

NQA:ISO13485

Certificate of Registration



兹证明

湖北维康防护用品有限公司

统一社会信用代码: 91429004757013938H
 经营地址: 湖北仙桃市叶王路共青创业园
 注册地址: 湖北仙桃市叶王路共青创业园

的质量管理体系适用于

非灭菌: 一次性使用医用口罩的生产和销售(许可资质范围内); 一次性医用无纺布制品(衣服、袖套、鞋套、帽子)的生产和销售(出口欧美)

已经 NQA 根据标准

ISO 13485: 2016

审核和注册

注册要求组织必须按照上述标准保持其质量管理体系, 并由 NQA 进行监督。
 获证组织必须定期接受监督审核并经审核合格, 此证书方继续有效。
 本证书信息可在国家认证认可监督管理委员会官方网站(www.cnca.gov.cn)上查询
 SNQA 查询网站: www.snqa.com.cn

Managing Director
 Managing Director



Certificate Number **42327**

Date: 28 July 2016
 Reissue Date: 06 November 2018
 Valid Until: 06 November 2021
 EAC Code: 04/14



The use of the UKAS Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 015 held by NQA.
 NQA is a trading name of NQA Certification Limited, Registration No: 09351756. Registered Office: Warwick House, Houghton Hall Park, Houghton Regis, Dunstable, LU5 5XZ, UK.
 This certificate is the property of NQA and must be returned on request.

CE

Certificate of Registration



This is to certify that the Quality Management System of

Hubei Weikang Protective products Co., Ltd.

Unified Social Credit Code : 91429004757013938H
 Operation Address : Gongqing Chuangye Industrial Zone, Yewang Road, Xiantao City, Hubei Province, China
 Registered Address : Gongqing Chuangye Industrial Zone, Yewang Road, Xiantao City, Hubei Province, China

applicable to

Non-sterile: Production and sales of disposable medical mask(within the scope of license qualification); production and sales of disposable medical non-woven products (clothes, sleeve covers, shoe covers, hats)(exported to Europe and America)

has been assessed and registered by NQA against the provisions of

ISO 13485: 2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.
 Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.
 The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)
 SNQA's website : www.snqa.com.cn

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Review Report - 审查报告 - 검토 보고서 - Rapport d'Evaluation

CE Documentation Review Report



No. 30170626.HWPUN33

Holder: **HUBEI WEIKANG PROTECTIVE PRODUCTS CO., LTD.**
 Gongqing ChuangYe Garden, Yewang Rd.
 Xiantao Hubei, China

Review goal: Review of the Technical Documentation in regards of the requirements of the Medical Devices Directive 93/42/EEC Annex VII

Product: (see the following annex I)

Classification: Class I (accordingly to the Manufacturer's declaration)

Review output: The output of the Review of the Technical File identified with the no. CE/MDD-HBWK-2017 dated 07.06.2017 is that no Not-Conformity in regards to the requirements of Directive 93/42/EEC Annex VII has been detected

Date of issue 26 June 2017

Expiry date 25 June 2022

Chief Manager
Maria Motta

Deputy Manager
Antonio Spas

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Review Report - 审查报告 - 검토 보고서 - Rapport d'Evaluation

Annex I

No. 30170626.HWPUN33



Name	Type/Model
Face Mask	17.5cm*9.5cm, 14.5cm*9cm, 12.5cm*8.5cm
Isolation Gown	S:110*130cm, M:115*137cm, L:120*140cm, XL:125*145cm, XXL:130*150cm, XXXL:135*160cm or according to customer requirements
Surgical Gown	S:110*130cm, M:115*137cm, L:120*140cm, XL:125*145cm, XXL:130*150cm, XXXL:135*160cm or according to customer requirements
Lab Coat	S:110*130cm, M:115*137cm, L:120*140cm, XL:125*145cm, XXL:130*150cm, XXXL:135*160cm or according to customer requirements
Coveralls	S:110*130cm, M:115*137cm, L:120*140cm, XL:125*145cm, XXL:130*150cm, XXXL:135*160cm or according to customer requirements
Apron	95*56cm, 60*80cm, 70*100cm, 80*120cm or according to customer requirements
Shoe Cover	150*360mm, 150*390mm, 150*410mm or according to customer requirements
Sleeve Cover	20cm*40cm, 20cm*46cm, 22cm*40cm, 22cm*46cm or according to customer requirements
Caps	18", 19", 20", 21", 22", 23", 24" or according to customer requirements
Bed Sheets	80*200cm, 140*200cm or according to customer requirements
Pillow Cases	50*70cm, 60*60cm, 50*60cm or according to customer requirements
Bags	According to customer requirements
Beard Covers	10g, 18" or according to customer requirements

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