ICIM

CERTIFICATO N.
CERTIFICATE No. **10410/0**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

Isol8 Healthcare Ltd.

UNITÀ OPERATIVA / *OPERATIVE UNIT*

Unit 1 Westside, Monavalley Business Park V92 K258 Tralee
Ireland

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI CEI EN ISO 13485:2016

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

Management of manufacture, storage and distribution of sterile surgical gowns and non-sterile gowns, surgical masks, surgical headwear, non-sterile theatre apparel, shoe covers and patient gowns.

Management of manufacture, storage and distribution of sterile surgical gowns and non-sterile gowns, surgical masks, surgical headwear, non-sterile theatre apparel, shoe covers and patient gowns.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and Specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

DATA EMISSIONE	EMISSIONE CORRENTE	DATA DI SCADENZA
FIRST ISSUE	*CURRENT ISSUE*	*EXPIRING DATE*
26/05/2021	27/08/2021	25/05/2024

Vincenzo Delacqua
Rappresentante Direzione / Management Representative
ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

Digitally signed by Granaci Boris
Date: 2023.11.09 12:15:29 EET
Reason: MoldSign Signature
Location: Moldova

CE
0425

ICIM

Approvazione del Sistema di Garanzia di Qualità della Produzione
Production quality assurance system approval

Certificato N.
Certificate No. **0425-MED-004388-00**

Secondo l'Allegato V della Direttiva Europea 93/42/CEE (recepita con il Dlg n. 46 del 24/02/1997)
According to Annex V of EC Directive 93/42/CEE (as transposed into Dlg no. 46 issued on 24/02/1997)

ORGANISMO NOTIFICATO / *NOTIFIED BODY*

ICIM S.p.A. - Identification number: 0425
Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI) - ITALY

VISTO L'ESITO DELLE VERIFICHE CONDOTTE IN CONFORMITÀ ALL'ALLEGATO V DELLA DIRETTIVA EUROPEA 93/42/CEE DICHIARA CHE IL SISTEMA DI GARANZIA DI QUALITÀ DELLA PRODUZIONE ATTUATO DA:
ON THE BASIS OF THE ASSESSMENT PERFORMED ACCORDING TO ANNEX V OF EC DIRECTIVE 93/42/CEE DECLARES THAT THE PRODUCTION QUALITY ASSURANCE SYSTEM ENFORCED BY:

Isol8 Healthcare Ltd.

Head Office and Operative Unit
Unit 1 Westside, Monavalley Business Park V92 K258 Tralee
Ireland

PER I SEGUENTI TIPI DI PRODOTTI, PROCESSI, SERVIZI
FOR THE FOLLOWING KINDS OF PRODUCTS, PROCESSES, SERVICES

Camici chirurgici sterili.

Sterile Surgical Gown.

È CONFORME AI REQUISITI / *IS IN COMPLIANCE WITH REQUIREMENTS*

Allegato V della Direttiva Europea 93/42/CEE
Annex V of EC Directive 93/42/EEC

Per l'identificazione dei modelli di prodotto vedere l'Allegato / *For identification of the model type see Annex*

Il presente Certificato è da ritenersi valido solo se accompagnato dal relativo Allegato / *This Certificate is valid only with the relative Annex*

Gaetano Trizio
Rappresentante Direzione / Management Representative

ICIM S.p.A.

PRIMA EMISSIONE *FIRST ISSUE*	EMISSIONE CORRENTE *CURRENT ISSUE*	DATA DI SCADENZA *EXPIRING DATE*
05/05/2021	**05/05/2021**	**26/05/2024**

CE
0425

ICIM

Approvazione del sistema di garanzia di qualità della produzione
Production quality assurance system approval

ALLEGATO AL / *ANNEX TO*

Certificato N.
Certificate No. **0425-MED-004388-00**

Secondo l'Allegato V della Direttiva Europea 93/42/CEE (recepita con il Dlg n. 46 del 24/02/1997)
According to Annex V of EC Directive 93/42/CEE (as transposed into Dlg no. 46 issued on 24/02/1997)

IDENTIFICAZIONE TIPOLOGIE E MODELLI
IDENTIFICATION OF THE MODEL/TYPE

Tipologia/ Type: Camici chirurgici / *Surgical Gown*
Classe / Class: Is

Codice / Code	***Denominazione / Name***
IS8 X xx	Sterile Surgical Gown

Legenda:

X = Categoria / Sub-families (E = Elemental, P = Plush or S = Supreme)
xx = Taglia / Size

Gaetano Trizio
Rappresentante Direzione / Management Representative

ICIM S.p.A.

