013

### Specifications (for manufacturing commence w/c 27<sup>th</sup> April):

- Non-Woven Isolation Gown
- PP + Coated PE
- 35gsm waterproof
- Colour: White
- 120x140cm
- Tie on Neck & Waist
- Elastic Cuff

**N.B. The standard offering is for a 35gsm PP+PE non-sterile isolation gown. Materials can be altered subject to the client's requirements.**

LJ Specification Sheet			
Item No	<b>5002</b>		
Product Name:	<b>DISPOSABLE ISOLATION GOWN</b>		
Material	PP+PE 35	Tolerance	±1g/sm
Color	Blue/white/Yellow		
Specification			
	size	Details	
A	Length	115cm	
C	1/2 Chest	68cm	
D	Width	68cm	
H	Sleeve width	58cm	
J	Sleeve length	28cm	
M	Top to the waist	45cm	
N	Waist tie length	185cm	
H	Neck tie length	110cm	
Packing	10pcs/bag, 10bags/case		
Certificate	ISO13485,CE,FDA		





Isolation Gowns are classified as a non-sterile class I product, so they only require an EC Self-Declaration of Conformity. Please find the declaration below.

CE EC Declaration of Conformity CE

Regarding Medical Device Directi (93/42/EEC)

Manu facturer

Name: [REDACTED]

Address: [REDACTED]

Author: [REDACTED]

Address: [REDACTED]

Tel:86-[REDACTED]

Email:s [REDACTED]

Product:

Name:Nonwoven products:bouffant cap,mop cap,doctor cap,space cap,nylon mesh cap,  
working cap,face mask,paper face mask,isolation gown,surical gown,lab coat,coverall,  
kimono,apron,suit,sauna cloth,visitor gown,shoe cover,boot cover,oversleeve,beard cover,  
pants,shopping bag,underwear,full cape,bed sheet,bed cover,pillow cover,patient gown,  
snood cap,peaked cap,sock cover,disposable cape,non-woven bar,disposable hair band,  
disposable sliper

Type: NA

Classification:1

Rule:1

We undersigned hereby declare that our products specified above conform with the essential  
requirments listed in the European Norms:

EN ISO 14971:2009  
EN ISO 10993-1:2009  
EN ISO 10993-5:2009  
EN ISO 10993-10:2009  
EN 1041:2008

Signature: *Hu Jion Guw* [REDACTED]

Place& date issue:Xiantao,14 Jun 2018 [REDACTED]



## Compliance Report

Applicant:  
Address:



Product: See annex for details  
Type: See annex for details

Product Classification: Class I

**The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).**

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. **02911**  
Initial Issue Date: **14 Jun 2018**



General Manager (Signature)

This report is the property of NQA and should be returned to NQA upon request.



**Annex to Report ( [REDACTED] )**

**[REDACTED] Ltd**

Product Name	Type
Nonwoven products: bouffant cap, mob cap, doctor cap, space cap, nylon mesh cap, working cap, face mask, paper face mask, isolation gown, surgical gown, lab coat, coverall, kimono, apron, suit, sauna cloth, visitor gown, shoe cover, boot cover, oversleeve, beard cover, pants, shopping bag, underwear, full cape, bed sheet, bed cover, pillow cover, patient gown, snood cap, peaked cap, sock cover, disposable cape, Non-woven bra, disposable hair band, disposable slipper	Nonwoven, PE/CPE, PVC
PE/CPE products: shoe cover, boot cover oversleeves, shower cap, raincoat, lab coat, apron, surgical gown, bed cover, disposable poncho, disposable glove, CPE gown PVC products: apron, oversleeves, shoe cover, boot cover, bed cover	Nonwoven, PE/CPE, PVC

This annex is only valid if attached to the report mentioned above.

This report is the property of NQA and should be returned to NQA upon request.

**MATERIAL SGS REPORT: SMS Non-Woven Fabric**



超微量工業安全實驗室  
Ultra Trace & Industrial Safety Hygiene

Test Report

TEST REPORT NO: [REDACTED] Date: 2015/12/08 Page: 1 of 4

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

Type of Product:

Applicant:

Lot No:

Manufacturer:

Sample No:

Date of Sample Received: 2015/11/02

Date of Testing: 2015/11/02-2015/12/08

Test Requested:

1. Resistance to Microbial penetration(Dry & Wet) Test.
2. Cleanliness-Particulate matter Test.
3. Linting Test.
4. Water Resistance Hydrostatic Pressure Test.
5. Bursting Strength(Dry & Wet) Test.
6. Breaking Strength(Dry & Wet) Test.
7. Cleanliness-Microbial (Bioburden Test)

Test Method:

1. With reference to ISO 22612:2005 / ISO 22610:2006 method.
2. With reference to EN 13795:2011+A1:2013 / ISO 9073-10:2003 method.
3. With reference to EN 13795:2011+A1:2013 / ISO 9073-10:2003 method.
4. With reference to EN 20811:1992 method. (The rate of water pressure: 60±3 cmH<sub>2</sub>O/min)
5. With reference to EN ISO 13938-1:1999 method.
6. With reference to EN 29073-3:1992 method. (Speed:10±1cm/min,CRE)
7. The experiment was performed according to the guideline described in ISO 11737-1.

