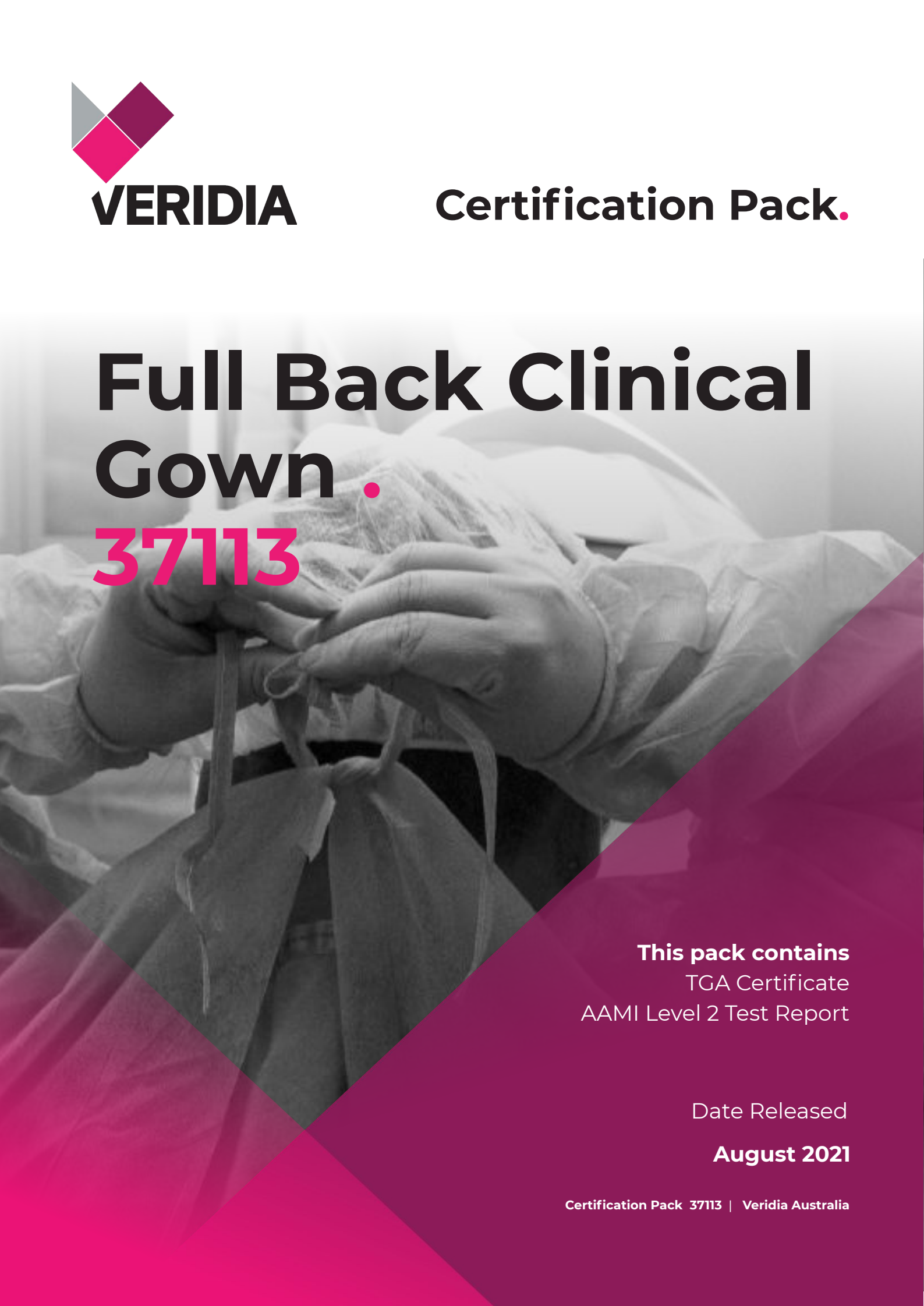
VERIDIA

Certification Pack.

Full Back Clinical Gown.

