

Surgical and Non-Surgical Isolation Gowns Brochure

EC Medical Certification

EC CERTIFICATE ISO 13485 Certificate

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Certificate

No. Q6 096662 0003 Rev. 01

Holder of Certificate:



Facility(ies):



Certification Mark:



Scope of Certificate: Production and Distribution of Surgical Gown, Surgical Drape, Surgical Pack, Coverall, and Isolation Gown

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH19111104

Valid from: 2019-10-17
Valid until: 2022-10-16

Date: 2019-08-30

Stefan Preis
Head of Certification/Notified Body

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EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)
No. G2S 16 08 96662 002

Manufacturer:



EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eifelstraße 80
20537 Hamburg
GERMANY

Product Category(ies): Surgical Gown, Surgical Drape, Surgical Pack

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH16111101

Valid from: 2016-10-17
Valid until: 2021-10-16



Date: 2016-10-17

Stefan Preis

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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FDA & TGA Certification



Certificate of Registration

2020

This Certified that:



is registered with the US food and drug administration, pursuant to the federal Food Drug and cosmetic Act, as amended by the Bioterrorism Act of 2002 and the FDA Food Safety Modernization Act, such registration having been verified as currently effective on the date hereof by Apexx Co

U.S.FDA Owner/ Operator Number: [REDACTED]

Device Listing Number:

Listing Number	Listing Status	Premarket Submission Number	Product Code(s)	Device Name
[REDACTED]	Active	[REDACTED]	FIA	GOWN, SURGICAL
[REDACTED]	Active	[REDACTED]	FIA	GOWN, SURGICAL
[REDACTED]	Active	[REDACTED]	FIA	GOWN, SURGICAL
[REDACTED]	Active	[REDACTED]	FX	Mask, surgical
[REDACTED]	Inactive	[REDACTED]	FYF	CAP, SURGICAL
[REDACTED]	Active	[REDACTED]	FX	Mask, surgical
[REDACTED]	Active	[REDACTED]	FX	Mask, surgical
[REDACTED]	Inactive	[REDACTED]	FYC	Gown, isolation, surgical
[REDACTED]	Inactive	[REDACTED]	FYC	Gown, isolation, surgical
[REDACTED]	Active	[REDACTED]	FUI	Hand hygiene

US Agent:
SUSAN BARNETT
BAM Corporation LTD.



Australian Government
Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

[REDACTED]
for approval to supply

ARTG Identifier: [REDACTED]
ARTG Start date: 9/04/2020
Product Category: Medical Device Included Class 1
GMDN: 35492
GMDN Term: Gown, isolation, single use
Intended Purpose: This is a non-sterile isolation and single-use gown worn by healthcare professionals to protect both healthcare professionals and patients from transfer of airborne particles, micro-organisms, body fluids and contagious agents.

Manufacturer Details	Address	Certificate number(s)
[REDACTED]	[REDACTED]	[REDACTED]

ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following conditions:

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. Gown, isolation, single use

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Identifier: [REDACTED]
ARTG Start Date: 9/04/2020

Surgical Gown



- Product: Surgical gown
- Material: SMS / Spunlace /Laminated Material
- Fabric Weight: 35-70gsm
- ETO Sterile
- Size: M/L/XL/XXL
- Package: 1 pcs/Pouch, 30 pcs/case
- Carton Size: 60x40x36cm
- Weight: GW:9.5KG NW:10.2KG

Surgical Gown

- **AAMI Level 2 surgical gowns are intended to be used in procedures with a low risk of exposure.**



High intensity stitching

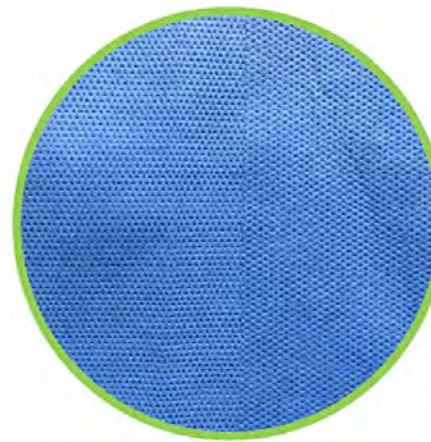


Velcro

- **AAMI Level 3 surgical gowns are intended to be used in procedures with a mandatory risk of exposure**

