



DEVICE DETAILS

NAME OF DEVICE	FACE MARKS FOR VENTILATORS AND ANESTHESIA SYSTEMS
ESTABLISHMENT NAME	AMBU SALES & SERVICES SDN. BHD.
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB2753721-73676
BRAND NAME	AMBU® SILICONE FACE MASK
MEDICAL DEVICE CATEGORY	MD 0101 - Non-active devices for anaesthesia, emergency and intensive care
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	Ambu® Silicone Face Mask consist of a transparent dome for visual check of bleeding, vomit, and patient breathing condition. To perform safe mask ventilation, Ambu® Silicone Face Mask have a cuff that is designed to ensure a tight seal without compressing any facial nerves. The dome of the Ambu® Silicone Face Mask has an ergonomic design to ensure a good and easy hand grip. The Ambu® Silicone 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® Silicone Face Mask and a resuscitator.
DEVICE INTENDED PURPOSE	Ambu® Silicone Face Masks are reusable facemasks intended for oxygenating and ventilating the airway or to direct anaesthetic gases to the upper airway. The Open Cuff Silicone Facemask are for use in hospital and pre-hospital (EMS) environments.
VALIDITY DATE OF REGISTRATION	23/09/2021 - 22/09/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Ambu® Silicone Face Mask	000 316 000
2	Ambu® Silicone Face Mask	000 312 000
3	Ambu® Silicone Face Mask	000 317 000
4	Ambu® Silicone Face Mask	000 319 000
5	Ambu® Silicone Face Mask	000 315 000
6	Ambu® Silicone Face Mask	000 313 000