37113



This pack contains

TGA Certificate

AAMI Level 2 Test Report

Date Released

August 2021

Clinical Gown Full Back PP/PE Fluid Resistant Yellow 10 x 10 — 37113

Features	- This gown provides protection for those working infectious environments, with a full back design that is finished with comfort knit cuffs. The Gown meets AAMI Level 2 standards and includes: - Two Layer 43GSM construction - PE & PP - Tie at Back - Long Sleeves - Complies with ASTM F1671 - TGA Approved - ARTG ID: 333749
Colour	- Yellow
Unit	- Carton
Pack Qty	- 10
Carton Qty	- 10

Australian Government

Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	333749	Medical Industries Australia Hold Co Pty Ltd - Gown, isolation, single use
ARTG entry for	Medical Device Included Class 1	
Sponsor	Medical Industries Australia Hold Co Pty Ltd	
Postal Address	2 Imperata Close, Kemps Creek, NSW, 2178 Australia	
ARTG Start Date	8/04/2020	
Product Category	Medical Device Class 1	
Status	Active	
Approval Area	Medical Devices	

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.

Manufacturers

Name	Address
Dansu-China Health Care Co Ltd	No 366 Pengjialing Yongfeng Street Hanyang District, Wuhan, 430050 China

Products

1 . Gown, isolation, single use

Product Type	Single Device Product	**Effective Date**	8/04/2020
GMDN	35492 Gown, isolation, single use		
Intended Purpose	This is a multipurpose garment that is intended to be worn by healthcare providers or person to enable them to be isolated them from the patient. The isolation gown is designed to protects the patient from the transfer of infectious agents carried by the healthcare provider or person they are associated with as well as it can protect the healthcare provider or person from a contagious agent which has infected the patient.		

Specific Conditions

No Specific Conditions included on Record

Public Summary

DANSU-CHINA HEALTH CARE CO., LTD.
NO.366 PENGJIALING, YONGFENG STREET, HANYANG DISTRICT, WUHAN, PEOPLE'S REPUBLIC OF CHINA

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

Sample Description	:	(A)Isolation gown
Composition	:	(A)PP+PE
Sample Color	:	(A)yellow
Style No.	:	S,M,L,XL,XXL
Manufacturer	:	DANSU-CHINA HEALTH CARE CO., LTD.
Sample Receiving Date	:	Feb 03, 2021
Testing Period	:	Feb 03, 2021 - Feb 20, 2021
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

Conclusion: the provided sample meets ANSI/AAMI PB70-2012 Level 2.

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

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 (Critical zone-Back)	0.0	0.0	0.0	0.0	0.0
Seam between areas A&B	0.0	0.0	0.0	0.0	0.0
Seam between areas A&C	0.0	0.0	0.0	0.0	0.0
Seam between areas B&C	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_2O)	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	44.1	>50.0	>50.0
Area C (Critical zone-Back)	>50.0	>50.0	>50.0	>50.0	>50.0
Seam between areas A&B	36.8	>50.0	>50.0	>50.0	>50.0
Seam between areas A&C	47.2	>50.0	>50.0	41.4	>50.0
Seam between areas B&C	>50.0	43.4	>50.0	>50.0	41.2

Remark:
- Level 2: all critical zone components shall have a hydrostatic resistance of at least 20cmH_2O
- Level 3: all critical zone components shall have a hydrostatic resistance of at least 50cmH_2O

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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_2O)	Resistance to Bacteriophage Phi-X174 ASTM F 1671	Level	**Final classification**
Area A (Critical zone-front)	0.0	>50.0	/	Level 3	Level 2
Area B (Critical zone-sleeve)	0.0	44.1	/	Level 2	
Area C (Critical zone-Back)	0.0	>50.0	/	Level 3	
Seam between areas A&B	0.0	36.8	/	Level 2	
Seam between areas A&C	0.0	41.4	/	Level 2	
Seam between areas B&C	0.0	41.2	/	Level 2	

Remark:

- 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.
- Level 1: Impact Penetration Test-AATCC 42: ≤4.5g;
- Level 2: Impact Penetration Test-AATCC 42: ≤1.0g; Hydrostatic Pressure Test-AATCC 127: ≥20cmH_2O;
- Level 3: Impact Penetration Test-AATCC 42: ≤1.0g; Hydrostatic Pressure Test-AATCC 127: ≥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.

