

Declaration of Conformity

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

Manufacturer address : No.9 Jinfeng Road, Suzhou Science & Technology Town,
215163 Suzhou, Jiangsu, PEOPLE' S RERUBLIC OF CHINA

Tel : +86-512-67373001 **Fax :** +86-512-67373008

http:// www.yuyue.com.cn

EC-Representative name : Metrax GmbH

Address: Rheinwaldstr.22, D- 78628 Rottweil, Badenwuerttemberg, Germany

Tel : +49-741-257-223 **Fax :** +49-741-257-214

E-mail : heiko.borkowsky@primedic.com

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

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

General Manager:



Date : 29.1.19.