



## DEVICE DETAILS

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|-------------------------------|---|
| NAME OF DEVICE                | FACE MASKS FOR VENTILATORS AND ANESTHESIA SYSTEMS   |
| ESTABLISHMENT NAME            | AMBU SALES & SERVICES SDN. BHD.   |
| ROLE OF ESTABLISHMENT         | AUTHORIZED REPRESENTATIVE   |
| REGISTRATION NO               | GB51605240617   |
| BRAND NAME                    | AMBU® DISPOSABLE FACE MASKS   |
| MEDICAL DEVICE CATEGORY       | MD 0101 - Non-active devices for anaesthesia, emergency and intensive care  |
| DEVICE GROUPING TYPE          | FAMILY  |
| DEVICE DESCRIPTION            | <p>Ambu® Disposable Face Mask consist of a transparent dome for visual check of bleeding, vomit, and patient breathing condition. To perform safe mask ventilation, Ambu® Disposable Face Mask has a cuff that is designed to ensure a tight seal without compressing any facial nerves. The dome of the facemask has an ergonomic design to ensure a good and easy hand grip. Ambu® Disposable Face Mask can be used in a situation of high-pressure ventilation and are available in different sizes. Facemask ventilation can be performed using either a single hand or a two hand ventilation technique allowing for oxygenation and ventilation of patients until a more definitive airway can be established and in cases where endotracheal intubation or other definitive control of the airway is not possible. In an unconscious patient an oropharyngeal airway can be inserted in order to prevent the tongue from covering the epiglottis. An oropharyngeal airway can be used together with Ambu® Disposable Face Mask and a resuscitator.</p> |
| DEVICE INTENDED PURPOSE       | The Disposable Facemasks are disposable facemasks intended for oxygenating and ventilating the airway. The Disposable Facemasks are for use in hospital and pre-hospital (EMS) environments. For use by CPR trained personnel only.   |
| VALIDITY DATE OF REGISTRATION | 13/06/2022 - 12/06/2027   |

## LIST OF DEVICE

| NO | NAME OF DEVICE              | IDENTIFIER  |
|----|-----------------------------|-------------|
| 1  | Ambu® Disposable Face Masks | 000 252 051 |
| 2  | Ambu® Disposable Face Masks | 000 252 052 |
| 3  | Ambu® Disposable Face Masks | 000 252 053 |
| 4  | Ambu® Disposable Face Masks | 000 252 054 |
| 5  | Ambu® Disposable Face Masks | 000 252 055 |
| 6  | Ambu® Disposable Face Masks | 000 252 056 |

| NO | NAME OF DEVICE              | IDENTIFIER  |
|----|-----------------------------|-------------|
| 7  | Ambu® Disposable Face Masks | 000 252 951 |
| 8  | Ambu® Disposable Face Masks | 000 252 952 |
| 9  | Ambu® Disposable Face Masks | 000 252 953 |
| 10 | Ambu® Disposable Face Masks | 000 252 954 |
| 11 | Ambu® Disposable Face Masks | 000 252 955 |
| 12 | Ambu® Disposable Face Masks | 000 252 956 |

