

# Declaration of Conformity

## FULL QUALITY ASSURANCE PROCEDURES

Manufacturer name : Suzhou Yuyue Medical Technology Co., Ltd.

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[http:// www.yuyue.com.cn](http://www.yuyue.com.cn)

EC-Representative name : Metrax GmbH

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Product Name: Sleep apnea breathing therapy mask

Product Category: Full Face Mask / Nasal Mask / Nasal Pillows Mask

Classification: II a

Models: YF-01、YF-02、YF-03 / YN-01、YN-02、YN-03、YN-05 、YP-01

Sizes: L/M/S

UMDNS Coad : 12447

UMDN Name : Masks

Conformity assessment route: Annex V

We herewith declare that:

The above mentioned CE marked products meet the provisions of the following EC Council Directives. All technical documentations are retained under the promise of the manufacturer.

### Directives

COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES (MDD 93/42/EEC), AMENDED BY 2007/47/EC OF 5 SEPTEMBER 2007.

We are exclusively responsible for this declaration of conformity.

Notified Body Name : TÜV SÜD Product Service GmbH ( identification no.0123 )

Address : Ridlerstrasse 65, 80339 Munich, Germany

CE Certificate No.: G2 092486 0010 Rev.00

CE mark starting batch or date: 2020-01-09

Name: Zhao Ning

General Manager:

Date : 09/01/2019