





DEVICE DETAILS

NAME OF DEVICE	FACE MASK
ESTABLISHMENT NAME	A R MEDICOM (M) SDN BHD
ROLE OF ESTABLISHMENT	MANUFACTURER
REGISTRATION NO	GMD4546584017A
BRAND NAME	Medicom
MEDICAL DEVICE CATEGORY	SINGLE-USE DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	A single-use and non-sterile procedure masks that are intended to be worn by personnel during surgical or other medical procedures to protect both the patient and the operating personnel from transfer of microorganisms, body fluids and particulate material transfer.
DEVICE INTENDED PURPOSE	The procedure masks are intended to be worn by personnel during medical procedures to protect both the patient and the operating personnel from transfer of microorganisms, body fluids and particulate material transfer.
VALIDITY DATE OF REGISTRATION	01/01/2022 - 31/12/2026

LIST OF DEVICE

NO	NAME OF DEVICE 	IDENTIFIER
1	Premier Earloop Mask	Safe + Mask 2011M
2	Premier Earloop Mask	Safe + Mask 2015M
3	Premier Earloop Mask	Safe + Mask 2016M
4	Premier Earloop Mask	Safe + Mask 2018M
5	Medicom Child Mask	Safe + Mask 2115kid
6	Tie-On Mask	Safe + Mask 2000B
7	Pro-Shield Earloop Mask	Safe + Mask 2025-Earloop
8	Pro-Shield Tie-on Mask	Safe + Mask 2026 Tie-on
9	Full Face Shield	Safe + Mask 2033
10	Procedure Earloop Face Mask	Safe + Mask-2120
11	Premier Plus Level 2 Earloop Face Mask	Safe + Mask 2027
12	Premier Plus Level 2 Tie-On Mask	Safe + Mask 2127

NO	NAME OF DEVICE	IDENTIFIER
13	Sof-Skin Earloop Mask (ASTM Level 1)	Safe + Mask 2330
14	Anti-Fog Tie-On Mask (ASTM Level 1)	Safe + Mask 2050
15	SFM Premier Elite Earloop Mask (ASTM Level 3)	Premier Elite Mask GMK201915
16	Pro-Lane Relax Individual Pack Earloop Mask (ASTM Level 3)	Pro-Lane Relax GMK211014 (White)
17	Pro-Lane Relax Individual Pack Earloop Mask (ASTM Level 3)	Pro-Lane Relax GMK211015 (Blue)
18	Pro-Lane Relax Individual Pack Earloop Mask (ASTM Level 3)	Pro-Lane Relax GMK211016 (Pink)
19	Defender Earloop Mask (ASTM Level 1)	Safe + Mask 2111
20	Defender Earloop Mask (ASTM Level 1)	Safe + Mask 2114
21	Defender Earloop Mask (ASTM Level 1)	Safe + Mask 2115
22	Defender Earloop Mask (ASTM Level 1)	Safe + Mask 2116
23	Defender Earloop Mask (ASTM Level 1) 	Safe + Mask 2117
24	Defender Earloop Mask (ASTM Level 1)	Safe + Mask 2118
25	Premier Earloop Mask (ASTM Level 1)	Safe + Mask PMRHMB2115
26	Earloop Face Mask For Children (ASTM Level 1)	Safe Mask GMK200015
27	Face Mask For Kids (Age Under 6) (ASTM Level 1)	Safe Mask SFMHMK2331