PRIMA EMISSIONE *FIRST ISSUE*	EMISSIONE CORRENTE *CURRENT ISSUE*	DATA DI SCADENZA *EXPIRING DATE*
05/05/2021	**05/05/2021**	**26/05/2024**

0667CM_01_IT

EC Declaration of Conformity

to the 93/42/EEC Medical Device Directive

Isol8 Healthcare Ltd declare under our sole responsibility that the medical device specified in the Appendix 1 meets all provisions of the Medical Device Directive 93/42/EEC and all relevant modifying Directives.

Manufacturer:	**ISOL8 Healthcare Ltd**
Address:	**Unit 4 Joyce House, Ballincollig, Co. Cork, Ireland, P31 HW35**
Device:	**Surgical gown**
Device Classification:	**Class Is under Rule 1**
CE marking first applied:	**05 May 2021**
GMDN code and term:	**35091, Surgical gown, single use**

This Declaration of Conformity is issued on the basis of fulfilment of requirements of Annex I and Annex V of the Council Directive 93/42/EEC:

- Quality Management System certification to ISO 13485:2016 under the supervision of ICIM SpA
- EC Certificate No. 0425-MED-004388-00 issued by ICIM SpA
- Availability of technical documentation per Annex VII of the Medical Device Directive.

Standards applied:

- EN ISO 14971:2019
- EN 13795-1:2019
- EN ISO 11135:2014
- EN 556-1:2001
- EN ISO 11607-1 and -2:2019
- EN ISO 11737-1:2018
- EN ISO 11737-2:2019
- EN ISO 11138-1 and -2:2017
- EN 14644-1:2015
- EN 14698-1:2003
- EN ISO 10993-1:2018
- EN ISO 10993-5:2013
- EN ISO 10993-7:2008
- EN ISO 10993-10:2013
- ISO 15223-1:2021
- EN ISO 20417:2021

Authorised Signatory:

Date: 1st August 2022

Dr Fergal Whitehead,

Place: Cork

Director of Operations of ISOL8 Healthcare Ltd

Appendix I

List of devices, components and accessories

Basic UDI-DI - 539154127IS88SGBZ

ID	Trade Name	Class/Rule	UDI-DI
IS8E01	Elemental Standard Surgical Gown M	Class Is/ Rule 1	05391541270003
IS8E02	Elemental Standard Surgical Gown L	Class Is/ Rule 1	05391541270010
IS8E03	Elemental Standard Surgical Gown XL	Class Is/ Rule 1	05391541270027
IS8E04	Elemental Standard Surgical Gown XL – Long	Class Is/ Rule 1	05391541270041
IS8E05	Elemental Standard Surgical Gown 2XL	Class Is/ Rule 1	05391541270058
IS8E06	Elemental Standard Surgical Gown 2XL – Long	Class Is/ Rule 1	05391541270065
IS8E07	Elemental Standard Surgical Gown 3XL	Class Is/ Rule 1	05391541270072
IS8E08	Elemental Poly-Reinforced Surgical Gown M	Class Is/ Rule 1	05391541270089
IS8E09	Elemental Poly-Reinforced Surgical Gown L	Class Is/ Rule 1	05391541270096
IS8E10	Elemental Poly-Reinforced Surgical Gown XL	Class Is/ Rule 1	05391541270102
IS8E11	Elemental Poly-Reinforced Surgical Gown XL–Long	Class Is/ Rule 1	05391541270119
IS8E12	Elemental Poly-Reinforced Surgical Gown 2XL	Class Is/ Rule 1	05391541270126
IS8E13	Elemental Poly-Reinforced Surgical Gown 2XL–Long	Class Is/ Rule 1	05391541270133
IS8E14	Elemental Poly-Reinforced Surgical Gown 3XL	Class Is/ Rule 1	05391541270140
IS8P01	Plush Standard Surgical Gown M	Class Is/ Rule 1	05391541270157
IS8P02	Plush Standard Surgical Gown L	Class Is/ Rule 1	05391541270164
IS8P03	Plush Standard Surgical Gown XL	Class Is/ Rule 1	05391541270171
IS8P04	Plush Standard Surgical Gown XL – Long	Class Is/ Rule 1	05391541270188
IS8P05	Plush Standard Surgical Gown 2XL	Class Is/ Rule 1	05391541270195
IS8P06	Plush Standard Surgical Gown 2XL – Long	Class Is/ Rule 1	05391541270201
IS8P07	Plush Standard Surgical Gown 3XL	Class Is/ Rule 1	05391541270218
IS8P08	Plush Poly-Reinforced Surgical Gown M	Class Is/ Rule 1	
IS8P09	Plush Poly-Reinforced Surgical Gown L	Class Is/ Rule 1	
IS8P10	Plush Poly-Reinforced Surgical Gown XL	Class Is/ Rule 1	
IS8P11	Plush Poly-Reinforced Surgical Gown XL – Long	Class Is/ Rule 1	
IS8P12	Plush Poly-Reinforced Surgical Gown 2XL	Class Is/ Rule 1	
IS8P13	Plush Poly-Reinforced Surgical Gown 2XL – Long	Class Is/ Rule 1	
IS8P14	Plush Poly-Reinforced Surgical Gown 3XL	Class Is/ Rule 1	
IS8S01	Supreme Impervious Surgical Gown L	Class Is/ Rule 1	05391541270225
IS8S02	Supreme Impervious Surgical Gown XL	Class Is/ Rule 1	05391541270232
IS8S03	Supreme Impervious Surgical Gown XL – Long	Class Is/ Rule 1	05391541270249
IS8S04	Supreme Impervious Surgical Gown 2XL	Class Is/ Rule 1	05391541270256
IS8S05	Supreme Impervious Surgical Gown 2XL – Long	Class Is/ Rule 1	05391541270263
IS8S06	Supreme Impervious Surgical Gown 3XL	Class Is/ Rule 1	05391541270270

Test Report

Verification Code: NCNY-2948-44
Verification Website: www.gttc.net.cn

No:21R002065MO Issue Date: 2022-02-10

Applicant: Isol8 Healthcare Ltd
Address: Unit 1 Westside, Monavalley Business Park, Tralee, CO. Kerry, Ireland, V92 K258

Information confirmed by applicant:
Nonwoven Standard Surgical Gown (SMS)
Quantity: 16 pieces
Model: ISOL/8 Elemental (MPC: IS8E01-IS8E07)

Standard Adopted:
EN 13795-1:2019 <Surgical clothing and drapes- Requirements and test methods. Part 1:Surgical drapes and gowns>

Date Received/Date Test Started: 2021-08-12

Conclusion:

Breaking strength(dry state)[Material]	M
Breaking strength(dry state)[Sleeve seam]	M
Breaking strength(wet state)[Material]	M
Breaking strength(wet state)[Sleeve seam]	M
Bursting strength(dry state)[Material]	M
Bursting strength(dry state)[Sleeve seam]	M
Bursting strength(wet state)[Material]	M
Bursting strength(wet state)[Sleeve seam]	M
Static hydrostatic resistance[Material]	M
Static hydrostatic resistance[Sleeve seam]	M
Cleanliness-microorganism	M
The resistance to dry microbial penetration[Material]	M
The resistance to dry microbial penetration[Sleeve seam]	M
The resistance to wet bacterial penetration[Material]	M
The resistance to wet bacterial penetration[Sleeve seam]	M
Lint and other particles generation in the dry state[Material]	M

Approved By: Wan Li Hu
WanLi Hu Engineer

广州检验检测认证集团有限公司 检验检测专用章 (GPZ)

总部:广州市番禺区珠江路1号
花都实验室:广州市花都区狮岭镇旗岭河滨西路1号
电话:020-61994598/61994599
电话:020-37721161/66348638

Test Report

Verification Code: NCNY-2948-44
Verification Website: www.gttc.net.cn

No:21R002065MO Issue Date: 2022-02-10

Lint and other particles generation in the dry state[Sleeve seam]	M

Note: "M"-Meet the standard's requirement "F"-Fail to meet the standard's requirement "---"-No comment

Remark:
This report replaces test report 21R002065 which has become invalid automatically.
All the tested items are tested under the standard condition (except for indication).
Copies of the report are valid only re-stamped.
The experiment was carried out at No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.

