



DEVICE DETAILS

NAME OF DEVICE	ANAESTHESIA FACE MASKS PACKS
ESTABLISHMENT NAME	T T MEDICAL MANAGEMENT SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB655471188318
BRAND NAME	FLEXICARE
MEDICAL DEVICE CATEGORY	MD 0100 - GENERAL NON-ACTIVE, NON-IMPLANTABLE MEDICAL DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>PRE-FILLED INFLATABLE ANAESTHETIC FACE MASK THE PRE-FILLED DISPOSABLE ANAESTHESIA FACE MASK IS AVAILABLE IN 6 SIZES FROM NEONATAL TO LARGE ADULT, WITH INDIVIDUALLY COLOUR CODED HOOKS FOR EASE OF IDENTIFICATION. COMPATIBLE WITH ALL STANDARD CATHETER MOUNTS AND BREATHING SYSTEMS WITH 22 MM & 15MM CONNECTORS. SCENTED INFLATABLE DISPOSABLE FACE MASK SOME PATIENTS RECEIVING ANAESTHESIA, PARTICULARLY CHILDREN, CAN FIND THE EXPERIENCE UNPLEASANT. THE FLEXICARE RANGE OF SCENTED ANAESTHESIA FACE MASKS ARE TO HELP OVERCOME THIS PROBLEM AND ARE AVAILABLE IN LEMON, STRAWBERRY AND VANILLA. SILICONE REUSABLE ANAESTHETIC FACE MASK THE REUSABLE SILICONE ANAESTHESIA FACE MASKS ARE FULLY AUTOCLAVABLE UP TO 50 TIMES. THE MOULDED TEXTURE OF THE RIM ENSURES MAXIMUM PATIENT COMFORT AND A TIGHT SEAL, WHILE THE TRANSPARENT FACE PIECES ALLOWS PATIENT MONITORING, AT ALL TIMES. 22MM AND 15 MM CONNECTORS ENSURE COMPATIBILITY WITH ALL STANDARD CATHETER MOUNTS AND BREATHING SYSTEMS. THE DEVICES ARE SUPPLIED NON-STERILE AND SINGLE-USE EXCLUDING SILICONE REUSABLE FACE MASK WHICH IS SUPPLIED NON-STERILE AND IS REUSABLE.</p>
DEVICE INTENDED PURPOSE	<p>FLEXICARE'S ANAESTHESIA FACE MASK ARE GENERALLY USED FOR PRE-OXYGENATING THE PATIENT IN THE OPERATING THEATRE BEFORE THEY INTUBATE AND PUT THE PATIENT UNDER ANAESTHESIA. THE FACE MASK CAN ALSO BE USED FOR DELIVERING ANAESTHETIC GASSES IF THE PATIENT REFUSES INTRAVENOUS NEEDLES, ESPECIALLY WITH CHILDREN. THE FACEMASK CAN ALSO BE USED FOR BAG-MASK VENTILATION (BMV) IN A RESUSCITATION SETTING. FINALLY, IT CAN ALSO BE USED FOR NON-INVASIVE VENTILATION (NIV) IN PATIENTS WITH RESPIRATORY COMPROMISE. EACH ANAESTHESIA FACE MASK VARIANT CONSISTS OF A CONTOURED SHELL THAT SITUATES ON PATIENT FACE AND CAN BE SUPPLIED WITH OXYGEN TUBES, BREATHING SYSTEM AND CATHETER MOUNT IF REQUIRED. FLEXICARE SUPPLIES A RANGE OF ANAESTHESIA FACE MASK WITH DETACHABLE HOOK RING, WHICH ALLOW THE MASK TO BE HELD IN PLACE WITH A HEAD STRAP FOR DELIVERING NIV. FLEXICARE'S FACE MASKS ARE INTENDED TO BE USED FOR ANAESTHETIC GAS OR OXYGEN SUPPLY TO THE PATIENT BY TRAINED PERSONNEL, IN HOME, HEALTHCARE AND EMERGENCY ENVIRONMENTS.</p>
VALIDITY DATE OF REGISTRATION	02/11/2023 - 01/11/2028

