符合性声明
Declaration of Conformity

制造商名称：苏州鱼跃医疗科技有限公司
Manufacturer name: Suzhou Yuyue Medical Technology Co., Ltd.
生产商地址：中华人民共和国江苏省苏州市科技城锦峰路 9 号 邮编：215163；
Manufacturer address: No.9 Jinfeng Road., Suzhou Science & Technology Town, 215163 Suzhou, Jiangsu, PRC

欧盟授权代表名称：上海国际（欧洲）集团公司
EC-Representative name: Shanghai International Holding Corp. GmbH (Europe)
地址：德国汉堡艾路 80 号
Address: Eiffestra β e 80, 20537 Hamburg, Germany
电话 Tel: 0049-40-2513175 **传真 Fax:** 0049-40-255726

产品名称：正压呼吸机
Product name: Positive Airway Pressure Units
分类: 规则 9, II a
Classification: Rule 9, II a
型号 Models: YH-360、YH-560、YH-580、YH-450、YH-480、
YH-720、YH-725、YH-730、YH-820、YH-825、YH-830
符合性路径：MDD 附录 V
Conformity assessment route: MDD Annex V
我们在此申明 We declare that:
在此申明上述带有 CE 标志的产品符合下列欧盟指令，所有 CE 技术文件由生产商承诺其真实性。我们对符合性声明负责。
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. We are exclusively responsible for the Declaration of Conformity.

指令 Directives

医疗器械指令 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.

公告机构名称 Notified Body Name: TUV SUD Product Service GmbH
地址 Address: Ridlerstraβe, 6580339, Munchen, Germany
公告机构代码 Identification Code no: 0123
CE 证书编号 CE Certificate No. G20924860008 Rev.01
CE 开始标贴的日期 CE mark starting batch or date: 2017-06-27
有效期 Period of validity:该符合性声明的有效期是受产品发生更改后和/或者相关的由公告机构发行的证书（附录 V）失效前修订的符合性声明发行限制的。The validity period of this declaration of conformity is limited by the issuing of a revised declaration of conformity after change of the product and/or by the expiration date of the related Annex V certificate issued by the notified body.

总经理 General Manager:

日期 Date: 2019.11.27
地址 Place: *Suzhou, CHINA*

The products meet the following standards

No.	Reference	Title
1	IEC60601-1:2005+AMD1:2012	Medical electrical equipment – Part 1. General requirement for basic safety and essential performance
2	IEC 60601-1-2:2014	Medical electrical equipment – Part 1-2. General requirement for basic safety and essential performance - Collateral standard: Electromagnetic disturbances – Requirements and tests
3	IEC 60601-1-11:2015	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
4	ISO 80601-2-70:2015	Medical electrical equipment – Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment
5	ISO 8185:2007	Respiratory tract humidifiers for medical use — Particular requirements for respiratory humidification systems
6	ISO 18562-1:2017	Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 1: Evaluation and Testing Within a Risk Management Process
7	ISO 18562-2:2017	Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 2: Tests for Emissions of Particulate Matter
8	ISO 18562-3:2017	Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 3: Tests for Emissions of Volatile Organic Compounds
9	MDD 93/42/EEC	Medical Device Directives of EU
10	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for Regulatory Purposes
11	EN ISO 14971:2012	EN ISO 14971:2012 Medical devices - Application of risk management to medical devices