

HYGISUN[®]

Infektionsschutzkittel

REF CN308



CE 0624

EN 14126



HYGISUN[®]

Infektionsschutzkittel

REF CN308



CE 0624

EN 14126



CARTON DIMENSION

(HYGISUN Infektions-Schutzkittel gem. EN 14126)

HYGISUN[®]

1 Stk./PP Bag

10 Stk./PP Bag

100 Stk./Ukt

CE 0624

SIZE: M

EAN: 4260676530324

SIZE: L

EAN: 4260676530171

SIZE: XL

EAN: 4260676530331

M

HYGISUN® REF CN308
HYGISUN Infektionsschutzkittel

10 STÜCK **M**

ON SET:

2020-10

2025-10

LOT 202010 4 260676 530171

CHONGWU HANWU GEDESIGSABLE HYGIENE PRODUCTS PTE. LTD.
 Changzhou Industrial Zone, Zhenjiang Ave., Xianhuo 410101,
 Wuxue, Jiangsu, P.R. CHINA

HYGISUN PTE. LTD.
 Singapore, Suburban 22, 10 West, 299544, The Hague, Netherlands

IMPORTER: SURBANI INTERNATIONAL SDN BHD
 57, Jalan Puchong 1, 47100, Puchong, Selangor

QUALIFIED CERTIFICATE

1. 认证依据: GB 19081-2009
 2. 认证范围: 一次性使用医用防护服
 3. 认证日期: 2020年10月10日
 4. 有效期至: 2025年10月10日
 5. 获证企业: 常州汉武防护服有限公司
 6. 获证产品: 一次性使用医用防护服
 7. 获证型号: M
 8. 获证规格: 10件/包
 9. 获证标准: GB 19081-2009
 10. 获证地点: 江苏省无锡市
 11. 获证机构: 江苏省医疗器械质量监督检验中心
 12. 获证证书编号: 苏械注准 20200101 000000
 13. 获证企业名称: 常州汉武防护服有限公司
 14. 获证产品名称: 一次性使用医用防护服
 15. 获证产品规格: M
 16. 获证产品数量: 10件/包
 17. 获证标准: GB 19081-2009
 18. 获证地点: 江苏省无锡市
 19. 获证机构: 江苏省医疗器械质量监督检验中心
 20. 获证证书编号: 苏械注准 20200101 000000

HYGISUN®

HYGISUN Infektionsschutzkittel

CE 0624

GEBRAUCHSANLEITUNG



Handschuhe
nicht tragen
Handschuhe
nicht tragen

EN 14126



Handschuhe
nicht tragen
Handschuhe
nicht tragen

REF: CN308

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 Changzhou Industrial Zone, Zhenjiang Ave., Xianhuo 410101,
 Wuxue, Jiangsu, P.R. CHINA

HYGISUN PTE. LTD.
 Singapore, Suburban 22, 10 West, 299544, The Hague, Netherlands

IMPORTER: SURBANI INTERNATIONAL SDN BHD
 57, Jalan Puchong 1, 47100, Puchong, Selangor

4 260676 530171

XL

HYGISON REF: CN308
HYGISON Infektionsschutzkittel

10 STÜCK XL

EN 14126
CE 0624

2020-10
2025-10

LOT: 202010 4 260676 530171

CHOWHI NAMA RESPONSABLE HYGIENE PRODUCTS PTE. LTD.
Changhui Industrial Zone, Huochang Ave., Suzhou District,
Wuxi, Hubei, 431002, China

LOTUS Pte. S.C.
Singapore, 508015, S.S. 16, 16958A, The Ridge, Netherlands

IMPORTEUR: VANERAM INTERNATIONAL GmbH
Schwanenstr. 12, 52146 Monheim, Germany

**QUALIFIED CERTIFICATE
PAPER**

Product: 10pcs/lot
Lot: 202010
Date of Issue: 2020-10-10
Valid until: 2025-10-10

CHOWHI NAMA RESPONSABLE HYGIENE PRODUCTS PTE. LTD.
Changhui Industrial Zone, Huochang Ave., Suzhou District,
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HYGISON

HYGISON Infektionsschutzkittel

CE 0624

GEBRAUCHSANLEITUNG



1. Full-body protection
2. Protection for the front and arms
3. Protection for the front and back



1. Full-body protection
2. Protection for the front and arms
3. Protection for the front and back
4. Protection for the front and back with gloves



1. Correct use of gloves
2. Correct disposal of the suit

EN 14126



REF: CN308

CHOWHI NAMA RESPONSABLE HYGIENE PRODUCTS PTE. LTD.
Changhui Industrial Zone, Huochang Ave., Suzhou District,
Wuxi, Hubei, 431002, China

LOTUS Pte. S.C.
Singapore, 508015, S.S. 16, 16958A, The Ridge, Netherlands

IMPORTEUR: VANERAM INTERNATIONAL GmbH
Schwanenstr. 12, 52146 Monheim, Germany

4 260676 530171

DOKUMENTATION

INFEKTIONSSCHUTZKITTEL gemäß EN 14126

EINLEGEBLATT IN JEDEM KARTON



HYGISUN[®]		REF CN308
HYGISUN Infektionsschutzkittel		
1 STÜCK	L	
EN 14126		
		CE 0624
	2020-10	
	2025-10	
LOT	202010	
		4 260676 530171
	CROWN NAME DISPOSABLE HYGIENE PRODUCTS FTY., LTD. Chengbei industrial zone, Zhucheng ave., Xinzhou district, Wuhan, Hubei, 431400, China	
EC REP	LOTUS NL B.V. Koningin Julianaplein 10, le Verd, 2595AA, The Hague, Netherlands	
IMPORTEUR	SUNBEAM INTERNATIONAL GMBH Schumanstr.12, 52146 Würselen, Germany	



HYGISUN Infektionsschutzkittel

GEBRAUCHSANLEITUNG



1. Schlüpfen Sie zuerst mit den Armen in den Schutzkittel und legen Sie ihn dann über die Schultern.



2. Knoten Sie die oberen hinteren Bänder zu einer festen Schleife.



3. Knoten Sie nun die unteren hinteren Bänder zu einer festen Schleife.

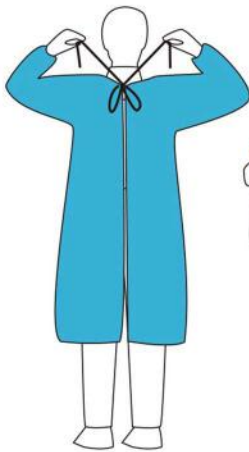
Artikelbezeichnung:
Schutzkittel Typ CN
308 B

Außenseite:
ohne Etikett

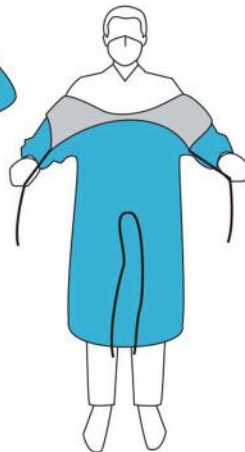
Innenseite:
mit Etikett am Nacken



1. Lösen Sie die untere hintere Schleife zuerst.



2. Lösen Sie nun die obere hintere Schleife.



3. Nehmen Sie den Schutzkittel ab, indem Sie an den oberen Bändern ziehen.



4. Der Schutzkittel kann nun entsorgt werden.

Achtung!
Beim Ausziehen Kontakt mit Außenseite vermeiden. Nur Innenseite berühren!



