

CE Documentation Review



No. 3J200322.JHMUN39

Holder: Jiangxi Hongxin Medical Equipment Group Co., Ltd.

No 8 Jinxian Medical Devices Industrial Zone,
Nanchang Jiangxi, China

Review goal: Verification of the presence of Technical Documentation compatible with the Medical Devices Directive 93/42/EEC Annex VII

Product: Disposable surgical mask (Not Sterile)
Model(s): 190mm*130mm 175mm*155mm
170mm*170mm 155mm*130mm

Classification: Class I (Not Sterile)
(accordingly to the Manufacturer's declaration)

Review output: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European Standard for Medical Devices. The manufacturer is responsible for the CE Marking process, and not exempted to carry out all necessary compliance activities. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Date of issue 22 March 2020

Expiry date 21 March 2025

Approver
ECM Service Director
Luca Redonni

Technical Expert
Amanda Payne



Declaration of Conformity

Manufacturer: JIANGXI HONGXIN MEDICAL EQUIPMENT GROUP CO., LTD

Address: NO. 8, JINXIAN MEDICAL DEVICES ZONE, NANCHANG CITY, JIANGXI PROVINCE, CHINA 331700

Product Description: Disposable Surgical Mask (not Sterile)

Specification: 190mm X 130mm, 175mm X 155mm, 170mm X 170mm, 155mm X 130mm.

We herewith declare that above mentioned product(s) meet the provisions of the EC-CERTIFICATE PRODCUTION QUALITY ASSURANCE SYSTEM which applies to them and stated in Directive 93/42/EEC Annex VII and EN: 14683:2019, on medical devices.

This declaration is based upon:

PRODUCTION QUALITY ASSURANCE SYSTEM

Certificate No.: 3J200322.JHMUN39

(Check website: <http://certificate.entecerma.it/it/VerificaCertificato.aspx#>)

Notified Body: ENTE CERTIFICAZIONE MACCHINE, CE 1282

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Signature/Legal Representative:

Name: Yaozheng Zhou

Title: Director of Operations & Regulatory Affairs