Sample Photo

Face Back

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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武汉金瑞达医疗用品有限公司
DANSU-CHINA HEALTH CARE CO., LTD.
No. 366, Pengjialing, Yongfeng Street, Hanyang District, Wuhan, China

PRODUCT SPECIFICATION SHEET

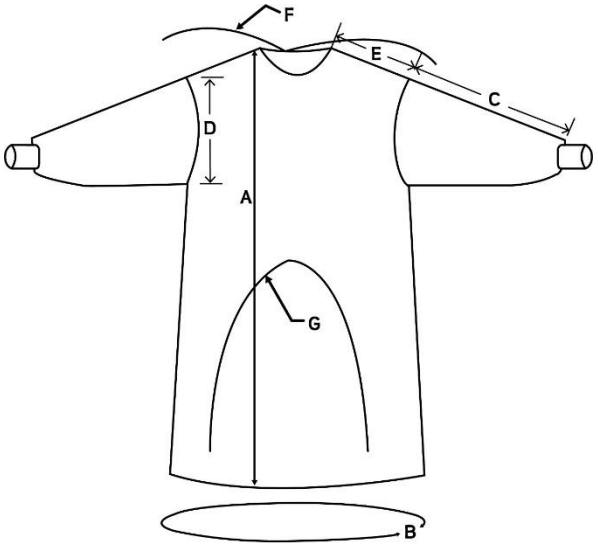
Product Name	level 2 non-sterile PP&PE Isolation Gown
REF	DSU-ISOG and DSU-ISOGY
Type	**Seaming/Ultrasonic Seal, Back Neck with Tie-on, Waist with Tie-on, Knitted Cuffs**
Material	PP&PE Light, breathable and waterproof
Weight	30gsm
Size	S: 115x135cm; M:120x140cm; L:125x145cm; XL:130x150cm; XXL: 135x155cm; XXXL: 140x160cm
Color	Light Blue or Yellow Colour
Type of Gown	PPE products, not medical device
Standard	EN14126; ISO 16604
Application	General Medical, Labs, Patient Care, and Critical Care Units
Package	10pcs/bag, 10bags/case; Carton Size: 36x28x45cm
	 Back Neck  Long sleeve, Knitted cuffs  2 ties around the waist

武汉金瑞达医疗用品有限公司

DANSU-CHINA HEALTH CARE CO., LTD.

No. 366, Pengjialing, Yongfeng Street, Hanyang District, Wuhan, China

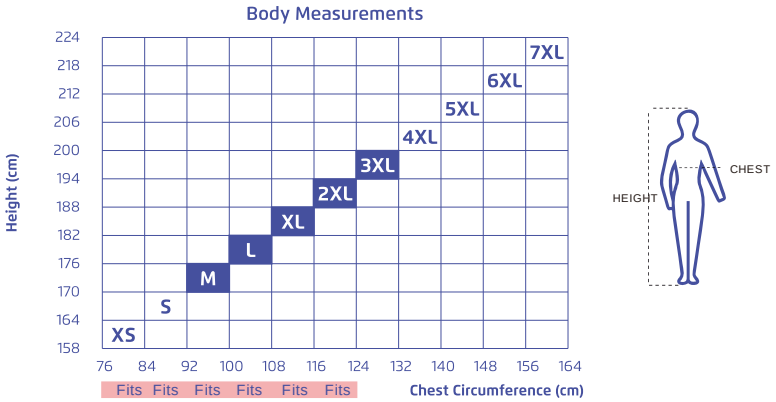
Size	A	B	C	D	E	F	G
M	120cm	140cm	57cm	27cm	23cm	35cm	97cm
L	125cm	145cm	57cm	27cm	25cm	40cm	105cm
XL	130cm	150cm	59cm	28cm	27cm	40cm	110cm
XXL	135cm	155cm	60cm	28cm	28cm	40cm	120cm
XXXL	140cm	160cm	60cm	29cm	29cm	40cm	130cm
Tolerance±	5cm	5cm	3cm	2cm	2cm	3cm	5cm



Size

Isolation gown would fit in following instances.

Use the table below to determine the most appropriate size for you



武汉金瑞达医疗用品有限公司

DANSU-CHINA HEALTH CARE CO., LTD.

