



## DEVICE DETAILS

<b>NAME OF DEVICE</b>	PORTABLE MESH NEBULIZER
<b>ESTABLISHMENT NAME</b>	PFLEGE MEDICAL SUPPLIES SDN. BHD.
<b>ROLE OF ESTABLISHMENT</b>	AUTHORIZED REPRESENTATIVE
<b>REGISTRATION NO</b>	GB5934019-36085
<b>BRAND NAME</b>	PROFIX/ YS31
<b>MEDICAL DEVICE CATEGORY</b>	MD 1102 - Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anaesthesia
<b>DEVICE GROUPING TYPE</b>	SINGLE
<b>DEVICE DESCRIPTION</b>	PROFIX Portable Mesh Nebulizer (YS31) is designed for respiratory diseases treatment and respiratory tract infection prevention. The device is pushed by certain circuit frequency vibration to make piezoelectric ceramic vibrate harmony that caused high speed vibration of metal mesh. And the medicine liquid will be quickly popped through micro mesh hole of metal mesh plate to be countless micro atomizing particles. This will further transfer by inhalation treatment using masks or mouthpieces to patients' respiratory system. The nebulizer shall be used with face mask, and the face mask's connection tube diameter shall be $20.0 \pm 0.1$ mm, therefore the face mask can be connected to the nebulizer tightly. The nebulizer can be used at home hold environment, and it complies with requirement of IEC 60601-1-11.
<b>DEVICE INTENDED PURPOSE</b>	PROFIX Portable Mesh Nebulizer (YS31) is intended for respiratory diseases treatment and respiratory tract. It is widely used in curing diseases of respiratory system, such as cold, fever, bronchitis, asthma, pneumonia, pneumonic mycosis and pulmonary heart disease. It can also be used to cure occupational disease; give throat care to the artists, cure ENT (ear, nose, throat) diseases like chronic allergic rhinitis, acute laryngitis, acute pharyngitis, acute tonsillitis, etc.
<b>VALIDITY DATE OF REGISTRATION</b>	10/12/2024 - 09/12/2029

## LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	PORTABLE MESH NEBULIZER	YS31