



**Manufacturer** Jiande Chaomei Daily Chemicals Co., Lt

**Address:** Shangshan Village, Yangcunqiao Town, Jiande City, Zhejiang Province, China

**EU Authorised representative:** Batist Medical a.s., Nerudova 309, 549 41 Cervený Kostelec, Czech Republic

**Products:** Medical Protective Masks

**Models:**

See attachment

**Product classification:**

The product is classified according to the rule of Annex IX of the Council Directive 93/42/EEC concerning medical devices as **Class I, non-sterile**, non-active, non-invasive devices for short term duration of use.

**We declare on our responsibility that the CE marked products meet the provisions of the EC Council Directives concerning medical devices 93/42/EEC when used in accordance with their intended uses.**

**Conformity assessment procedure:**

Annex VII of Directive 93/42/EEC.

**Applied Standards:**

ISO 13485:2016 – Medical devices – QMS – Requirements for regulatory purposes

EN 14971:2012 – Application of risk management to medical devices

EN 14683:2019 + AC:2019 Medical face masks - Requirements and test methods

The issued Declaration of Conformity is related to the corresponding Technical file for the given products, and to the first and to any subsequent batches of the given product.

In Shangshan Village Yangcunqiao Town Jiande City

Aston "Guoqiang" Zhu 朱国强

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Quality Manager