No. 366, Pengjialing, Yongfeng Street, Hanyang District, Wuhan, China

EN14126 Test Report

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coepto GmbH
Oskar-Jaeger-Str. 173
50825 Cologne
Germany

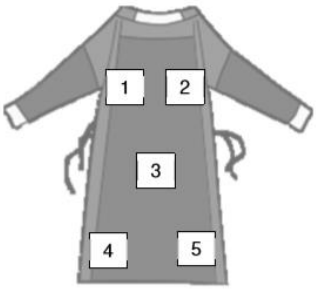
Bischofshofen, 31.08.2020

Prüfbericht / *test report* B 25190

Labor-Nr. / *identification of the test laboratory:*	B 25190
Prüfprodukt / *test product*:	PP+PE Isolation Gown
Musterbezeichnung / *sample designation:*	Isolation Gown
Bar-Code:	sample picked out of mass production
Hersteller / *manufacturer:*	Dansu-China Health Care Co., Ltd No. 366 Pengjialing, Yongfeng Street, Hanyang District, Wuhan PEOPLE'S REPUBLIC OF CHINA
Auftragsdatum / *date of order*:	2020-07-15
Materialeingang / *date of delivery*:	2020-07-23
Prüfzeitraum / *period of analysis*:	2020-08-27 bis / *to* 2020-08-30
Prüfbedingungen / *test conditions:*	Die Prüfung erfolgte im Anlieferungszustand. / *The test was done in the delivery state.*
Prüfauftrag / *test order:*	Schutzkleidung - Leistungsanforderungen und Prüfverfahren für Schutzkleidung gegen Infektionserreger / *Protective clothing - Performance requirements and test methods for protective clothing against infective agents* EN 14126:2003/AC:2004

Prüfmethoden / *test methods*:	SOP 12-013 Widerstand gegen die Penetration mit Bakteriophagen / *penetration by blood-borne pathogens - Test method using Phi-X 174 bacteriophage;* ISO 16604
	SOP 12-001 Widerstandsfähigkeit gegen Keimpenetration – nass / *Resistance to microbial penetration WET Penetration*, EN ISO 22610
	SOP 12-010 Widerstandsfähigkeit gegen Keimpenetration – trocken / *Resistance to microbial penetration DRY Penetration*, EN ISO 22612

Entnahmestellen der Prüfkörper / *extraction points of the samples*:



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Ergebnis des Widerstands gegen die Penetration mit Bakteriophagen / *test results viral penetration*
ISO 16604 / SOP 12-013

Information: 4.1.4.1 der EN 14126:2003/AC:2004

Prüfprodukt / *test product*:	PP+PE Isolation Gown
Prüfdatum / *date of testing*:	2020-08-27
Druckanstieg / *increase in pressure*:	10 cm / = 9.8±0.5 mBar / min
Prüfkeim / *test strain*:	x 174 bacteriophage ATCC 13706-B1 *E.coli* C. ATCC 13706
Anzahl der Prüfkörper / *number of samples*:	5 Prüfstücke / *5 test samples*
Raumtemperatur / *room temperature*:	22.0 °C
Luftfeuchte / *relative humidity*:	44 %
Inkubation / *incubation*:	48h bei / *at* 36 ±1°C

Prüfdruck / *pressure*: 0 kPa / 5 Minuten / minutes

	Testmaterial / *test material*	Test I	Test II	Test III	Test IV	Test V
2020-08-27	PP+PE Isolation Gown	-	-	-	-	-
Kontrolle / *Control*						
2020-08-27	Negative Control-Packaging Film	-				
2020-08-27	Positive Control-100% Cotton M 3623.OK 002.1	+				

Prüfdruck / *pressure*: 20 kPa / 5 Minuten / minutes

	Testmaterial / *test material*	Test I	Test II	Test III	Test IV	Test V
2020-08-27	PP+PE Isolation Gown	-	-	-	-	-
Kontrolle / *Control*						
2020-08-27	Negative Control-Packaging Film	-				
2020-08-27	Positive Control-100% Cotton M 3623.OK 002.1	+				

Legende / *Legend*:
\+ = Penetration der Bacteriophagen / *penetration of bacteriophage*
\- = keine Penetration der Bacteriophagen / *no penetration of bacteriophage*