EN 14126



REF CN308



CROWN NAME DISPOSABLE HYGIENE PRODUCTS FTY., LTD.
Chengbei industrial zone, Zhucheng ave., Xinzhou district,
Wuhan, Hubei, 431400, China



LOTUS NL B.V.
Koningin Julianaplein 10, le Verd, 2595AA, The Hague, Netherlands

IMPORTEUR SUNBEAM INTERNATIONAL GMBH
Schumanstr.12, 52146 Würselen, Germany





DECLARATION OF CONFORMITY

According to **REGULATION (EU) 2016/425**.

Manufacturer:

Company name: Crown Name Disposable
Hygiene Products Fty., Ltd.
Address: Chengbei Industrial Zone, Zhucheng
Avenue, Xinzhou District., Wuhan, Hubei
China Tel: +86-27-82761385 extension 1802

Whose Authorized Representative:

Name: Lotus NL B.V.
Address: Koningin Julianaplein 10, 1e
Verd, 2595AA, The Hague, Netherlands.
E-mail: peter@lotusnl.com

We, the manufacturer, herewith declare under our sole responsibility that the PPE Category III

CN308B CN308Y

“Disposable isolation gown with round collar, neck with ties, adjustable with lace at waist, elasticated cuffs, color blue(CN308B) or yellow(CN308Y)”

- is in conformity with the provisions of REGULATION (EU) 2016/425 and with the national standard transposing harmonized standards EN 14126:2003+AC:2004;
- is identical to the PPE which is the subject of EU type-examination (Module B) N° **CE 0784200148-00-00** issued by CENTRO TESSILE COTONIERO e ABBIGLIAMENTO S.p.a. Piazza Sant’Anna 2, 21052 Busto Arsizio, ITALY, notified body 0624;
- the PPE is subject to the conformity assessment procedure ... (either conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) under the supervision of the notified body n. 0624, CENTRO TESSILE COTONIERO e ABBIGLIAMENTO S.p.a.

Signed:

Place: Hubei, China

Date: April 4, 2020

Name of authorized signatory:

Position held in the company: General Manager

Seal/Stamp:

Crown Name Disposable Hygiene Products Fty., Ltd.





> Retouradres Postbus 16114 2500 BC Den Haag

Lotus NL B.V.
T.a.v. de heer X. Wei
Koningin Julianaplein 10
2595 AA 's-Gravenhage

Datum: 7 april 2020
Betreft: aanmelding medisch hulpmiddel klasse I

Geachte heer Wei,

Graag bevestig ik hierbij de ontvangst op 28 maart 2020 van de mededeling ex artikel 5 van het Besluit medische hulpmiddelen (BMH) dat bedrijf Crown Name Disposable Hygiene Products Fty., Ltd. met Europees gemachtigde Lotus NL B.V. onderstaand medisch hulpmiddel, ingedeeld in risicoklasse I, aflevert. Het product is onder volgend kenmerk geregistreerd. Ik verzoek u om in alle verdere correspondentie betreffende dit product het bijbehorende kenmerk te vermelden.

**Disposable medical face mask(non-sterile) with ties, Disposable medical face mask(non-sterile) with earloops
(geen merknaam) (NL-CA002-2020-50105)**

Toekomstige wijzigingen in bovengenoemde gegevens – waaronder een eventuele wijziging van de indeling in risicoklasse in verband met wijzigingen van Europese regelgeving inzake de classificatie van medische hulpmiddelen, en aan voortschrijdend wetenschappelijk inzicht (zie art.9, lid 3 van Europese Richtlijn 93/42/EEG) – dient u te zijner tijd mede te delen.

Volledigheidshalve wijs ik u erop dat het - ongeacht uw mededeling – verboden is een medisch hulpmiddel ter aflevering voorhanden te hebben, dan wel af te leveren indien niet aan de voor dat medisch hulpmiddel geldende regels gesteld bij of krachtens de Wet op de Medische Hulpmiddelen (WMH) wordt voldaan. Met name wijzen wij u op de Nederlandse-taaleis, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Market Surveillance- en vigilantiesysteem.

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag
T 070 340 6161

<http://hulpmiddelen.farmatec.nl>

Inlichtingen bij:

T.I. van Langeveld - Baas

medische_hulpmiddelen@
minvws.nl

Ons kenmerk:

CIBG-20201034

Bijlagen

-

Uw aanvraag

28 maart 2020

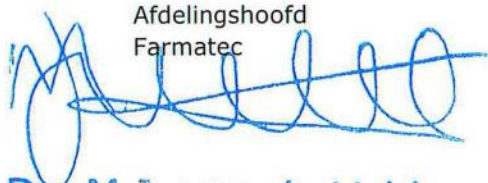
Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Tevens wijs ik u er voor de goede orde nog op dat de registratie van uw mededeling betreffende de aflevering van het bovengenoemde product slechts een administratieve handeling betreft. Deze ontvangstbevestiging behelst dan ook geen besluit betreffende de kwalificatie van het desbetreffende product als medisch hulpmiddel in de zin van art. 1 WMH, noch betreffende de indeling in risicoklasse I.

Let op: de notificatie van uw MDD klasse I product vervalt per 26 mei 2020. Valt uw MDD klasse I (laag risico) product onder de nieuwe VERORDENING (EU) 2017/745 (MDR) onder een hogere risicoklasse? Dan mag uw product tot en met uiterlijk 25 mei 2024 op de markt blijven als MDD klasse I product.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec



Dr. M.J. van de Velde

Dhr. M.J. van de Velde

DOKUMENTATION

INFEKTIONSSCHUTZKITTEL gemäß EN 14126



**Infektions-Schutzkittel
gem. EN 14126**

Lieferant für:



Hessisches Ministerium
für Soziales und Integration



Niedersächsisches Ministerium
für Soziales, Gesundheit
und Gleichstellung



POLIZEI
Hamburg

Bayerisches Staatsministerium für
Gesundheit und Pflege



DOKUMENTATION

INFEKTIONSSCHUTZKITTEL gemäß EN 14126

PRODUKTFOTO



Hinweis: Die Infektionsschutzkittel sind üblicherweise gelb, aufgrund der aktuellen Materialknappheit sind sie in der Farbe blau gefertigt. Wir garantieren die gleiche Materialqualität und -funktionalität.

