



DEVICE DETAILS

NAME OF DEVICE	VERASEAL 2 FULL FACE MASK
ESTABLISHMENT NAME	KL MED SUPPLIES (M) SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB10852224-181231
BRAND NAME	SLEEPNET
MEDICAL DEVICE CATEGORY	MD 0100 - GENERAL NON-ACTIVE, NON-IMPLANTABLE MEDICAL DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>The Veraseal 2 full face mask is an externally placed device covering the nose and mouth of a patient with an aesthetically pleasing visual design and geometry. It provides a seal to allow positive gas pressure from a bi-level, CPAP or other positive airway pressure device to be directed to the patient's airway. It is held in place with headgear that is both adjustable and quickly detachable. The mask comprises a hard plastic shell with a proprietary polyurethane encased silicone gel cushion to provide a comfortable seal that easily conforms to the patient's facial features. Two mask shells have been designed for the mask, one with vents and one without. The mask is available in four sizes.</p>
DEVICE INTENDED PURPOSE	<p>Vented Mask, The Veraseal 2 Full Face Vented Mask is a disposable mask intended to be used with positive airway pressure devices, such as CPAP or bi-level, operating at or above 3 cm H₂O. The mask is to be used on adult patients (>30kg) for whom positive airway pressure therapy has been prescribed. The mask is intended for SHORT TERM SINGLE PATIENT USE (maximum of 7 days). Non-Vented AAV Mask, The Veraseal 2 Full Face Non-Vented AAV Mask is a disposable device intended to provide a patient interface for application of noninvasive ventilation. The mask is to be used as an accessory to ventilators that have adequate alarms and safety systems for ventilator failure, and which are intended to administer positive pressure ventilation. The mask is intended for SHORT TERM SINGLE PATIENT USE (maximum of 7 days) on adult patients (>30 kg) who are appropriate candidates for noninvasive ventilation in the hospital or institutional environment. Non-Vented Mask, The Veraseal 2 Full Face Non-Vented Mask is a disposable device intended to provide a patient interface for the application of noninvasive ventilation. The mask is to be used as an accessory to ventilators that have adequate alarms and safety systems for ventilator failure, and which are intended to administer positive pressure ventilation. The mask is intended for SHORT TERM SINGLE PATIENT USE (maximum of 7 days) on adult patients (>30 kg) who are appropriate candidates for noninvasive ventilation in the hospital or institutional environment.</p>
VALIDITY DATE OF REGISTRATION	26/08/2024 - 25/08/2029

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	VERASEAL 2 FULL FACE VENTED MASK	50827
2	VERASEAL 2 FULL FACE VENTED MASK	50828
3	VERASEAL 2 FULL FACE VENTED MASK	50829
4	VERASEAL 2 FULL FACE VENTED MASK	50830
5	VERASEAL 2 FULL FACE NON VENTED MASK	50933
6	VERASEAL 2 FULL FACE NON VENTED MASK	50934
7	VERASEAL 2 FULL FACE NON VENTED MASK	50935
8	VERASEAL 2 FULL FACE NON VENTED MASK	50936
9	VERASEAL 2 FULL FACE AAV NON VENTED MASK	50937
10	VERASEAL 2 FULL FACE AAV NON VENTED MASK	50938
11	VERASEAL 2 FULL FACE AAV NON VENTED MASK	50939
12	VERASEAL 2 FULL FACE AAV NON VENTED MASK	50940

MEDICAL DEVICE AUTHORITY