Test Results:

-Please see the next page(s)-

Signed for and on behalf of  
SGS Taiwan Ltd.

Yuan Min Wen  
Manager



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No.38, Wu Chyuan 7th Rd., New Taipei Industrial Park, Wu-Ku District, New Taipei City, 24866, Taiwan 中華台北新莊區中興路七段48號  
Tel: (886-2) 2289-3399 Fax: (886-2) 2289-1339 www.sgs.com



超微量工業安全實驗室  
Ultra Trace & Industrial Safety Hygiene

Test Report

TEST REPORT NO: [REDACTED] Date: 2015/12/08 Page: 2 of 4

Test Results:

1. Resistance to Microbial penetration(Dry & Wet) Test.

Test Item	Challenge Conc.(CFU/g talc)	Test Results
Resistance to Microbial Penetration-Dry	Colonies(CFU)	1.3 E+8
	Colonies(CFU)	16.0

Test Item		Test Results					
		1	2	3	4	5	
Resistance to Microbial Penetration-Wet	Test Time(CFU)	15 min	75	157	198	225	194
		30 min	313	246	594	693	286
		46 min	616	731	241	743	245
		60 min	699	364	318	467	251
		75 min	276	423	372	249	292
Barrier Index,IB	Donor	603	268	348	236	321	
	Individual	4.006	3.654	3.539	3.200	3.707	
	Mean			3.621			

2. Cleanliness-Particulate matter Test.

Test Item	Test Results
Cleanliness-Particulate matter(IPM)	2.95

3. Linting Test.

Test Item	Test Results	
Linting	Average	1328.1
	Log 10 (lint count)	3.12

4. Water Resistance Hydrostatic Pressure Test.

Test Item	Test Results
Water Resistance Hydrostatic Pressure(mmH <sub>2</sub> O)	567.1

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Test Report

TEST REPORT NO: [REDACTED] Date: 2015/12/08 Page: 3 of 4

5. Bursting Strength(Dry & Wet) Test.

Test Item	Test Results	
Bursting Strength (Kpa)	Dry	137.9
	Wet	117.2

6. Breaking Strength(Dry & Wet) Test.

Test Item	Test Results		
Breaking Strength (N/5cm)	Dry	Length wise	56.1
		Width wise	30.7
	Wet	Length wise	56.9
		Width wise	31.3

7. Cleanliness-Microbial (Bioburden Test)

Sample No.	Aerobic		Anaerobic		Fungal	
	CFU	CFU	CFU	CFU	CFU	CFU
01	50	57	0	0	20	0
Negative control	0	0	0	0	0	0

Dilution Factor

30
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Note:

1. Suspension Conc. 1.5E+4 CFU/mL.
2. 5cm<sup>2</sup> of the unit of Breaking Strength is the wide of test specimen.
3. The content of this report is invalid if it is not presented as the entire report.
4. The test was conducted in ISO 17025 accordance laboratory.
5. The test report is the test result issued by the testing institutions as requested by the consignors. Regarding to the legitimacy of the product, it shall be determined by the authorities according to the law.

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

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Test Report

TEST REPORT NO: [REDACTED] Date: 2015/12/08 Page: 4 of 4

Sample Photo



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### Proof of Verification of SGS Report



Henry Newman &lt;henry@dtstrading.com&gt;

**[support-corpsec.sgs.com #112352] [EXTERNAL] Verify SGS Documents Request via SGS.com**

 certificates@sgs.com <certificates@sgs.com>  
 Reply-To: certificates@sgs.com  
 Cc: henry@dtstrading.com

11 April 2020 at 05:15

Dear Henry,

Thank you for submitting the attached document reference No. UO/2015/B0001A-01 for verification of authenticity. We can confirm this document is genuine, issued by SGS Taiwan.

 Best Regards  
 Corporate Security Team  
[Quoted text hidden]
 **SGS SMSEN13795 test report.pdf**  
 289K

### Internal Test Report: 25gsm PP

#### TEST PHYSICAL PROPERTIES

 Product:PP material,25g/m<sup>2</sup>

Color:Yellow

Item		Unit	Average	Max/Min		Judge	Implementation of standards	Note
Basic weight		g/m <sup>2</sup>	24.6	25.2	24	conformity	GB/T24218.1-2009	Testing size 100cm <sup>2</sup>
Tensile strength	MD	N/5cm	25.48	27	23.5	conformity	FZ/T60005	Testing state(distance 100mm width 50mm test speed 100mm/min)
	CD	N/5cm	17.1	18	16.5	conformity		
Elongation	MD	%	113.4	138.4	102	conformity		
	CD	%	108.2	125	94	conformity		
Appearance & Visual Defect	Properties	Quality requirements						
	Surface	No obvious uneven,no broken edge,consistent rolls.						
	Contamination	No obvious defect(including metal,oil,grease,powder)						
	Polymer drop	No continuous Polymer drops,less than one drop/1cm <sup>2</sup> every 100 square metres.						
	Hole/Tears/Cut	No hole/tears/cuts.						
	Other	Flat end face.						