DOKUMENTATION

INFEKTIONSSCHUTZKITTEL gemäß EN 14126

PRODUKTSPEZIFIKATION



CROWN NAME (WH) UNITED CO., LTD.

TECHNICAL DATA SHEET

Date: 2020/3/17

PRODUCT: PP/PE Isolation Gown, neck with ties or velcro, waist with ties, elastic wrists

Code: CN308

BASE MATERIAL FOR GOWN

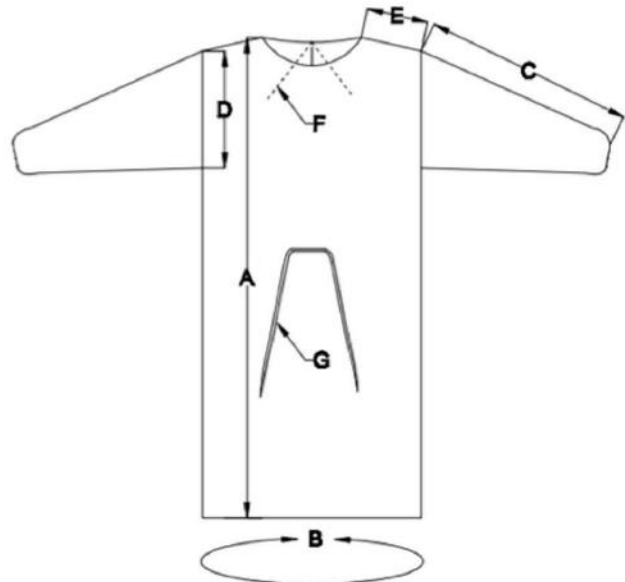
PP laminated with PE 40gsm \pm 10%, yellow

OTHER BASE MATERIALS:

Velcro

DIMENSIONS OF FINISHED PRODUCT:

Length	A	115 \pm 2cm
Width	B	135 \pm 2cm
Sleeve Length	C	58 \pm 1cm
Armhole Width	D	26 \pm 1cm
Shoulder Width	E	22 \pm 1cm
Neck Tie Length	F	29 \pm 1cm
Waist Best Length	G	87 \pm 2cm



PACKAGING

Inner packaging:

QUANTITY

10 pieces per bag

Outer packaging:

10 bags per outer carton
100 pieces per outer carton (\pm 2%)
SIZE OF CARTON
L – 49cm x W – 32cm x H – 40cm

DOKUMENTATION

INFEKTIONSSCHUTZKITTEL gemäß EN 14126

CE CERTIFIKAT

CE 0784200148 00 00

CENTROCOT Notified Body Nr. 0033



EU TYPE-EXAMINATION CERTIFICATE

n° **CE 0784200148 -00 - 00**

According to "Regulation (EU) 2016/425 of the European Parliament and of the Council" of 9th March 2016 on Personal Protective Equipment and repealing Council Directive 89/686/EEC

Centro Tessile Cottoniero e Abbigliamento S.p.A.
P.zza Sant'Anna, 2 - 21052 Busto Arsizio (VA) - Italia

EEC Notified Body N° 0624

- in view of the firm's application submitted on: 30th October 2019;
- in view of the positive results of the Technical File verification submitted by the manufacturer together with the above mentioned request;
- in view of the manufacturer's declaration stated in the Technical File attached to the above mentioned request
- having verified that technical specification of design and manufacture is in compliance with basic requirements specified in annex II of Regulation (EU) 2016/425 and that technical manufacturing documentation is in compliance with above mentioned specifications;
- in view of the positive test results carried out on the basic model representative of production according to paragraph 4 of annex V of Regulation (EU) 2016/425.

Issues to:

CROWN NAME DISPOSABLE HYGIENE PRODUCTS FTY.LTD
Changhang building, Rm 1805, No. 69 Yanjiang Avenue - China

the EU Type-Examination Certificate concerning the following PPE model:

PROTECTIVE GOWN AGAINST INFECTIVE AGENTS

Code CN308

Category: **III** (third)

The model of Personal Protective Equipment is subject to conformity to type assessment according to Section 19 c) of Regulation (EU) 2016/425 (Module C2 or D)



Basic type description

Gown CN308

Disposable lab coat with round collar, opening at back with hook and loop tape on the neck, adjustable with lace at waist, elasticated cuffs.

Fabric: Polypropylene + polyethylene film 42 g/m², color yellow



Variations description

Knitted cuffs – 100% polyester.

Neck with ties instead of hook and loop tape.

Sizes

M - XXL

Standards

EN ISO 13688:2013	Protective clothing - general requirements
EN 14126:2003+ AC:2004 Type PB6B	Protective clothing - Performance requirements and tests methods for protective clothing against infective agents
EN 14325:2004	Protective clothing against chemicals - Test methods and performance classification of chemical protective clothing materials, seams, joins and assemblages

Performance levels

EN 14126	Class 6	Resistance to penetration by contaminated liquids under hydrostatic pressure.
	Class 6	Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids.
	Class 3	Resistance to penetration by contaminated liquid aerosols.
	Class 3	Resistance to penetration by contaminated solid particles



Use

Clothing to be worn to protect against infective agents
Other uses than those listed above are excluded.

Tests

The test results are included in the report: 20RA00516,
20RA00517, 20RA00527, 20RA00529

Marking

The following information are listed on the label inside the garment:

- CE marking
- Company name
- Article code
- Standards
- Standardized pictograms
- Maintenance symbols
- PPE category

Validity

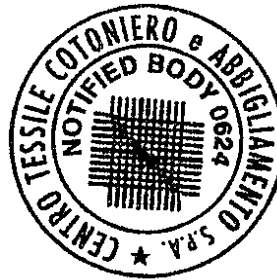
- This certificate has 5-year validity from issue date. On expiration date the Manufacturer will be responsible to require the renewal.
- Any change on model and materials object of this Certificate shall be notified and then approved by Centrocot.

