



## **YUYAO YUFENG MEDICAL EQUIPMENT CO., LTD**

No. 168 Sihai Avenue, Simen Town, Yuyao, Zhejiang, China

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### **URGENT FIELD SAFETY NOTICE**

#### **NOTIFICATION OF UPDATE TO OXYGEN REGULATOR INSTRUCTION MANUAL**

**Date Issued** December 12, 2018

**Product** Oxygen Regulator

**Model No.:** YF-86-A

#### **Reason for Field Safety Notice**

Yuyao Yufeng Medical Equipment Co., Ltd is issuing a Field Safety Notice to advise users of an update to the Instructions For Use (IFU) for Oxygen Regulator YF-86-A per the enclosed attachment (Attachment 1). This information will be included in the IFU & Cartons of all future units distributed by Yufeng Medical.

This IFU update provides clear information about cleaning & disinfection method for oxygen regulator YF-86-A.

#### **Explanation**

This product belongs to non-sterile medical devices, belongs to conventional medical devices. Its usage & intended use is the same as the same kind of product in the market. Our regulators have already been cleaned during the production. It is better for customers to re-disinfect before use .

#### **Required actions for you and your Healthcare Facility relating to this FSN**

1. Pass this Field Safety Notice to all personnel involved with the use of Oxygen Regulator YF-86-A.
2. Ensure that the contents of this Field Safety Notice is understood by the associated personnel.
3. If you have further distributed this product then please identify the organisation and notify them at once of this notification.

We appreciate your cooperation and assistance in dealing with this matter and sincerely apologies for any inconvenience that may result from this action.

Should you have any questions or require assistance in this matter, please contact your local sales specialist .



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1. Attachment 1: Text to be added to Oxygen Regulator IFU

### RECOMMENDED CLEANING & DISINFECTION METHOD

Clean using a pH neutral disinfectant for wiping clean. Wipe with a damp cloth and dry with paper towel to remove residue. Do not wipe the contact areas of the inlet and outlet connectors.

Use high temperature disinfection for the humidifier bottles, and the degree is 121 °C. The cap can't be autoclavable.

余姚市宇峰医疗器械有限公司  
YUYAO YUFENG MEDICAL EQUIPMENT CO., LTD.

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