


Safety Communication

Urgent FSN's of Oxygen Regulator Manufactured by Yuyao Yufeng Co., Ltd.

Device/ Product Name:	Oxygen Regulator
Lot numbers/Serials:	Model No.: YF-86-A
Manufacturer:	Yuyao Yufeng Medical Equipment Co., Ltd.
Problem:	<p>SFDA want to clarify to healthcare providers and consumers in Saudi Arabia of an update from Yuyao Yufeng Medical Equipment Co about the Instructions For Use (IFU) for Oxygen Regulator YF-86-A.</p> <p>The information about cleaning & disinfection method for Oxygen regulator YF-86-A will be included in the IFU & Cartons of all future units distributed by Yufeng Medical.</p> <p>SFDA becomes aware that some customers/ users bought the mentioned tables directly from showrooms and the Authorized Representative unable to complete the corrective action.</p> <p>This Safety Communication is being issued to ensure that all hospitals are aware of the issue and that adequate action is taken to mitigate potential risk to the patients.</p>
Recommendation/Actions:	<p style="text-align: center;">RECOMMENDED CLEANING & DISINFECTION METHOD</p> <ul style="list-style-type: none"> • 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, the degree is 121 °C.

	<ul style="list-style-type: none"> • The cap can't be autoclavable. • Report any adverse events or suspected adverse events experienced with the use of Oxygen Regulator and through National Center for Medical Devices Reporting (NCMDR) Or Saudi Vigilance Prompt reporting of adverse events can help the SFDA identify and better understand the risks associated with medical devices. 	
<p>Devices/Products photo:</p>	<div style="text-align: center;">  <p>Oxygen Regulator Model: YF-86-A</p> </div>	
<p>Authorized Representative Details</p>	<p>Company name:</p>	<p>Al-Asemah Medical Company</p>
	<p>Contact Person:</p>	<p>Mohammed Sulaiman Al Ghimlas</p>
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For further information, please **see the FSN below** or [Click Here](#).

Healthcare Professionals should **report** any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.

Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority (3292)
North Ring Road - Al Nafal Unit (1)
Riyadh 13312 - 6288
Tel: +966 (11) 2038222 Ext: 2406, 2412
Fax: +966 (11) 2757245

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Sincerely,
NCMDR Team