This certificate must be filed by the manufacturer and must be shown, if requested, to the Body that performs controls or to the surveillance authority

Busto Arsizio,

Issue date:
14th April 2020

Expiry date:
14th April 2025

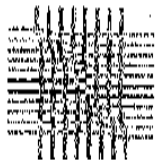


General Manager
Dr. Grazia Cerini

DOKUMENTATION

INFEKTIONSSCHUTZKITTEL gemäß EN 14126

TEST REPORTS



CENROCOT
Innovation experience

Centrosile Cottoniero e Abbigliamento S.p.A.
Piazza Anna, 2 Busto Ars (VA)
Tel. 03396711 Fax 03310056
email i@centrocot.it www.centrocot.it
C.F. e VA 01724710122



LAB N° 13 L

Test Report 20R/0516

of 20/02/20

Messrs
**CROWNAME DISPCABLE HYGIEN PRODUCTS
FTY. LD**
Changing Building, R1805, n.69, Yang Avenue
WUHA - CN

Samples identifications

Sample 0LA00856

Receipt date/01/2020

Sample receg date: 09/01/2020

Description: unwoven fabric used to manufacture gc item CN308

Color: yellow

Composition: 10% polypropylene/polyethylene film

Mass per un. ea: 42 g/m²

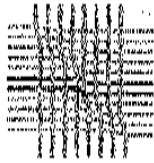
Sampling cad out by: customer

This Test Report consists of the following results

- 90102 Protee clothing. Penetra: by blood and bodyds. Synthetic blood method
- 90112 Protee clothing. Penetra: by blood and otherdy fluids-born pathca. Phi-X174 bacterhage method
- 90123 Protee clothing. Wet bacal penetration
- 90134 Protee clothing. Penetra: by biologically coninated aerosola
- 90135 Protee clothing. Penetra: by biologically coninated powders

Protective ching. Penetration by blood and body fluids. Synthetic blood method

Product stand	UNI EN 14120:4
Test method	ISO 18603:2 + UNI EN 14126:2 Par. 4.1.4.1
Test solution	Synthetic blic
Test equipment	Penetration I cell
Time and press protocol	Procedure D
Test time	5 min for ea pressure tested
Specimens dimensions	(75x75) mm
Number of specimens	3
Specimens conditioning	24 h at (21 ± 2) °C - (60 ± 10)% U.R
Pretreatment	No
Test began on: 07/02/2020	Test ended on: 7/02/2020



Results for sample	20LA0085	UM	result
Specimen°1	0kPa		Pass
Specimen°2	0kPa		Pass
Specimen°3	0kPa		Pass
Specimen°1	1.75kPa		Pass
Specimen°2	1.75kPa		Pass
Specimen°3	1.75kPa		Pass
Specimen°1	3.5kPa		Pass
Specimen°2	3.5kPa		Pass
Specimen°3	3.5kPa		Pass
Specimen°1	7kPa		Pass
Specimen°2	7kPa		Pass
Specimen°3	7kPa		Pass
Specimen°1	14kPa		Pass
Specimen°2	14kPa		Pass
Specimen°3	14kPa		Pass
Specimen°1	20kPa		Pass
Specimen°2	20kPa		Pass
Specimen°3	20kPa		Pass

Pass. The specimen resist to penetration and synthetic blood doesn't pass through the fabric.
Fail. The specimen doesn't resist penetration and the synthetic blood pass through the fabric.

Protective clothing. Penetration of blood and other body fluids-biopathogens. Phi-X1 bacteriophage method

Product standard	UNI EN 14120:04
Test method	ISO 16004:04 + UNI EN 14126:04 Par. 4.1.4.1
Test equipment	Penetration cell
Name of test microorganism	Bacteriophage Phi-X 174 (ATCC 116-B1 LOT: CNCM 112)
Specimens dimensions	(75x75) mm
Penetration assay method	Plaque-form units (PFU)
Number of specimens	3
Procedure	Procedure C
Pre-treatment	No
Test began on	10/02/2020
Test ended on:	13/02/2020

Results for sample	20LA0085	UM	result
Pre-test bacteriophage titer		FU/ml	5.4E+008
Post-test bacteriophage titer		FU/ml	5.2E+008
Test pressure		kPa	20.0
1st specimen			Pass
2nd specimen			Pass
3rd specimen			Pass
Negative control (polyethylene 0 µm)			Pass
Positive control			Fail

Pass. The specimen resist to penetration and micro-organism used for test does not pass through the fabric.
Fail. The specimen doesn't resist penetration and microorganism used for tests through the fabric.
The sample pass the test when the 1 particles don't penetrate them through the sample to one determined pressure and don't come from plaques to cell lysis.



All acceptance criteria was met.

Protective thing. Wet bacterial penetration

Product stand: UNI EN 14:2004
 Test method: UNI EN ISO 610:2006 + UNI EN 126:2004 Par. 4.1.
 Specimens dilution: 24 h a (20 °C o (65 ± 5)% U.R.
 Name of test microorganism: Staphylococcus aureus (ATCC 29) LOT: DSM2589-00
 Culture media: Nutrient agar Oxoid LOT: 239077
 Donor material: Polyurethane membrane; thick 30
 Testing time: 5 steps of 15 minutes
 Pretreatment: No
 Test began on: 10/02/2020 Test ended on: 13/02/2020

Results for sample	20LA0005	UM	result
Break through time		min	>75

Distance from agar surface to brim of petri dish (mm): 3

Concentration of test suspension (CFU/ml): $\times 10^4$

	Interval (min)	n° colonies 1 st specimen	n° colonies 2 nd specimen	n° colonies 3 rd specimen	n° colonies 4 th specimen	n° colonies 5 th specimen	Average
Petri dish 1 (X1)	0-15		0	0	0	0	0
Petri dish 2 (X2)	15-30		0	0	0	0	0
Petri dish 3 (X3)	30-45		0	0	0	0	0
Petri dish 4 (X4)	45-60		0	0	0	0	0
Petri dish 5 (X5)	30-75		0	0	0	0	0
Petri dish 6 (reference) (Z)			215	228	197	04	204
T			215	228	197	04	204
ln (EPP)			0.0	6.0	6.0	1.0	6.0

Legend

$I_a (P)$ = Barrier Index

$$I_a (P) = 6 - (CUM1 + CUM2 + CUM3 + CUM4 + CUM5)$$

wh:

$$CU = X1/T$$

$$CU = (X2 + X1)/T$$

$$CU = (X3 + X2 + X1)$$

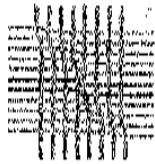
$$CU = (X4 + X3 + X2 + X1)/T$$

$$CU = (X5 + X4 + X3 + X2 + X1)/T$$

$$T = X5 + X4 + X3 + X2 + X1$$

X1), X3, X4 e X5: number of colonies on 15 plates in one replicate test

Z = number of colonies in the top side (plate 6 reference)