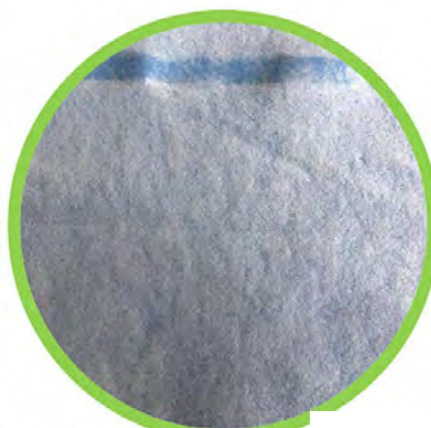


Ultrasonic stitching



Sleeves are glued with cold glue

- **AAMI Level 4 surgical gowns are intended to be used in procedures with a high risk of exposure.**

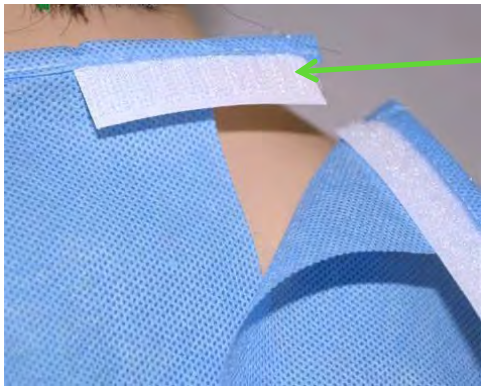


Heat-seal stitching



Knitted Cuffs are optional for more comfortable

Surgical Gown



- Velcro



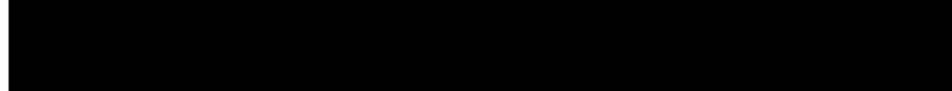
- Knitted Cuffs are optional for more comfortable

SGS Test Report



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

Sample Description	(A)Surgical gown
Sample Color	(A)blue
Sample Receiving Date	May 25, 2020
Testing Period	May 25, 2020 - May 27, 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).
Test Performed	Selected test(s) as requested by applicant

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

Sara Guo (Account Executive)



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AAMI LEVEL3 Test Report



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Test Result

Liquid Barrier Performance and Classification of Protective apparel and Drapes Intended for Use in Health Care Facilities (ANSI/AAMI PB70-2012)

Section 4.2.1 Water Resistance: Impact Penetration Test (AATCC 42 2017)

As received

Weight of blotter gained (g)	1#	2#	3#	4#	5#
Area A (Critical zone-front)	0.0	0.0	0.0	0.0	0.0
Area B (Critical zone-sleeve)	0.0	0.0	0.0	0.0	0.0
Area C(Front)	0.0	0.0	0.0	0.0	0.0
Area D(Back)	0.0	0.0	0.0	0.0	0.0
Seam between areas C&D	0.0	0.0	0.0	0.0	0.0

Remark:

- Level 1: all critical zone components shall have a blotter weight gain of no more than 4.5grams(g)
- Level 2: all critical zone components shall have a blotter weight gain of no more than 1.0 grams(g)
- Level 3: all critical zone components shall have a blotter weight gain of no more than 1.0 grams(g)

Section 4.2.1 Water Resistance: Hydrostatic Pressure Test

(AATCC 127-2018; Hydrostatic Head; Rate of increase of water pressure:60mbar/min; temp. of distilled water: 21°C, fabric face side of water)

As received

Water Column (cmH ₂ O)	1#	2#	3#	4#	5#
Area A (Critical zone-front)	>50.0	>50.0	>50.0	>50.0	>50.0
Area B (Critical zone-sleeve)	>50.0	>50.0	>50.0	>50.0	>50.0
Area C(Front)	13.4	12.0	15.1	13.6	17.6
Area D(Back)	>50.0	>50.0	>50.0	>50.0	>50.0
Seam between areas C&D	11.6	15.9	18.7	20.9	17.2

Remark:

- Level 2: all critical zone components shall have a hydrostatic resistance of at least 20cmH₂O
- Level 3: all critical zone components shall have a hydrostatic resistance of at least 50cmH₂O



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AAMI LEVEL3 Test Report



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Barrier performance of each component and final classification commended

	Impact Penetration Test AATCC 42 (α)	Hydrostatic Pressure Test AATCC 127 (cmH ₂ O)	Resistance to Bacteriophage Phi-X174 ASTM F 1671	Level	Final classification
Area A (Critical zone-front)	0.0	>50.0	/	Level 3	Level 3
Area B (Critical zone-sleeve)	0.0	>50.0	/	Level 3	
Area C(Front)	0.0	12.0	/	Level 1	
Area D(Back)	0.0	>50.0	/	Level 3	
Seam between areas C&D	0.0	11.6	/	Level 1	