Approved By: Wan Li Hu

WanLi Hu Engineer

广州检验检测认证集团有限公司 检验检测专用章 (GPZ)

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电话:020-61994598/61994599
电话:020-37721161/66348638

Test Report

No: 21R002065MO

广州广检检验检测认证集团有限公司 检验检测专用章 (GF2)

总部：广州市番禺区珠江路1号
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电话：020-61994598/61994599
电话：020-37721161/66348638

Test Report

No: 21R002065MO

Breaking strength（dry state）[Material]
Test Method: EN 29073-3:1992

Test principle:
Application of a force longitudinally to a test piece of a specified length and width at a constant rate of extension. Determination of values for breaking strength and elongation from the recorded force-elongation curve.

Test equipment:
Tensile testing machine

The environmental conditions of the laboratory and test condition:
Testing and conditioning environment: Temperature: 20.1℃，relative humidity: 65.1%
The distance between the clamps: 200mm
Rate: 100 mm/min

Results:

Sample	MD (N)	CD (N)	Requirement (N)	Conclusion
1	83.5	46.6	≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	93.9	42.0		
3	88.9	46.1		
4	94.7	43.3		
5	85.4	45.2		

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电话：020-61994598/61994599
电话：020-37721161/66348638

Test Report

No: 21R002065MO

Breaking strength（dry state）[Sleeve seam]
Test Method: EN 29073-3:1992

Test principle:
Application of a force longitudinally to a test piece of a specified length and width at a constant rate of extension. Determination of values for breaking strength and elongation from the recorded force-elongation curve.

Test equipment:
Tensile testing machine

The environmental conditions of the laboratory and test condition:
Testing and conditioning environment: Temperature: 20.1℃，relative humidity: 65.1%
The distance between the clamps: 200mm
Rate: 100 mm/min

Results:

Sample	(N)		Requirement (N)	Conclusion
1	34.1		≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	27.5			
3	32.2			
4	26.2			
5	40.4			

总部：广州市番禺区珠江路1号
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电话：020-61994598/61994599
电话：020-37721161/66348638

Test Report

No: 21R002065MO

Breaking strength（wet state）[Material]
Test Method: EN 29073-3:1992

Test principle:
Application of a force longitudinally to a test piece of a specified length and width at a constant rate of extension. Determination of values for breaking strength and elongation from the recorded force-elongation curve.

Test equipment:
Tensile testing machine

Test condition:
The distance between the clamps: 200mm
Rate: 100 mm/min

Results:

Sample	MD (N)	CD (N)	Requirement (N)	Conclusion
1	92.4	44.2	≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	90.7	46.0		
3	94.5	44.4		
4	94.3	44.8		
5	94.3	47.6		

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

总部：广州市番禺区珠江路1号
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电话：020-61994598/61994599
电话：020-37721161/66348638

Test Report

No: 21R002065MO

Breaking strength（wet state）[Sleeve seam]
Test Method: EN 29073-3:1992

Test principle:
Application of a force longitudinally to a test piece of a specified length and width at a constant rate of extension. Determination of values for breaking strength and elongation from the recorded force-elongation curve.

Test equipment:
Tensile testing machine

Test condition:
The distance between the clamps: 200mm
Rate: 100 mm/min

Results:

Sample	(N)		Requirement (N)	Conclusion
1	36.9		≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	29.0			
3	28.3			
4	39.6			
5	35.1			

总部：广州市番禺区珠江路1号
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电话：020-61994598/61994599
电话：020-37721161/66348638

Test Report

No: 21R002065MO

Bursting strength（dry state）[Material]
Test Method: EN ISO 13938-1:1999

Test principle:
A test specimen is clamped over an expansive diaphragm by means of a circular clamping ring. Increasing fluid pressure is applied to the underside of the diaphragm, causing distension of the diaphragm and the fabric. The volume of fluid is increased at a constant rate per unit time until the test specimen bursts. The bursting strength and bursting distension are determined.

