



DEVICE DETAILS

NAME OF DEVICE	AF531 ORO-NASAL SE FACE MASK
ESTABLISHMENT NAME	PHILIPS MALAYSIA SENDIRIAN BERHAD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB4966425-209783
BRAND NAME	PHILIPS RESPIRONICS
MEDICAL DEVICE CATEGORY	MD 0100 - GENERAL NON-ACTIVE, NON-IMPLANTABLE MEDICAL DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>The AF531 Oro-Nasal SE Face Mask are devices that have only indirect clinical benefit in that they are used within device systems for the provision of non-invasive ventilation therapy. They do not, by themselves, deliver any therapeutic benefit to patients. The principles of operation and technology for the AF531 Oro-Nasal SE Face Mask have been in use for >35 years to aid treatment of sleep disordered breathing and respiratory insufficiency and failure, and the AF531 Oro-Nasal SE Face Mask detailed in this registration application have been on the market since 2008. The principle of operation and technology have been in the marketplace for >35 years for the purpose of facilitating the provision of continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation or positive airway pressure therapy. The device design, material, principles of operation, technology, and medical indication are not entirely new. Any new components as compared to previous generations of devices were tested for safety and performance. Hence, it is determined that there are no known emerging risks associated with innovation of these devices at this time.</p>
DEVICE INTENDED PURPOSE	<p>Intended Use Medium and Large Size: The AF531 Oro-Nasal SE Face Mask is intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators which have adequate alarms and safety systems for ventilation failure, and which are intended to administer CPAP or positive pressure ventilation for treatment of respiratory failure, respiratory insufficiency or obstructive sleep apnea. The mask is for single use in the hospital/institutional environment only. The mask is to be used on patients (>30 kg) who are appropriate candidates for noninvasive ventilation. Small Size: The AF531 Oro-Nasal SE Face Mask is intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators which have adequate alarms and safety systems for ventilation failure, and which are intended to administer CPAP or positive pressure ventilation for treatment of respiratory failure, respiratory insufficiency or obstructive sleep apnea. The mask is for single use in the hospital/institutional environment only. The mask is to be used on patients 7 years or older (>20 kg) who are appropriate candidates for noninvasive ventilation.</p>
VALIDITY DATE OF REGISTRATION	27/08/2025 - 26/08/2030

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	AF531 Oro-Nasal, Single-Use, with SE standard elbow, four-point headgear, small	1072624
2	AF531 Oro-Nasal, Single-Use, with SE standard elbow, four-point headgear, medium	1072625
3	AF531 Oro-Nasal, Single-Use, with SE standard elbow, four-point headgear, large	1072626
4	AF531 Oro-Nasal, Single-Use, with SE standard elbow, CapStrap headgear, small	1072630
5	AF531 Oro-Nasal, Single-Use, with SE standard elbow, CapStrap headgear, medium	1072631
6	AF531 Oro-Nasal, Single-Use, with SE standard elbow, CapStrap headgear, large	1072632
7	SE standard elbow with NIVO port	1120969
8	Bronchoscopy elbow	1120984