Remark:

- The barrier performance of all critical zone components, including seams and points of attachments, shall be determined;
- The critical zone comprises at least area A and B. The classification of the surgical gown is based on the lower-performing component of the two;
- The back of the surgical gown (area D) may be nonprotective;
- Seams between protective and nonprotective areas have no barrier requirements;
- Seams between two protective areas are required to have at least the barrier performance of the lower-performing area;
- Level 1: Impact Penetration Test-AATCC 42: $\leq 4.5g$;
- Level 2: Impact Penetration Test-AATCC 42: $\leq 1.0g$; Hydrostatic Pressure Test-AATCC 127: $\geq 20cmH_2O$;
- Level 3: Impact Penetration Test-AATCC 42: $\leq 1.0g$; Hydrostatic Pressure Test-AATCC 127: $\geq 50cmH_2O$;
- Level 4: Resistance to Bacteriophage Phi-X174-ASTM F 1671: Pass.
- Only test the barrier performance of the sample. Label request, construction and other classed in ANSI/AAMI PB70-2012 is not checked.



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AAMI LEVEL3 Test Report

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Sample Photo



Face

Back

End of Report



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Isolation Gown



- **Product:** AMMI LEVEL 2 / 3 / 4 Isolation gowns
- **Material:** 20g PP + 15gPE coating
- **Fabric Weight:** 38gsm
- **Size:** Regular, Large, X-Large
- **Cuff:** elastic cuff / Knitted cuff
- **Color:** Blue, white, Yellow
- **Package:** 10pcs / bag, 10bags / carton
- **Carton Size:** 59x39x35.5cm (100pcs/ctn)
- **Applications:** Hospital, Laboratory, all kinds of areas need fluid resistance protection.

Isolation Gown



Easy to wear



20gPP + 15gPE coating
Measures the resistance of fabrics to the liquid penetration of water by impact



High intensity stitching



Knitted Cuffs are optional for more comfortable

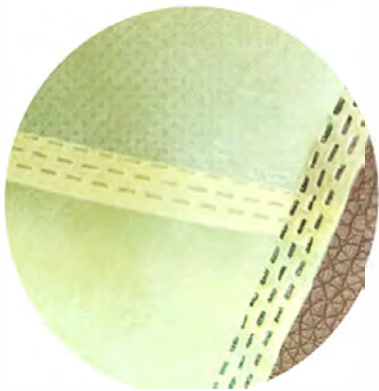
AAMI Level 3 Isolation Gown



Easy to wear



Knitted Cuffs are optional for more comfortable



Ultrasonic stitching



20gPP + 15gPE coating, Isolation Gowns feature strong sealed seams that are designed to withstand tough conditions

AAMI Level 4 Isolation Gown



Easy to wear



Knitted Cuffs are optional for more comfortable



Tape stitching



20gPP + 15gPE coating, Isolation Gowns measure the resistance of fabrics to blood borne pathogens using viral penetration at 2 psi and ambient pressure

AAMI Level 3 Test Report



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Barrier performance of each component and final classification commended.

	Impact Penetration Test AATCC 42(g)	Hydrostatic Pressure Test AATCC 127(cmH ₂ O)	Resistance to Bacteriophage Phi-X174 ASTM F 1671	Level	Final classification
Area A (Critical zone-front)	0.0	>50.0	/	Level 3	Level 3
Area B (Critical zone-sleeve)	0.0	>50.0	/	Level 3	
Area C (Critical zone-Back)	0.0	>50.0	/	Level 3	
Seam between areas A&B	0.0	>50.0	/	Level 3	
Seam between areas A&C	0.0	>50.0	/	Level 3	
Seam between areas B&C	0.0	>50.0	/	Level 3	

Remark:

- 1) The barrier performance of all critical zone components, including seams and points of attachments, shall be determined. The classification of isolation gown shall be a number denoting the performance of the critical zone component having the lower barrier performance.
- 2) Level 1: Impact Penetration Test-AATCC 42: ≤4.5g;
- 3) Level 2: Impact Penetration Test-AATCC 42: ≤1.0g; Hydrostatic Pressure Test-AATCC 127: ≥20cmH₂O;
- 4) Level 3: Impact Penetration Test-AATCC 42: ≤1.0g; Hydrostatic Pressure Test-AATCC 127: ≥50cmH₂O;
- 5) Level 4: Resistance to Bacteriophage Phi-X174-ASTM F 1671: Pass.
- 6) Only test the barrier performance of the sample. Label request, construction and other classed in ANSI/AAMI PB70-2012 is not checked.

Sample Photo



Face

Back

End of Report



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