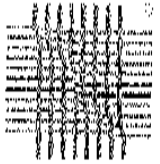
Protective thing. Penetration by biologically contaminated aerosols

Product stand: UNI EN 1412004
 Test method: ISO/DIS 22:2003 + UNI EN 1412004 Par. 4.1.4.3
 Name of test microorganism: Staphylococcus aureus (ATCC 6521; DSM 799-041)
 Culture media: Nutrient agar Oxoid LOT: 239077
 Test equipment: Perspex booth Collison atomizer
 Specimens dimensions: Diameter 2m
 Number of specimens: 4
 Pretreatment: No
 Test began on: 11/02/2020 Test ended on: 13/02/2020

Results for sample	20LA0085	*	UM	result
Micro-organisms extract to membrane REFERENCE (Value A)				
1st specimen			CFU	279
2nd specimen			CFU	314
3rd specimen			CFU	284
4th specimen			CFU	294
Average)			CFU	292.0
Micro-organisms extract to membrane specimen value B)				
1st specimen			CFU	0
2nd specimen			CFU	0
3rd specimen			CFU	0
4th specimen			CFU	0
Average)			CFU	0.0
Penetration ratio (A/B)			10 CFU	>5

Protective thing. Penetration by biologically contaminated powder

Product stand: UNI EN 1412004
 Test method: UNI EN ISO812:2005 + EC1-20+ UNI EN 14126:20Par. 4.1.4.4
 Name of test microorganism: Spores of Bacillus subtilis (ATCC 9372; SIMICON 7 S0817/9-9)
 Culture media: TGE agar (Cd LOT: 1625559)
 Test equipment: Vibrating apparatus
 Number of specimens: 10
 Specimens dimensions: (200x200) m
 Test time: 30 minutes
 Pretreatment: No
 Test began on: 12/02/2020 Test ended on: 4/02/2020



CENROCOT
Innovation experience



LAB N° 33 L

Results for sample **20LA0061**

	UM	result
Talcum concentration	CFU/g	7.7E+007
1st specimen	CFU	0
2nd specimen	CFU	0
3rd specimen	CFU	0
4th specimen	CFU	0
5th specimen	CFU	0
6th specimen	CFU	0
7th specimen	CFU	0
8th specimen	CFU	0
9th specimen	CFU	0
10th specimen	CFU	0
Average	CFU	0.0
Penetration	110 CFU	<1

(*): no accredited by Accredia

Issue date
20/02/2020

Microbiological Laboratory Manager
dott. Giovanna Chis

End of Test Report **20RA00616**



CROWN NAME (WH) UNITED CO., LTD.

TECHNICAL DATA SHEET

Date: 2020/3/17

PRODUCT: PP/PE Isolation Gown, neck with ties or velcro, waist with ties, elastic wrists

Code: CN308

BASE MATERIAL FOR GOWN

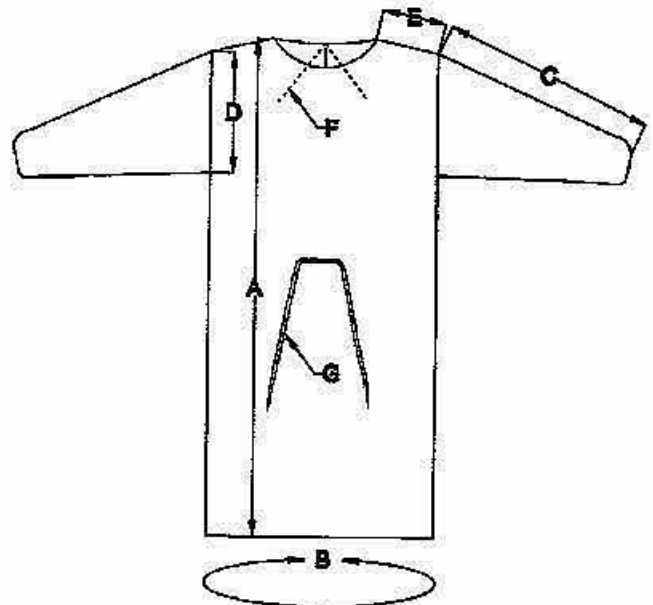
PP laminated with PE 40gsm \pm 10%, yellow

OTHER BASE MATERIALS:

Velcro

DIMENSIONS OF FINISHED PRODUCT:

Length	A	115 \pm 2cm
Width	B	135 \pm 2cm
Sleeve Length	C	58 \pm 1cm
Armhole Width	D	26 \pm 1cm
Shoulder Width	E	22 \pm 1cm
Neck Tie Length	F	29 \pm 1cm
Waist Best Length	G	87 \pm 2cm



PACKAGING

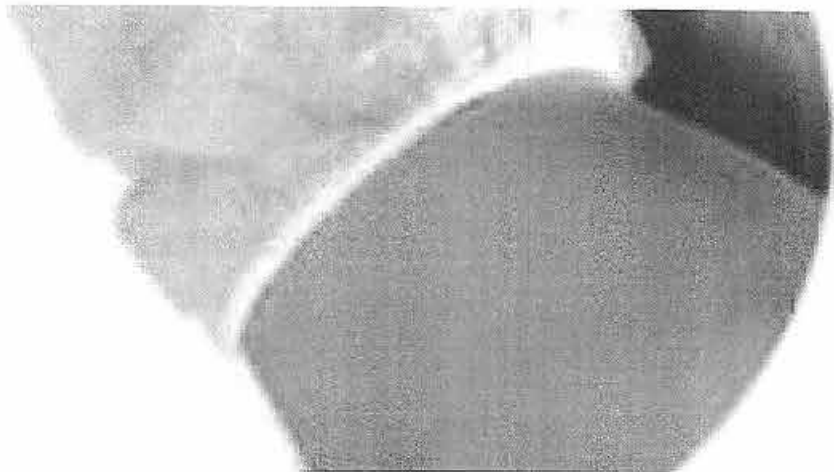
Inner packaging:

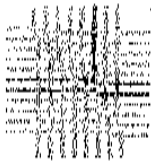
QUANTITY

10 pieces per bag

Outer packaging:

10 bags per outer carton
100 pieces per outer carton (\pm 2%)
SIZE OF CARTON
L – 49cm x W – 32cm x H – 40cm





CENTROCOF
Innovative experience

Centro Tili Cotone e Abbigliamento S.p.A.
Piazza Enna, 2 - Busdo Arso (VA)
Tel. 03316711 - Fax 0331 056
email info@centrocof.it - webwww.centrocof.it
C.F. e P.I. 01724710192



LAB N° 01 L

Test Report 20RA0517

of 27/02/20

Messrs
CROWNAME DISPOSABLE HYGIENPRODUCTS
FTY. L1
Changhg Building, Rn805, n.69, Yang Avenue
WUHAN- CN

