



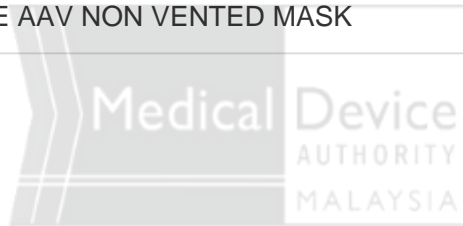
## DEVICE DETAILS

|                                      |   |
|--------------------------------------|---|
| <b>NAME OF DEVICE</b>                | VERASEAL 3 FULL FACE MASK   |
| <b>ESTABLISHMENT NAME</b>            | KL MED SUPPLIES (M) SDN BHD   |
| <b>ROLE OF ESTABLISHMENT</b>         | AUTHORIZED REPRESENTATIVE   |
| <b>REGISTRATION NO</b>               | GB10325224-182053   |
| <b>BRAND NAME</b>                    | SLEEPNET  |
| <b>MEDICAL DEVICE CATEGORY</b>       | MD 0100 - GENERAL NON-ACTIVE, NON-IMPLANTABLE MEDICAL DEVICES   |
| <b>DEVICE GROUPING TYPE</b>          | FAMILY  |
| <b>DEVICE DESCRIPTION</b>            | 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.  |
| <b>DEVICE INTENDED PURPOSE</b>       | 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 H <sub>2</sub> O. 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. |
| <b>VALIDITY DATE OF REGISTRATION</b> | 02/09/2024 - 01/09/2029   |

## LIST OF DEVICE

| NO | NAME OF DEVICE                   | IDENTIFIER |
|----|----------------------------------|------------|
| 1  | VERASEAL 3 FULL FACE VENTED MASK | 50843      |

| NO | NAME OF DEVICE                           | IDENTIFIER |
|----|--|------------|
| 2  | VERASEAL 3 FULL FACE VENTED MASK         | 50844      |
| 3  | VERASEAL 3 FULL FACE VENTED MASK         | 50845      |
| 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      |



**MEDICAL DEVICE AUTHORITY**