



DEVICE DETAILS

NAME OF DEVICE	DREAMWEAR FULL FACE MASK
ESTABLISHMENT NAME	PHILIPS MALAYSIA SDN BERHAD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB910651134618
BRAND NAME	RESPIRONICS
MEDICAL DEVICE CATEGORY	MD 0101 - Non-active devices for anaesthesia, emergency and intensive care
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	THE DREAMWEAR FULL FACE MASK IS INTENDED TO PROVIDE AN INTERFACE FOR APPLICATION OF CPAP OR BI-LEVEL THERAPY TO PATIENTS. THE MASK IS FOR SINGLE PATIENT USE IN THE HOME OR MULTI-PATIENT USE IN THE HOSPITAL/INSTITUTIONAL ENVIRONMENT. THE MASK IS TO BE USED ON PATIENTS (>66LBS/30KG) FOR WHOM CPAP THERAPY OR BI-LEVEL THERAPY HAS BEEN PRESCRIBED. DREAMWEAR DESIGN ALLOWS PATIENTS TO QUICKLY AND EASILY SWITCH BETWEEN FULL FACE, NASAL AND GEL PILLOWS CUSHIONS WITHOUT CHANGING MASKS.
DEVICE INTENDED PURPOSE	THIS MASK IS INTENDED TO PROVIDE AN INTERFACE FOR APPLICATION OF CPAP OR BI-LEVEL THERAPY TO PATIENTS. THE MASK IS FOR SINGLE PATIENT USE IN THE HOME OR MULTI-PATIENT USE IN THE HOSPITAL/INSTITUTIONAL ENVIRONMENT. THE MASK IS TO BE USED ON PATIENTS (>66LBS/30KG) FOR WHOM CPAP THERAPY OR BI-LEVEL THERAPY HAS BEEN PRESCRIBED.
VALIDITY DATE OF REGISTRATION	26/09/2023 - 25/09/2028

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Small, DreamWear Full, Small & Medium Frame, International	1133370
2	Medium,, DreamWear Full, Small & Medium Frame, International	1133371
3	Large, DreamWear Full, Small & Medium Frame, International	1133372
4	Medium Wide, DreamWear Full, Small & Medium Frame, International	1133373
5	S, DreamWear Full Cushion	1133430
6	M, DreamWear Full Cushion	1133431
7	L, DreamWear Full Cushion	1133432
8	MW, DreamWear Full Cushion	1133433

NO	NAME OF DEVICE	IDENTIFIER
9	DreamWear, Small Frame	1116745
10	DreamWear, Medium Frame	1116746
11	DreamWear, Large Frame	1116747
12	DreamWear Full Headgear	1133450
13	Headgear Magnet Clip	1133454
14	DreamWear Fabric Wraps	1116754
15	Small, DreamWear Full, Small & Medium Frame, International	1133370
16	Medium,, DreamWear Full, Small & Medium Frame, International	1133371
17	Large, DreamWear Full, Small & Medium Frame, International	1133372
18	Medium Wide, DreamWear Full, Small & Medium Frame, International	1133373
19	S, DreamWear Full Cushion	1133430
20	M, DreamWear Full Cushion	1133431
21	L, DreamWear Full Cushion 	1133432
22	MW, DreamWear Full Cushion	1133433
23	DreamWear, Small Frame	1116745
24	DreamWear, Medium Frame	1116746
25	DreamWear, Large Frame	1116747
26	DreamWear Full Headgear	1133450
27	Headgear Magnet Clip	1133454
28	DreamWear Fabric Wraps	1116754