



DEVICE DETAILS

NAME OF DEVICE	SILICONE FACE MASK
ESTABLISHMENT NAME	AMSMEDIPRO SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GMD28181884918A
BRAND NAME	COMFY
MEDICAL DEVICE CATEGORY	REUSABLE DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	soft, latex-free, silicone face mask. Designed for attachment to Space Chamber aerosol spacer.
DEVICE INTENDED PURPOSE	Attachment to Space Chamber aerosol spacers to deliver asthma or COPD medication for inhalation by patient.
VALIDITY DATE OF REGISTRATION	30/11/2023 - 29/11/2028

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Comfy Silicone Face Mask size 0, Neonate	PN-0501-21
2	Comfy Silicone Face Mask size 1, Infant	PN-0501-22
3	Comfy Silicone Face Mask size 2, Toddler	PN-0501-23
4	Comfy Silicone Face Mask size 3, Child	PN-0502-21
5	Comfy Silicone Face Mask size 4, Adult	PN-0502-22
6	Comfy Silicone Face Mask size 5, Adult Large	PN-0502-23