



Declaration of Conformity

Manufacturer: Yancheng Acme Medical Technology Co.,Ltd.
Building 3, Group 7, Wuxu Village, Yanlong Street, Yandu
District, Yancheng City, P.R.China

whose single Luxus Lebenswelt GmbH
Authorized EU- Kochstr.1, 47877, Willich, Germany
Representative: DIMID: DE/0000047791
Lin Sun
Tel: 0049- 1715605732
E-mail: info.m@luxuslw.de

Product Name: Disposable Mask (ACME001-2020)

Classification: I of ANNEX IX of Directive 93/42/EEC

Conformity Assessment Route: Annex VII

We, the manufacturer, herewith declare that the above mentioned product 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.

General Applicable Directives:

Medical Devices DIRECTIVE

Harmonized Standards:

EN ISO 13485:2016

EN ISO 10993

EN 980-2003

EN 14683

EN ISO 14971-2007

Signature:

Date:

10-May-2020

Title:

CEO

Position:

Yancheng

EC Declaration of Conformity

Manufacturer:

**Yancheng Acme Medical Technology
Co.,Ltd.**
**Building 3, Group 7, Wuxu Village,
Yanlong Street, Yandu District, Yancheng
City,P.R.China**
Chen Genhai
Tel: 0086-0515-88806088
E-mail: ftlight@163.com

whose single Authorized EU-Representative:

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Disposable Mask(ACME001-2020)

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

Yancheng Acme Medical Technology Co.,Ltd.

**Building 3, Group 7, Wuxu Village, Yanlong Street, Yandu District, Yancheng
City,P.R.China**

Yancheng 10-May-2020

Place, date

EC Declaration of Conformity

CEO

Legally binding signature, Yancheng

