




DEVICE DETAILS

NAME OF DEVICE	FACE MASKS FOR VENTILATORS AND ANESTHESIA SYSTEMS
ESTABLISHMENT NAME	AMBU SALES & SERVICES SDN. BHD.
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB2586021-74852
BRAND NAME	AMBU® KING MASK
MEDICAL DEVICE CATEGORY	MD 0101 - Non-active devices for anaesthesia, emergency and intensive care
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>Ambu® King Mask consist of a transparent dome for visual check of bleeding, vomit, and patient breathing condition. To perform safe mask ventilation, Ambu® King Mask have a cuff that is designed to ensure a tight seal without compressing any facial nerves. The dome of the Ambu® King Mask has an ergonomic design to ensure a good and easy hand grip. The Ambu® King Masks 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® King Mask and a resuscitator.</p>
DEVICE INTENDED PURPOSE	<p>Ambu® King Mask are intended to direct anaesthesia or other medical gases into the patient's upper airway without introducing any apparatus into the trachea. The King Masks are in connection with a breathing circuit apparatus (anaesthetic circuit, manual resuscitators, automatic resuscitators and ventilators), covering the patient's mouth and nose during anaesthesia, or medical gas inhalation. The King Masks are single patient use disposables. For use by CPR trained personnel only.</p>
VALIDITY DATE OF REGISTRATION	23/09/2021 - 22/09/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Ambu® King Mask	1012UB
2	Ambu® King Mask	1022UB
3	Ambu® King Mask	1032UH
4	Ambu® King Mask	1045UH
5	Ambu® King Mask	1055UH

NO	NAME OF DEVICE	IDENTIFIER
6	Ambu® King Mask	1065UH
7	Ambu® King Mask	1075UH
8	Ambu® King Mask	2012SB
9	Ambu® King Mask	2022SB
10	Ambu® King Mask	2032SH
11	Ambu® King Mask	2045SH
12	Ambu® King Mask	2055SH
13	Ambu® King Mask	2065SH
14	Ambu® King Mask	2075SH
15	Ambu® King Mask	1122SB
16	Ambu® King Mask	1132SH
17	Ambu® King Mask	1145SH
18	Ambu® King Mask 	1222SB
19	Ambu® King Mask	1232SH
20	Ambu® King Mask	1245SH
21	Ambu® King Mask	1322SB
22	Ambu® King Mask	1332SH
23	Ambu® King Mask	1345SH
24	Ambu® King Mask	1423SB
25	Ambu® King Mask	1433SH
26	Ambu® King Mask	1443SH