

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: Eiffestrasse 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-350, YH-550

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: Ridlerstraße 65.80339, Munich, Germany

代码 Code: 0123

CE 证书编号 CE Certificate No.: No. G2 092486 0008 Rev. 01

CE 开始标贴的日期 CE mark starting batch or date: 2020-07

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 II certificate issued by the notified body.

总经理 General Manager:

日期 Date: 2021-04-12

