Certificate CN14/21395

The management system of

Crown Name Disposable Hygiene Products Fty. Ltd.

No. 508, Qi'an Road, 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
Design & Development, Manufacture of non-sterile single use non-woven medical devices: Isolation Gown and Scrub Suits. Manufacture of sterile and non-sterile single use non-woven medical devices: Sterile and Non-sterile Surgical Gown, Sterile and Non-sterile Surgical Drape, Sterile and Non-sterile Coverall, Non-sterile Face Mask, Non-sterile Cap, Non-sterile Shoe Covers, Non-sterile Sleeves, Non-sterile Head Cover, Non-sterile Table Cover, Sterile and Non-sterile Surgical Kits (surgical gown, surgical drape, face mask, cap).

This certificate is valid from 11 October 2023 until 21 October 2026 and remains valid subject to satisfactory surveillance audits.
Issue 8. Certified since 22 October 2014

Certified activities performed by additional sites are listed on subsequent pages.

Authorised by
Jonathan Hall
Global Head - Certification Services

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UKAS MANAGEMENT SYSTEMS
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Crown Name Disposable Hygiene Products Fty. Ltd.

ISO 13485:2016
EN ISO 13485:2016

Issue 8
Sites
Crown Name Disposable Hygiene Products Fty. Ltd. No. 508, Qi'an Road, Zhucheng Avenue, Xinzhou District, Wuhan City, Hubei Province, 431400, P.R. China Design & Development, Manufacture of non-sterile single use non-woven medical devices: Isolation Gown and Scrub Suits. Manufacture of sterile and non-sterile single use non-woven medical devices: Sterile and Non-sterile Surgical Gown, Sterile and Non-sterile Surgical Drape, Sterile and Non-sterile Coverall, Non-sterile Face Mask, Non-sterile Cap, Non-sterile Shoe Covers, Non-sterile Sleeves, Non-sterile Head Cover, Non-sterile Table Cover, Sterile and Non-sterile Surgical Kits (surgical gown, surgical drape, face mask, cap).
Crown Name (WH) United Co., Ltd. Changhang Building Rm.1805 18/F, No. 69, Yanjiang Avenue, Wuhan City, Hubei Province, 430021, P.R. China Sales support of Design & Development, Manufacture of non-sterile single use non-woven medical devices: Isolation Gown and Scrub Suits. Sales support of Manufacture of sterile and non-sterile single use non-woven medical devices: Sterile and Non-sterile Surgical Gown, Sterile and Non-sterile Surgical Drape, Sterile and Non-sterile Coverall, Non-sterile Face Mask, Non-sterile Cap, Non-sterile Shoe Covers, Non-sterile Sleeves, Non-sterile Head Cover, Non-sterile Table Cover, Sterile and Non-sterile Surgical Kits (surgical gown, surgical drape, face mask, cap).

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