

# HYGISUN<sup>®</sup>

## Infektionsschutzkittel

REF CN308

CE 0624

EN 14126



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REF CN308



CE 0624

EN 14126











## 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.







CIBG  
Ministerie van Volksgezondheid,  
Welzijn en Sport

> 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



## EU TYPE-EXAMINATION CERTIFICATE

n° **CE 0784200148 -00 - 00**

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

**Centro Tessile Cotoniero 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: 30<sup>th</sup> 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/m<sup>2</sup>, color yellow



### Variations description

Knitted cuffs – 100% polyester.

Neck with ties instead of hook and loop tape.

### Sizes

M - XXL

### Standards

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

### Performance levels

|          |                |                                                                                                                          |
|----------|----------------|--------------------------------------------------------------------------------------------------------------------------|
| EN 14126 | <b>Class 6</b> | Resistance to penetration by contaminated liquids under hydrostatic pressure.                                            |
|          | <b>Class 6</b> | Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids. |
|          | <b>Class 3</b> | Resistance to penetration by contaminated liquid aerosols.                                                               |
|          | <b>Class 3</b> | 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**

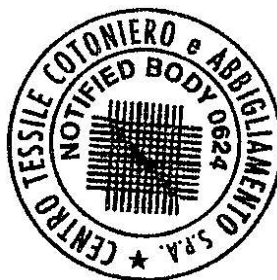
- This certificate has 5-year validity from issue date. On expiration date the Manufacturer will be responsible to require the renewal.
- Any change on model and materials object of this Certificate shall be notified and then approved by Centrocot.

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:  
14<sup>th</sup> April 2020

Expiry date:  
14<sup>th</sup> April 2025



General Manager  
*Dr. Grazia Cerini*



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](http://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](http://www.cnca.gov.cn)

HC SGS 9001 2015 0118

Page 1 of 1



0005



This document is issued by the Company subject to its General Conditions of  
Certification Services accessible at [www.sgs.com/terms\\_and\\_conditions.htm](http://www.sgs.com/terms_and_conditions.htm).  
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unauthorized alteration, forgery or falsification of the content or appearance of  
this document is unlawful and offenders may be prosecuted to the fullest extent  
of the law.



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

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](http://www.sgs.com)

HC SGS 13485 2016 0118 M2

Page 1 of 2



0005





# **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 CN/SZH/ 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](http://www.sgs.com)

LPMD5008 - Certificate CE1639 Annex V\_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**