Ergebnisse der Prüfung der Widerstandsfähigkeit gegen Keimpenetration – nass / *test results of resistance to microbial penetration, WET Penetration*
EN ISO 22610 – SOP 12-001

Information: 4.1.4.2 der EN 14126:2003/AC:2004

Prüfprodukt / *test product*:	PP+PE Isolation Gown
Prüfdatum / *date of testing*:	2020-08-28
Prüfdruck / *pressure*:	3 N
Prüfzeitraum / *test time*:	1h 15 min
Größe der Prüfkörper / *sample size*:	25 x 25 cm
Raumtemperatur / *room temperature*:	22.0 °C
Luftfeuchte / *relative humidity*:	50 %
Inkubation / *incubation*:	48h bei / *at* 36 ±1°C

		Test 1		Test 2		Test 3		Test 4		Test 5	
CSA / *TSA*	Testzeit / *test time*	KBE / *cfu*	log / *lg*	KBE / *cfu*	log / *lg*	KBE / *cfu*	log / *lg*	KBE / *cfu*	log / *lg*	KBE / *cfu*	log / *lg*
1.	15 min	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
2.	30 min	1	0.00	0	0.00	0	0.00	0	0.00	0	0.00
3.	45 min	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
4.	1 h	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
5.	1 h 15 min	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
	Testmaterial / *test material*	57	1.76	61	1.79	24	1.38	53	1.72	29	1.46

KBE der Ausgangskeimsuspension / *cfu test suspension*:
Staphylococcus aureus ATCC 29213 1.9×10^4 / ml

Ergebnis Berechnung / *results of calculation:*

	Test 1	Test 2	Test 3	Test 4	Test 5
I_B	5.931	6.000	6.000	6.000	6.000

Legende / *Legend*:
KBE / cfu = Kolonie bildende Einheiten / *colony forming units*
CSA / *TSA* = Caseinpepton-Sojabohnen-Mehlpepton Agar / *Trypton-Soya-Agar*
I_B = barrier index $I_B = 6-(R_{CUM1}+R_{CUM2}+R_{CUM3}+R_{CUM4}+R_{CUM5})$

Schlussfolgerung / *conclusion*:

Klasse / *class* 6: Einstufung der Widerstandsfähigkeit gegen die Penetration kontaminierter Flüssigkeiten unter hydrostatischen Druck (Abschnitt 4.1.4.1., Prüfung gemäß ISO 16604). /
Classification of resistance to penetration by contaminated liquids under hydrostatic pressure (part 4.1.4.1., testing according ISO 16603 and ISO 16604).

Klasse / *class* 6: Einstufung der Widerstandsfähigkeit gegen Penetration von Infektionserregern aufgrund mechanischen Kontaktes mit Substanzen, die kontaminierte Flüssigkeiten enthalten (Abschnitt 4.1.4.2., Prüfung gemäß EN ISO 22610). /
Classification of resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids (part 4.1.4.2., testing according EN ISO 22610).

Klasse / *class* 3: Einstufung der Widerstandsfähigkeit gegen die Penetration kontaminierter Feststoffteilchen (Abschnitt 4.1.4.4., Prüfung gemäß EN ISO 22612). /
Classification of resistance to penetration by contaminated solid particles (part 4.1.4.4., testing according EN ISO 22612).

Archivierung / *Archiving:* Eine Ausfertigung des Berichtes wird zusammen mit den Rohdaten im Archiv der HygCen Austria GmbH aufbewahrt. / *A copy of this report is kept together with the raw data in the archive of HygCen Austria GmbH.*

Hinweis / *Note*: Der vorliegende Prüfbericht bezieht sich ausschließlich auf die dem Labor vorliegenden Prüfgegenstände. Jede auszugsweise Vervielfältigung bedarf der schriftlichen Genehmigung durch die HygCen Austria GmbH. / *The present test report refers exclusively to the test objects available to the laboratory. Any duplication in extracts requires the written permission of*

