

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 16 December 2019 until 19 July 2022 and remains valid subject to satisfactory surveillance audits. Issue 1. 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

LPMD5008 - Certificate CE1639 AnnexV_EN rev. 01

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SGSS



Certificate CN19/41065, continued

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 1

Detailed scope

Sterile Surgical Kits (Surgical Gown used to protect the patient from contamination and also to protect the hospital staff, Surgical Drape, Face Mask, Cap used to protect the patient from contamination and also to protect the hospital staff)

Additional facilities

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

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