Test equipment:
Bursting tester

The environmental conditions of the laboratory and test condition:
Testing and conditioning environment: Temperature: 20.0℃, relative humidity: 65.0%
Test area: 10cm^2

Results:

Sample	Measured value (kPa)	Requirement (kPa)	Conclusion
1	138	≥40 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	182		
3	144		
4	138		
5	135		

总部:广州市番禺区珠江路1号
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电话:020-61994598/61994599
电话:020-37721161/66348638

Test Report

No: 21R002065MO

Bursting strength（dry state）[Sleeve seam]
Test Method: EN ISO 13938-1:1999

Test principle:
A test specimen is clamped over an expansive diaphragm by means of a circular clamping ring. Increasing fluid pressure is applied to the underside of the diaphragm, causing distension of the diaphragm and the fabric. The volume of fluid is increased at a constant rate per unit time until the test specimen bursts. The bursting strength and bursting distension are determined.

Test equipment:
Bursting tester

The environmental conditions of the laboratory and test condition:
Testing and conditioning environment: Temperature: 20.0℃，relative humidity: 65.0%
Test area: 10cm^2

Results:

Sample	Measured value (kPa)	Requirement (kPa)	Conclusion
1	128	≥40 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	140		
3	136		
4	175		
5	175		

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电话：020-37721161/66348638

Test Report

No: 21R002065MO

Bursting strength（wet state）[Material]
Test Method: EN ISO 13938-1:1999

Test principle:
A test specimen is clamped over an expansive diaphragm by means of a circular clamping ring. Increasing fluid pressure is applied to the underside of the diaphragm, causing distension of the diaphragm and the fabric. The volume of fluid is increased at a constant rate per unit time until the test specimen bursts. The bursting strength and bursting distension are determined.

Test equipment:
Bursting tester

The environmental conditions of the laboratory and test condition:
Test area: $10cm^2$

Results:

Sample	Measured value (kPa)	Requirement (kPa)	Conclusion
1	172	≥40 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	188		
3	166		
4	158		
5	150		

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电话：020-61994598/61994599
电话：020-37721161/66348638

Test Report

No: 21R002065MO

Bursting strength（wet state）[Sleeve seam]
Test Method: EN ISO 13938-1:1999

Test principle:
A test specimen is clamped over an expansive diaphragm by means of a circular clamping ring. Increasing fluid pressure is applied to the underside of the diaphragm, causing distension of the diaphragm and the fabric. The volume of fluid is increased at a constant rate per unit time until the test specimen bursts. The bursting strength and bursting distension are determined.

Test equipment:
Bursting tester

The environmental conditions of the laboratory and test condition:
Test area: $10cm^2$

Results:

Sample	Measured value (kPa)	Requirement (kPa)	Conclusion
1	158	≥40 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	123		
3	146		
4	172		
5	144		

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电话：020-37721161/66348638

Test Report

No: 21R002065MO

Static hydrostatic resistance[Material]
Test Method: EN ISO 811:2018

Test principle:
The hydrostatic head supported by a fabric is a measure of the opposition to the passage of water through the fabric. A specimen is subjected to a steadily increasing pressure of water on one side of the fabric, under standard conditions, until penetration occurs in three places. The pressure at which the water penetrates the fabric at the third place is noted.

Test equipment:
Hydrostatic tester
Water, grade 3 water in accordance with ISO 3696.

