



DEVICE DETAILS

NAME OF DEVICE	VERASEAL 3 FULL FACE MASK
ESTABLISHMENT NAME	KL MED SUPPLIES (M) SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB10325224-182053
BRAND NAME	SLEEPNET
MEDICAL DEVICE CATEGORY	MD 0100 - GENERAL NON-ACTIVE, NON-IMPLANTABLE MEDICAL DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The Veraseal 3 full face vented, non-vented AAV, and non-vented masks are externally placed devices covering the nose and mouth of a patient with an aesthetically pleasing visual design and geometry. The mask 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.
DEVICE INTENDED PURPOSE	Vented Mask, The Veraseal 3 Full Face Vented Mask is 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) in the hospital or institutional environment. Non-Vented AAV Mask, The Veraseal 3 Full Face Non-Vented AAV Mask is intended to provide an 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) in the hospital or institutional environment on adult patients (>30 kg) who are appropriate candidates for noninvasive ventilation. Non-Vented Mask, The Veraseal 3 Full Face Non-Vented Mask is intended to provide an 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) in the hospital or institutional environment on adult patients (>30 kg) who are appropriate candidates for noninvasive ventilation.
VALIDITY DATE OF REGISTRATION	02/09/2024 - 01/09/2029

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	VERASEAL 3 FULL FACE VENTED MASK	50843
2	VERASEAL 3 FULL FACE VENTED MASK	50844
3	VERASEAL 3 FULL FACE VENTED MASK	50845

NO	NAME OF DEVICE	IDENTIFIER
4	VERASEAL 3 FULL FACE VENTED MASK	50846
5	VERASEAL 3 FULL FACE NON VENTED MASK	50949
6	VERASEAL 3 FULL FACE NON VENTED MASK	50950
7	VERASEAL 3 FULL FACE NON VENTED MASK	50951
8	VERASEAL 3 FULL FACE NON VENTED MASK	50952
9	VERASEAL 3 FULL FACE AAV NON VENTED MASK	50953
10	VERASEAL 3 FULL FACE AAV NON VENTED MASK	50954
11	VERASEAL 3 FULL FACE AAV NON VENTED MASK	50955
12	VERASEAL 3 FULL FACE AAV NON VENTED MASK	50956