Prof. Dr. med. H.-P. Werner
Technischer Leiter / *technical manager*

Monika Feltgen
Stellvertretender technischer Leiter / *vice technical manager*

Anhang zum Prüfbericht B 25190
attachment to test report B 25190

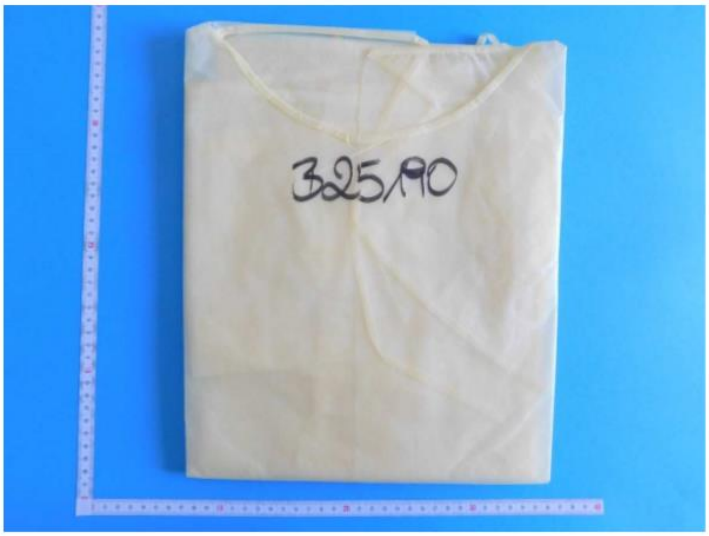

Abb. 1: PP+PE Isolation Gown

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No. 366, Pengjialing, Yongfeng Street, Hanyang District, Wuhan, China

ISO 16604

RESULTS

RESISTANCE OF MATERIALS USED IN PROTECTIVE CLOTHING TO PENETRATION BY BLOOD-BORNE PATHOGENS USING Phi-X174

Standard: ISO 16604:2004.

Procedure: C.

Principle:

In the method, the material is placed in the test cell. The good side of the test material is directly in contact with a suspension of bacteriophage (phi-X174) After assembly, the cell is placed in the apparatus as defined in the standard and the corresponding pressure is applied:

- 5 minutes in contact without pressure application.
- 5 minutes at 20 kPa.

End of test, the sample surface that has not been in contact with the bacteriophage suspension is clarified. The rinsing liquid is then placed on an agar plate which has previously been inoculated with *Escherichia coli* (used as host bacteria of bacteriophage).The plates are incubated for 24 hours at 37 ° C, the presence of colonies on the agar surface means that the bacteriophage has passed through the sample.

Results are expressed in the form: PASS or FAIL test. The detection of only one plaque constitutes a failure of the textile.

Date test: 29/06/2020 – 03/07/2020

Dimension of the test specimens: 7,5 cm x 7,5 cm.

Bacteriophage: Bacteriophage Phi-X174 (ATCC 13706-B1).

Host bacteria of the used of bacteriophage: *Escherichia Coli* (ATCC 13706).

Retaining screen: not use.

Bacteriophage concentration:

- Starting: $8 \cdot 10^8$ (PFU/ml)
- Ending: $7{,}4 \cdot 10^8$ (PFU/ml)

Compatibility ratio: 2,2

武汉金瑞达医疗用品有限公司
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No. 366, Pengjialing, Yongfeng Street, Hanyang District, Wuhan, China

RESULTS

RESISTANCE OF MATERIALS USED IN PROTECTIVE CLOTHING TO PENETRATION BY BLOOD-BORNE PATHOGENS USING Phi-X174

Results:

Reference	Test 1	Test 2	Test 3
ISOLATION-GOWN	PASS (-)	PASS (-)	PASS (-)
Negative Control	(-)	(-)	(-)
Positive Control	(+)	(+)	(+)

Remarks:

- Symbols used in the table of results meaning the following:

  (+) = Penetration of bacteriophages.

  (-) = No penetration of bacteriophages.

- In accordance with the standard point 4.1.4.1, the product should be classify as **CLASS 6** according with the following table:

Table of classification of resistance to penetration of contaminated liquids under hydrostatic pressure.

Class	Hydrostatic pressure at which the material passes the test
6	20 kPa
5	14 kPa
4	7 kPa
3	3,5 kPa
2	1,75 kPa
1	0 kPa[a]

[a] Means that the material is only exposed to the hydrostatic pressure of the liquid in the test cell.