The environmental conditions of the laboratory and test condition:
Testing and conditioning environment: Temperature: 20.1℃， relative humidity: 65.1%
Face side tested
Temperature of the water: 20.0℃
Rate of increasing water pressure: 10cmH_2O/min

Results:

Sample	Measured value (cmH_2O)	Requirement (cmH_2O)	Conclusion
1	77.5	≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	70.0		
3	70.5		
4	73.5		
5	72.5		

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

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电话:020-61994598/61994599
电话:020-37721161/66348638

Test Report

No: 21R002065MO

Static hydrostatic resistance[Sleeve seam]
Test Method: EN ISO 811:2018

Test principle:
The hydrostatic head supported by a fabric is a measure of the opposition to the passage of water through the fabric. A specimen is subjected to a steadily increasing pressure of water on one side of the fabric, under standard conditions, until penetration occurs in three places. The pressure at which the water penetrates the fabric at the third place is noted.

Test equipment:
Hydrostatic tester
Water, grade 3 water in accordance with ISO 3696.

The environmental conditions of the laboratory and test condition:
Testing and conditioning environment: Temperature: 20.1℃， relative humidity: 65.1%
Face side tested
Temperature of the water: 20.0℃
Rate of increasing water pressure: 10cmH_2O/min

Results:

Sample	Measured value (cmH_2O)	Requirement (cmH_2O)	Conclusion
1	65.5	≥20 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	70.0		
3	64.0		
4	72.5		
5	77.0		

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

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电话：020-61994598/61994599
电话：020-37721161/66348638

Test Report

No: 21R002065MO

Cleanliness-microorganism
Test Method: EN ISO 11737-1:2018

Test principle:
Take the required samples from the original packaging. Under sterile condition a sample of 100 cm^2 was cut and placed in a sterile bottle containing 300 ml of BPW. The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. After this extraction step, 100 ml of the extraction liquid is filtered through a 0.45 µm filter and laid down on a TSA plate for nonselective aerobic bacteria. Another100 ml of the extraction liquid is filtered through a 0.45 µm filter and laid down on a Sa AGAR plate for total number of yeast and molds. Another100 ml of the extraction liquid is filtered through a 0.45 µm filter and laid down on blood Agar plate for total number of anaerobic bacteria. Non-selective aerobic bacteria were cultured at 30℃ for 3 days and yeast and molds at 25℃ for 7 days and anaerobic bacteria at 30℃ for 3 days. The total bioburden is expressed by addition of three culture plates counts. Five parallel samples are tested.

Test equipment:
Constant temperature incubator
Electronic balance
Pressure steam sterilizer
Biosafety cabinet

The environmental conditions of the laboratory and test condition:
Test environment temperature: 24.5℃, Relative humidity: 56.0%
Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth
Culture temperature: Bacteria 30℃, Fungi 25℃; Culture time: Bacteria 3 days, Fungi 7 days.

Results:

Sample	Total plate count (CFU/100cm²)	Requirement (CFU/100cm²)	Conclusion
1	58	≤300 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	64		
3	59		
4	76		
5	70		

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

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Test Report

No: 21R002065MO

The resistance to dry microbial penetration[Material]
Test Method: EN ISO 22612:2005

Test principle:
The test is carried out on test pieces each fixed in a container. In every container except one a portion of talc contaminated with Bacillus subtilis is poured on the test piece. One container is left uncontaminated as a control. A sedimentation plate is inserted at the base of each container at a short distance below the test piece. The apparatus supporting the containers is then vibrated by a pneumatic ball vibrator. The talc that penetrates is captured on the sedimentation plate, the sedimentation plates are removed and incubated. The numbers of colonies produced are counted.

Test equipment:
Resistance to dry microbial penetration test
Incubator
Electronic balance
Autoclave

The environmental conditions of the laboratory and test condition:
Test environment temperature: 22.0℃, Relative humidity: 65.0%
Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth
Culture medium: TGE agar medium; Other materials: talc and ethyl alcohol.
Dimensions of the test specimens: 200mm×200mm
Sample: 12 pieces
Vibration frequency: 20800 times/min; Vibration time: 30 min.
Test bacteria: The fourth generation of spores of bacillus subtilis ATCC 9372
Concentration of bacterium: 2.0×10^{8} CFU/g

Results:

Sample	Measured value (CFU)	Requirement (CFU)	Conclusion
1	2	≤300 (Surgical gown: standard performance less critical product area) EN 13795-1:2019	Pass
2	2		
3	4		
4	3		
5	3		
6	2		
7	1		
8	1		
9	3		
10	5		