Samples and identifications

Sample LA00861

Receipt date: 01/2020

Sample receive date: 09/01/2020

Description: woven fabric used manufacture govtem CN308

Color: yellow

Composition: 1% polypropylene polyethylene film

Mass per unit: 42 g/m²

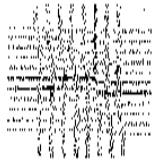
Sampling carried out by: customer

This Test Report consists of the following results

- 90270 Protec clothing. Tensile strength. Strip method
- 90302 Protec clothing. Tearing strength. Trapezoid method
- 90400 Protec clothing. Abrasion (circular)
- 90521 Protec clothing. Resistance to damage by repeated flexing
- 90541 Protec clothing. Perforation
- 70831 Protec clothing, textile. pH aqueous extract
- 76229 Protec clothing. Aromatic amines derived from azo dyes (without action)

Protective clothing. Tensile Strength. Strip method

Product standard	UNI EN 14126:04
Test method	UNI EN ISO 14-1:2013 + UNI EN325:2005 Par. 4.9 + UNI EN 14126:2004 F 4.1.2
Standard atmosphere in normal conditioning	(20 ± 2)°C - (64 ± 4)%U.R.
Rate of extension	(100 ± 10) mm
Pretension applied	2 N
Width test	(50 ± 0.5) mm
Length test	(100 ± 1) mm
Specimens conditioning	conditioned
Number of measured specimens	5 for direction
Number of discarded specimens	0
Test began on: 31/01/2020	Test ended on: 01/02/2020



CENTRO TESSILE
 innovative experience

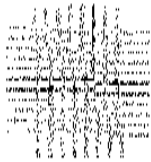


LAB N° 011

Results for sale	20LA00801	JM	result
Longitudir			
1st specin		N	58.0
2nd specin		N	53.3
3rd specin		N	58.0
4th specin		N	60.5
5th specin		N	52.0
Average		N	56
Maximum elongation (average)		%	113
C.V. of threacking force		%	6.5
C.V. of elqation		%	8.7
Transversa			
1st specin		N	30.6
2nd specin		N	30.7
3rd specin		N	33.3
4th specin		N	31.9
5th specin		N	32.8
Average		N	32
Maximum elongation (average)		%	91.0
C.V. of threacking force		%	3.8
C.V. of elqation		%	6.9

Protective cling. Tearing strqth. Trapezoid mod

Product standa	UNI EN 1412004
Test method	UNI EN ISO 9-4:1999 + UNI EN :25:2005 Par. 4.7 + I EN 14126:2004 P4.1.2
Standard atmierre in normal condiiing	(20±2)°C - (65%R.H.
Test equipmen	Dynamometere C.R.E.
Rate of extensi	(100 ± 10) min
Specimen dimeion	(75 ± 1)x(150) mm
Longht test	(25 ± 1) mm
Useful length oaring strength	(64 ± 1) mm
Tearing strengt	Average of thghest peaks
Number of mreed specimens	5
Number of disced specimens	0
Test began on:	31/01/2020
Test ended on:	01/2020



CENROCOPI
Innovation experience



(LAB N° 011)

Results for sale	20LA00861	JM	result
tearing of longitudinal direct			
Tearing force warpwise - 1st specimen		N	37.2
2nd specimen		N	29.1
3rd specimen		N	37.2
4th specimen		N	28.2
5th specimen		N	29.3
Average		N	32.2
C.V. force tearing		%	14.2
tearing of transversal direct			
Tearing force weftwise -1st specimen		N	12.4
2nd specimen		N	15.2
3rd specimen		N	15.2
4th specimen		N	15.1
5th specimen		N	11.8
Average		N	13.9
C.V. force tearing		%	12.1

Protective ching. Abrasion (Martindale)

Product standards	UNI EN 1412004
Test method	UNI EN 530:2004 Met. 2 + UNI EN 25:2005 Par. 4.4.1 - UNI EN 14126:2004 4.1.2
Number of tested specimens	4
Test equipment	Martindale
Pressure on specimen	9 kPa
Standard atmosphere for conditioning	(20±2)°C - (65±5)R.H.
Abradant	abrasive paper
Type of felt use	wool
End test	1° hole
Pretreatment	No
Test began on:	31/01/2020
Test ended on:	10/1/2020

Results for sale	20LA00861	M	result
Number of rings effective/lowest in which it was served the end of test			
1st specimen		rings	500
2nd specimen		rings	1000
3rd specimen		rings	1000
4th specimen		rings	1000
Lower value		rings	500



Protective ching. Resistance damage by reped flexing

Product Stand	UNI EN 1412004
Test method	UNI EN ISO 14:1999 Met. B + UNI 14325:2005 Par. 4 + UNI EN14120:2(Par. 4.1.2
Standard atmhere in normal conoring	(20±2)°C - (64) %R.H.
Test equipmer	Flexlometer
Stroke length he mobile disk	(11,7 ± 0,35)±
Mobile disk frency	(8,31(0,4) Hz)mpression pulse perute
Specimens dinstions	(105x50) mm
Number of cyc	100000 cycle
Number of mered specimens	3 for director
Test began on	31/01/2020
Test ended on:	3/02/2020

Results for sale	20LA00861	M	result
Maximum cction longitudinal			
Lowest va after 100.000 cys			2 - Null
Maximum taversa diratction			
Lowest va after 100.000 cys			2 - Null

Verification anescription of the dage UNI EN ISO 785

- 0 Any deteriorin
- 1 Light deteriorin
- 2 Moderated drioration
- 3 Important deoration

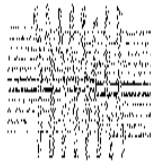
Depth of the cks UNI EN ISO 785:

- "Null" Any cra
- "A" Superfi-cracks or of the layof finish, not involvihe alveolar or middiyer penetrating.
- "B" Penetry cracks but that it can't cross the interriary layer or, in the e of covering to an v layer, that dosen'tlose the support of le.
- "C" Crossinracks the support oise.
- "D" Cracks ough the whole matl.