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Extra Large Adult Size 6	038-51-390
2	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Large Adult Size 5	038-51-400
3	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Large Adult Size 5+Elbow+HMEF with Luer Port	038-51-400/A
4	Anaesthesia Face Mask Inflatable Single Use Lemon Scented Large Adult Size 5	038-51-400SFL
5	Anaesthesia Face Mask Inflatable Single Use Vanilla Scented Large Adult Size 5	038-51-400SFP
6	Anaesthesia Face Mask Silicone Reusable Large Adult Size 5	038-51-400SIL
7	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Adult Size 4	038-51-410
8	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Adult Size 4 + HMEF with Luer Port + Elbow	038-51-410/A
9	Anaesthesia Face Mask Inflatable Single Use Lemon Scented Adult Size 4	038-51-410SFL
10	Anaesthesia Face Mask Inflatable Single Use Vanilla Scented Adult Size 4	038-51-410SFP
11	Anaesthesia Face Mask Silicone Reusable Adult Size 4	038-51-410SIL
12	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Large Child Size 3	038-52-415
13	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Large Child Size 3 + Mini HMEF + Elbow	038-52-415/A
14	Anaesthesia Face Mask Inflatable Single Use Lemon Scented Large Child Size 3	038-52-415SFL
15	Anaesthesia Face Mask Inflatable Single Use Vanilla Scented Large Child Size 3	038-52-415SFP
16	Anaesthesia Face Mask Inflatable Single Use Strawberry Scented Large Child Size 3	038-52-415SFS
17	Anaesthesia Face Mask Silicone Reusable Large Child Size 3	038-52-415SIL
18	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Medium Child Size 2	038-52-420
19	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Medium Child Size 2 + Mini HMEF + Elbow	038-52-420/A
20	Anaesthesia Face Mask Inflatable Single Use Lemon Scented Medium Child Size 2	038-52-420SFL
21	Anaesthesia Face Mask Inflatable Single Use Vanilla Scented Medium Child Size 2	038-52-420SFP

NO	NAME OF DEVICE	IDENTIFIER
22	Anaesthesia Face Mask Inflatable Single Use Strawberry Scented Medium Child Size 2	038-52-420SFS
23	Anaesthesia Face Mask Silicone Reusable Medium Child Size 2	038-52-420SIL
24	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Small Child Size 1	038-52-430
25	Anaesthesia Face Mask Inflatable Single Use Lemon Scented Small Child Size 1	038-52-430SFL
26	Anaesthesia Face Mask Inflatable Single Use Vanilla Scented Small Child Size 1	038-52-430SFP
27	Anaesthesia Face Mask Inflatable Single Use Strawberry Scented Small Child Size 1	038-52-430SFS
28	Anaesthesia Face Mask Silicone Reusable Small Child Size 1	038-52-430SIL
29	Anaesthesia Face Mask Pre-Filled Inflatable Single Use Neonatal Size 0	038-53-440
30	Anaesthesia Face Mask Inflatable Single Use Lemon Scented Neonatal Size 0	038-53-440SFL
31	Anaesthesia Face Mask Inflatable Single Use Vanilla Scented Neonatal Size 0	038-53-440SFP
32	Anaesthesia Face Mask Inflatable Single Use Strawberry Scented Neonatal Size 0	038-53-440SFS
33	Anaesthesia Face Mask Silicone Reusable Neonatal Size 0	038-53-440SIL
34	Anaesthesia Face Mask Small Child Size 1 with Detachable Elbow + Mini HMEF + Catheter Mount	038-61-351
35	Anaesthesia Face Mask Pack with Detachable Elbow + Mini HMEF + Catheter Mount Medium Child Size 2	038-61-352
36	Anaesthesia Face Mask Pack with Detachable Elbow + Mini HMEF + Catheter Mount Size Large Child 3	038-61-353
37	Anaesthesia Face Mask Pack with Detachable Elbow + HMEF + Catheter Mount Adult Size 4	038-61-354
38	Anaesthesia Face Mask Pack with Detachable Elbow + HMEF + Catheter Mount Size Large Adult 5	038-61-355