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Test Report

No: 21R002065MO

The resistance to dry microbial penetration[Sleeve seam]
Test Method: EN ISO 22612:2005

Test principle:
The test is carried out on test pieces each fixed in a container. In every container except one a portion of talc contaminated with Bacillus subtilis is poured on the test piece. One container is left uncontaminated as a control. A sedimentation plate is inserted at the base of each container at a short distance below the test piece. The apparatus supporting the containers is then vibrated by a pneumatic ball vibrator. The talc that penetrates is captured on the sedimentation plate, the sedimentation plates are removed and incubated. The numbers of colonies produced are counted.

Test equipment:
Resistance to dry microbial penetration test
Incubator
Electronic balance
Autoclave

The environmental conditions of the laboratory and test condition:
Test environment temperature: 22.0℃, Relative humidity: 65.0%
Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth
Culture medium: TGE agar medium; Other materials: talc and ethyl alcohol.
Dimensions of the test specimens: 200mm×200mm
Sample: 12 pieces
Vibration frequency: 20800 times/min; Vibration time: 30 min.
Test bacteria: The fourth generation of spores of bacillus subtilis ATCC 9372
Concentration of bacterium: 2.0×10^{8} CFU/g

Results:

Sample	Measured value (CFU)	Requirement (CFU)	Conclusion
1	3	≤300 (Surgical gown: standard performance less critical product area) EN 13795-1:2019	Pass
2	3		
3	6		
4	2		
5	4		
6	2		
7	6		
8	4		
9	4		
10	7		

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Test Report

No: 21R002065MO

The resistance to wet bacterial penetration[Material]
Test Method: EN ISO 22610:2006

Test principle:
A test specimen is placed on an agar plate. A sheet of donor material, of corresponding size and carrying the bacteria, is placed on the test specimen with the contaminated side face down and covered by a sheet of approximately 10 µm high density polyethylene (HDPE) film. Two tithing conical steel rings hold the three sheets together, applying a tensile force. An abrasion-resistant finger is placed on top of the materials with a specified force to bring the test specimen in contact with the agar. The finger is moved over the entire surface of the plate in less than 15 min by means of a pivoted lever moved by an exocentric cam. The assemblage of materials, stretched by the weight of the steel rings, ensures that only a small area of the test specimen is brought into contact with the agar surface at any one time. Due to the combined effect of rubbing and liquid migration, bacteria may pass from the donor material through the test specimen down to the agar surface. After being tested for 15 min, the agar plate is replaced by a fresh one, and the test is repeated with the same donor and test specimen. Allowing 15 min for each test, five tests are performed with the same pair of donor and test specimen. In this way, the test allows for an estimation of the penetration over time. Finally, the bacterial contamination on the top side of the test specimen is estimated using the same technique. The agar plates are incubated in order to observe the bacterial colonies, which are then enumerated.

Test equipment:
The resistance to wet bacterial penetration test
Incubator
Electronic balance
Autoclave

The environmental conditions of the laboratory and test condition:
Test environment temperature: 24.5℃, Relative humidity: 56.0%
Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth
Culture medium: Tryptone Soya Agar, Tryptic Soy Broth, peptone water and nutrient agar medium.
Dimensions of the test specimens: 25cm×25cm
The carrier material: solvent-cast polyurethane (PU) film of 30 µm thickness
Nutrient agar to from the brim: 3 mm
Test bacteria: The fifth generation of staphylococcus aureus ATCC 29213
Concentration of bacterium: 2.0×10^{4} CFU/ml

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Test Report

No: 21R002065MO

Results:

Sample	Barrier index	Requirement Barrier index	Conclusion
1	4.1	≥2.8 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	4.0		
3	4.1		
4	4.0		
5	4.1		

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Test Report

No: 21R002065MO

The resistance to wet bacterial penetration[Sleeve seam]
Test Method: EN ISO 22610:2006