Protective ching. Perforation

Product stands:	UNI EN 1412004
Test method	UNI EN 863:7 + UNI EN 14325:5 Par. 4.10 + UNI E4120:2001 Par. 4.1
Test apparatus	Dynamomete
Specimens conoring	24 h a (23 ± 2 - (50 ± 5) % U.R.
Test conditions	(20 ± 2)°C - (64) %U.R.
Rate of extensi	100 mm/min
Test began on	31/01/2020
Test ended on:	/01/2020

Results for sale	20LA00861	M	result
Puncture retance			
1st specin		4	5.30
2nd specin		4	5.07
3rd specin		4	6.48
4 th specin		4	5.53
Lower val.		4	5.3



Protective ching, textile. pH aqueous extract

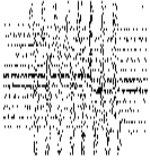
Product stand: UNI EN ISO 188:2013
 Test method: UNI EN ISO 13:2006 + UNI EN 13688:2013 Par. 4.
 Test equipmer: pH-meter with combined glass electrode
 Number of measured specimens: 3
 Extraction solin: KOH 0.1 mol/l
 pH of the extron solution: 5.3
 Temperature extracting solution: 25°C
 Resistance to tting: no
 Test began on: 03/02/2020 Test ended on: 4/02/2020

Results for sale 20LA00861 **JM** **result**
 Mean pH ue of 2° and 3° eacts **6.3**

Protective ching. Aromatic anes derived from colorants (w/out extraction)

Product stand: UNI EN ISO 88:2013
 Test method: UNI EN 1436:2017 + UNI EN 13688:2013 Par. 4.2
 Test equipmer: GC-MS and irtation with LC-MS
 Discolouring os sample: no
 Test began on: 14/01/2020 Test ended on: 1/02/2020

Results for sale	20LA00861	JM	result
4-aminobényl	02-67	g/kg	< 1
benzidine	92-87	g/kg	< 1
4-chloro-cluidine	95-66	g/kg	< 1
2-naphthylina	91-56	g/kg	< 1
o-aminoazluene	97-56	g/kg	< 1
2-amino-4rotoluene	99-55	g/kg	< 1
4-chloroane	106-41	g/kg	< 1
2,4-diamirnisole	615-01	g/kg	< 1
4,4'-diamiriphenylmethane	101-77	g/kg	< 1
3,3'-dichloenzidine	91-94	g/kg	< 1
o-dianisidi(3,3'-dimethoxybidine)	119-90	g/kg	< 1
o-tolidine (3'-dimethylbenzidi)	119-91	g/kg	< 1
3,3'-dimet(4,4'-diaminodiph/methane	838-88	g/kg	< 1
p-cresidin(4-methoxy-5-methniline)	120-77	g/kg	< 1
3,3'-dichlo(4,4'-diaminodiph/methane	101-14	g/kg	< 1
4,4'-diamiriphenyl ether	101-80	g/kg	< 1
4,4'-diamiriphenyl sulphide	139-66	g/kg	< 1
o-toluidine	95-53	g/kg	< 1
2,4-toluenamine	95-80	g/kg	< 1
2,4,5 trimelaniline	137-17	g/kg	< 1
o-anisidine-methoxyaniline)	90-04	g/kg	< 1
4-aminoazanzone	80-09	g/kg	< 1
2,4-xylidine	95-68	g/kg	< 1
2,6-xylidine	87-62	g/kg	< 1



CONROGOUT
Innovative experiences



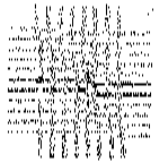
LAB N° 01 L

Issue date
27/02/2020

PPE Laboratory Manager
dott.ssa Valeriana Angoni

Valeriana Angoni

End of Test Report 0RA00517



CENTROCOOT
INNOVATION EXPERIENCE

Centro Tessile Cotoniere e Abbigliamento S.p.A.
Piazza Maria, 7 - Busto Arsiz (VA)
Tel. 033193711 - Fax 03310056
email: info@centrocoot.it - www.centrocoot.it
C.F. e P.A. 01724740122



LAB N° 6 L

Test Report 20RA0529

of 27/02/20

Messrs
**CROWNAME DISPOSABLE HYGIENPRODUCTS
PTY. L'**
Changhg Building, Rt1805, n.69, Yang Avenue
WUHAH- CN

Samples and identifications

Sample ILA00873

Receipt date: 01/2020

Sample receipt date: 09/01/2020

Description: n woven gown Item N308, size M

Sampling carried out by: customer

Sample LA00874

Receipt date: 01/2020

Sample receipt date: 09/01/2020

Description: n woven gown Item N308, size L

Sampling carried out by: customer

Sample LA00875

Receipt date: 01/2020

Sample receipt date: 09/01/2020

Description: n woven gown Item N308, size XL

Sampling carried out by: customer

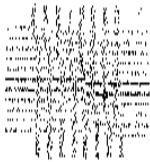
This Test Report consists of the following results

- 70000 Protective clothing. Size
- 70050 Protective clothing. Control ergonomic requirements
- 70160 Protective clothing. Control specific design requirements

Protective clothing. Size

Product standards: UNI EN ISO 98:2013
Test method: UNI EN ISO 98:2013 Par. 6
Test began on: 25/02/2020 Test ended on: /02/2020

Results for safe	20LA00873	M	result
Size analysed			M
Total length		m	112.0
Width		m	67.5
Results for safe	20LA00874	M	result
Size analysed			L
Total length		m	133.5
Width		m	68.5



CENROCOT
 innovation experience



LAB N° 3 L

Results for sale	20LA00871	UM	result
Size analysed			XL
Total len		cm	140.5
Width		cm	74.5

Protective ching. Control of ergonomic requirements

Product stand: UNI EN ISO388:2013
 Test method: UNI EN ISO388:2013 Par. 4
 Number of prypes tested: 1
 Size: M
 Test began on: 25/02/2020 Test ended on: 5/02/2020

Results for sale	20LA00873	*	UM	result
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The garment in accordance with section 4 EN ISO3689:2013

Protective ching. Control of specific design requirements

Product stand: UNI EN 1303009
 Number of prypes tested: 1
 Size: M
 Test began on: 25/02/2020 Test ended on: 5/02/2020

Results for sale	20LA00873	*	UM	result
------------------	-----------	---	----	--------

Requirements

There are noatures which may ect liquid chemicals hold them onto thbric surface, e.g. untested pockets etc **compliant**

The clothing all be made so that wearer has freedom of movement and shre as comfortable possible **compliant**

(*): no accredited by Accredia

Issue date
 27/02/2020

PPE Laboratory Manager
 dott.ssa Valeria Arangoni

End of Test Report 0RA00529

DOKUMENTATION

INFEKTIONSSCHUTZKITTEL gemäß EN 14126

ZERTIFIKATE

**QUALITÄTSMANAGEMENT
DIN ISO 9001:2015**

**STERILE PRODUKTION
DIN ISO 13485:2016
DIN ISO 13485:2016
DIRECTIVE 93/42/EEC**

Certificate CN14/21396

The management system of

Crown Name Disposable Hygiene Products Fty., Ltd.

