

EC Declaration of Conformity

Manufacturer:

Name: Hubei Zhongbao Protective Products Co., LTD
Add: Qiwei Village, Shazui District, Xiantao City,
Hubei, China
TEL: 0086/728-3600808 FAX: 0086-728-3271400

whose single Authorized EU-Representative:

Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany
DIMDI: DE/0000047791
Lin Sun
Tel: 0049- 1715605732 E-mail: info.m@luxuslw.de

We, the manufacturer, herewith declare that the products

Disposable Medical Mask

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark



following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Hubei Zhongbao Protective products Co., LTD
Address: Qiwei Village, Shazui District, Xiantao City, Hubei, China

Xiantao City, Hubei, China

May 11, 2020

Place, date



Legally binding signature, Function



CERTIFICATE OF MEDICAL DEVICE QUALITY MANAGEMENT SYSTEM CERTIFICATION

Certificate No. UKZB18MD20033R0S
Unified social credit code: 914290046703774802

This is to Certify that the Medical Device Quality Management System of

HUBEI ZHONGBAO PROTECTIVE PRODUCTS CO., LTD.

仅供查证 不作它用
is in conformity with
YY/T0287-2017/ISO13485:2016 Standard applies to

PRODUCTION AND SALES OF SINGLE-USE NON-STERILE NON-WOVEN PRODUCTS (MASKS, HATS, COVERALLS, GOWNS, SHOE COVERS, SURGICAL DRAPES/SURGICAL PACKS) (EXPORT TO EU ONLY); PRODUCTION AND SALES OF DISPOSABLE MEDICAL MASKS AND DISPOSABLE SURGICAL GOWNS

REGISTERED ADDRESS: QIWEI VILLAGE, SHAZUI OFFICE, XIANTAO CITY, HUBEI PROVINCE, P.R.C.

OPERATION ADDRESS: QIWEI VILLAGE, SHAZUI OFFICE, XIANTAO CITY, HUBEI PROVINCE, P.R.C.

Date of Initial Issuance: Oct. 23, 2018

Date of Expiration: Oct. 22, 2021

BCC Inc.

President:

尚志强



BCC Address: Room 1101, Floor 11, Building 1, Guoyingyuan, Xicheng District, Beijing, P.R.C.
This certificate is valid within state - specified validities of administrative and qualification licensing.
The effectiveness of this certificate shall be maintained by regular surveillance audit.
The validity of the certificate can be inquired through www.bcc.com.cn or by QR code.
The information of this certificate available for inquiry on CNCA's website: www.cnca.gov.cn.
Accreditation by UKAS is granted to BCC for providing audits and certifications of ISO9001/ISO13485

The transition work based on ISO13485:2016 should be completed by Feb.28, 2019.



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