Test principle:
A test specimen is placed on an agar plate. A sheet of donor material, of corresponding size and carrying the bacteria, is placed on the test specimen with the contaminated side face down and covered by a sheet of approximately 10 µm high density polyethylene (HDPE) film. Two tithing conical steel rings hold the three sheets together, applying a tensile force. An abrasion-resistant finger is placed on top of the materials with a specified force to bring the test specimen in contact with the agar. The finger is moved over the entire surface of the plate in less than 15 min by means of a pivoted lever moved by an exocentric cam. The assemblage of materials, stretched by the weight of the steel rings, ensures that only a small area of the test specimen is brought into contact with the agar surface at any one time. Due to the combined effect of rubbing and liquid migration, bacteria may pass from the donor material through the test specimen down to the agar surface. After being tested for 15 min, the agar plate is replaced by a fresh one, and the test is repeated with the same donor and test specimen. Allowing 15 min for each test, five tests are performed with the same pair of donor and test specimen. In this way, the test allows for an estimation of the penetration over time. Finally, the bacterial contamination on the top side of the test specimen is estimated using the same technique. The agar plates are incubated in order to observe the bacterial colonies, which are then enumerated.

Test equipment:
The resistance to wet bacterial penetration test
Incubator
Electronic balance
Autoclave

The environmental conditions of the laboratory and test condition:
Test environment temperature: 24.5℃, Relative humidity: 56.0%
Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth
Culture medium: Tryptone Soya Agar, Tryptic Soy Broth, peptone water and nutrient agar medium.
Dimensions of the test specimens: 25cm×25cm
The carrier material: solvent-cast polyurethane (PU) film of 30 µm thickness
Nutrient agar to from the brim: 3 mm
Test bacteria: The fifth generation of staphylococcus aureus ATCC 29213
Concentration of bacterium: 2.0×10^{4} CFU/ml

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Test Report

No: 21R002065MO

Results:

Sample	Barrier index	Requirement Barrier index	Conclusion
1	4.0	≥2.8 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
2	4.0		
3	4.1		
4	4.0		
5	4.0		

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Test Report

No: 21R002065MO

Lint and other particles generation in the dry state[Material]
Test Method: EN ISO 9073-10:2004

Test principle:
This procedure describes a modified Gelbo Flex method in which the sample is subjected to a combined twisting and compression action in a test chamber. During the flexing, air is withdrawn from chamber and particulates in the air stream are counted and classified in a particle counter. Depending on the choice of counter, the size ranges can fall within the limits of 0.3 μm or 0.5 μm to 25 μm.

Test equipment:
Gelbo Flex tester with particle counter

The environmental conditions of the laboratory:
Test environment temperature: 20.0℃, Relative humidity: 65.0%

Results:

Size of particles counted (μm)	Sample		Measured value Coefficient of linting log_{10}	Requirement Coefficient of linting log_{10}	Conclusion
3～25	A: face	1	3.1	≤4.0 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
		2	3.0		
		3	3.1		
		4	3.0		
		5	2.9		
	B: face	1	3.1		
		2	2.9		
		3	2.9		
		4	3.0		
		5	3.0		

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Test Report

No: 21R002065MO

Lint and other particles generation in the dry state[Sleeve seam]
Test Method: EN ISO 9073-10:2004

Test principle:
This procedure describes a modified Gelbo Flex method in which the sample is subjected to a combined twisting and compression action in a test chamber. During the flexing, air is withdrawn from chamber and particulates in the air stream are counted and classified in a particle counter. Depending on the choice of counter, the size ranges can fall within the limits of 0.3 μm or 0.5 μm to 25 μm.

Test equipment:
Gelbo Flex tester with particle counter

The environmental conditions of the laboratory:
Test environment temperature: 20.0℃, Relative humidity: 65.0%

Results:

Size of particles counted (μm)	Sample		Measured value Coefficient of linting log_{10}	Requirement Coefficient of linting log_{10}	Conclusion
3～25	A: face	1	3.1	≤4.0 (Surgical gown: standard performance critical product area) EN 13795-1:2019	Pass
		2	3.1		
		3	3.1		
		4	3.0		
		5	3.0		
	B: face	1	2.7		
		2	2.9		
		3	2.9		
		4	2.9		
		5	2.7		

广州检验检测认证集团有限公司 检验检测专用章 (GF2)

———End of Report———

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