Chengbei Industrial Zone, Zhucheng Avenue, Xinzhou District, Wuhan City, Hubei Province, P.R. China

Unified Social Credit Code 91420117755148433P

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

**Manufacture of sterile and non sterile nonwoven medical devices:
Surgical Gowns, Surgical drapes, Face masks, Caps, Overalls, Shoe covers, Sleeves, Head covers, Table Cover, Isolation gown, Air-laid paper, Surgical kits (surgical gown, surgical drape, face mask, cap) (Only for export)**

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2015 requirements may be obtained by consulting the organisation

This certificate is valid from 20 December 2018 until 19 December 2021 following a re-certification audit on 13 November 2018 and remains valid subject to satisfactory surveillance audits. Recertification audit due a minimum of 60 days before the expiration date. Issue 4. This certificate was previously valid from 22 October 2014 until 15 September 2018

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t+44 (0)151 350-6666 f+44 (0)151 350-6600 www.sgs.com

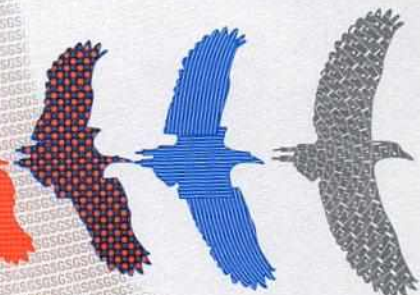
The certification information can be verified on the web site of Certification and Accreditation Administration of the People's Republic of China www.cnca.gov.cn

HC SGS 9001 2015 0118

Page 1 of 1



0005



Certificate CN14/21395

The management system of

Crown Name Disposable Hygiene Products Fty., Ltd.

Also trading as Crown Name (WH) United Co., Ltd.

Chengbei Industrial Zone, Zhucheng Avenue, Xinzhou District, Wuhan City, Hubei Province, 431400, P.R. China

has been assessed and certified as meeting the requirements of



ISO 13485:2016 EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 21 October 2020 until 21 October 2023 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 25 April 2023
Issue 6. Certified since 22 October 2014

This is a multi-site certification.

Additional site details are listed on the subsequent page.

Authorised by

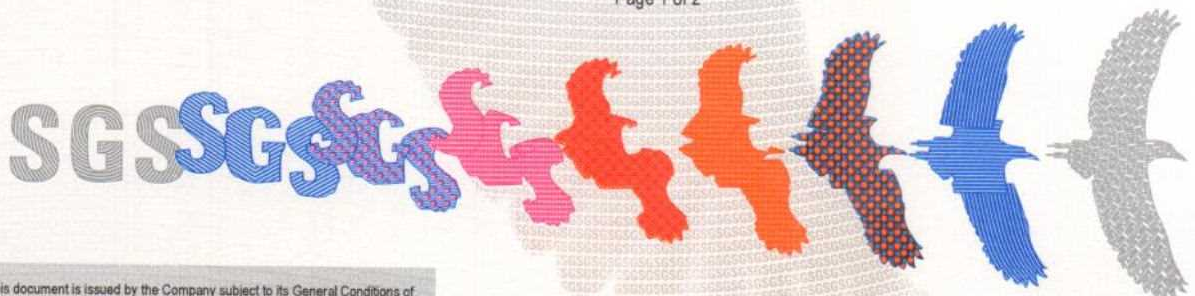


0005

SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118 M2

Page 1 of 2



Crown Name Disposable Hygiene Products Fty., Ltd.

Also trading as Crown Name (WH) United Co., Ltd.

ISO 13485:2016 EN ISO 13485:2016



Issue 6

Detailed scope

**Manufacture of sterile and non sterile nonwoven medical devices:
Surgical Gowns, Surgical drapes, Face masks, Caps, Overalls,
Shoe covers, Sleeves, Head covers, Table Cover, Isolation gown,
Surgical kits (surgical gown, surgical drape, face mask, cap)**

Additional facilities

**Changhang Building Rm.1805 18/F, No. 69, Yanjiang Avenue,
Wuhan City, Hubei Province, 430021, P.R. China**



0005

EC Certificate Production Quality Assurance System: Certificate CN19/41065

The management system of

Crown Name Disposable Hygiene Products Fty., Ltd.

Also trading as Crown Name (WH) United Co., Ltd.

Chengbei Industrial Zone, Zhucheng Avenue, Xinzhou District,
Wuhan City, Hubei Province, 431400, P.R. China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

Restricted to the aspects of manufacture concerned with securing and
maintaining sterile conditions

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 01 October 2020 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 24 November 2015
and first certified by SGS Belgium NV since 16 December 2019.

Certification is based on reports numbered CNSZH/ 8618

This is a multi-site certification.
Additional site details are listed on subsequent pages.

Authorised by

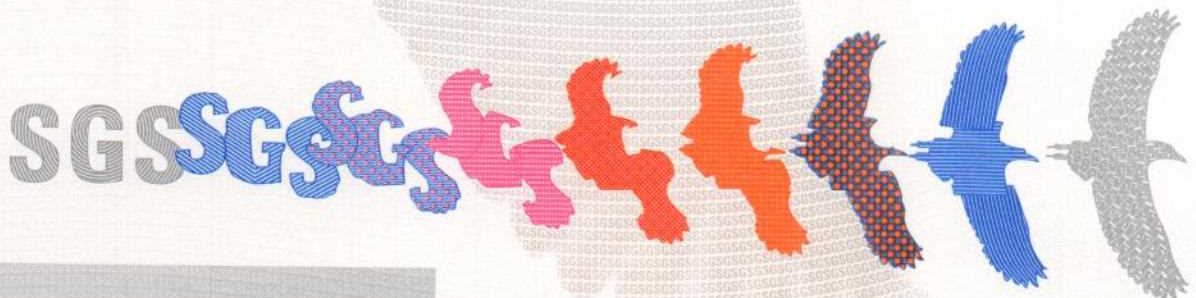
Pieter Weterings
Certification Manager

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5008 - Certificate CE1639 AnnexV_EN rev. 01

Page 1 of 2



Crown Name Disposable Hygiene Products Fty., Ltd.

Also trading as Crown Name (WH) United Co., Ltd.

Directive 93/42/EEC

on medical devices, Annex V

Restricted to the aspects of manufacture concerned with securing and
maintaining sterile conditions

Issue 2

Detailed scope

**Sterile Surgical Kits (Surgical Gown used to protect the patient
from contamination, Surgical Drape, Face Mask,
Cap used to protect the patient from contamination)**

Additional facilities

**Changhang Building Rm.1805 18/F, No. 69, Yanjiang Avenue,
Wuhan City, Hubei Province, 430021, P.R. China**