



常州市双马医疗器材有限公司  
CHANGZHOU SHUANGMA MEDICAL DEVICES CO.,LTD

Document number: CE-FM-05

## Declaration of Conformity

MANUFACTURER: **CHANGZHOU SHUANGMA MEDICAL DEVICES CO., LTD**  
San He Kou Development Zone, Zhenglu, Tianning  
Changzhou, Jiangsu, China 213115

MEDICAL DEVICE: Medical Face mask

CLASSIFICATION: CLASS 1 (NON-sterile), RULE 1

CONFORMITY ASSESSMENT ROUTE: ANNEX VII

TRADEMARK: **SHUANGMA**

PRODUCT Medical facemask

TYPE Type II, Type IIR

We herewith declare in our sole responsibility that above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. The declaration of conformity is issued under our sole responsibility.

### DIRECTIVES

General applicable directives: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning Medical devices, amended by Council directive 2007/47/EEC

Applicable Standard EN 14683:2019+AC:2019

EC	REP
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EUROPEAN REPRESENTATIVE:

CMC Medical Devices& Drugs S.L  
C/ Horacio Lengo n18 C.P 29006 Málaga, Spain

PLACE, DATE OF DECLARATION:

SIGNATURE:

冯国林

2020.12.4

