



DEVICE DETAILS

NAME OF DEVICE	QUATTRO AIR FULL FACE MASK
ESTABLISHMENT NAME	RESMED MALAYSIA OPERATIONS SDN. BHD.
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB75964191917
BRAND NAME	RESMED
MEDICAL DEVICE CATEGORY	MD 0100 - GENERAL NON-ACTIVE, NON-IMPLANTABLE MEDICAL DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	THE QUATTRO AIR AND QUATTRO AIR FOR HER IS AN ACCESSORY THAT IS EXTERNALLY PLACED COVERING THE MOUTH AND THE NOSE OF A PATIENT TO CHANNEL AIR FLOW FROM NON-CONTINUOUS POSITIVE AIRWAY PRESSURE VENTILATORS (CPAP OR BI-LEVEL FLOW GENERATORS) TO THE PATIENT FOR THE TREATMENT OF OBSTRUCTIVE SLEEP APNEA (OSA) OR VENTILATORY SUPPORT. IT ACHIEVES BOTH OF THESE THERAPY FUNCTIONS BY PROVIDING A SEAL FROM THE PAP DEVICE TO THE PATIENT'S NOSE, THEREBY ENABLING THE DELIVERY OF POSITIVE AIR PRESSURE GENERATED BY THE PAP DEVICE TO THE PATIENT'S AIRWAY
DEVICE INTENDED PURPOSE	THE QUATTRO AIR MASK SYSTEMS ARE A NON-INVASIVE ACCESSORIES USED FOR CHANNELLING AIR-FLOW (WITH OR WITHOUT SUPPLEMENTAL OXYGEN) TO A PATIENT FROM A POSITIVE AIRWAY PRESSURE DEVICE SUCH AS CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP) OR BILEVEL SYSTEM. THE QUATTRO AIR MASK SYSTEMS ARE: - TO BE USED BY PATIENTS (WEIGHING >66 LB/30 KG) FOR WHOM POSITIVE AIRWAY PRESSURE THERAPY HAS BEEN PRESCRIBED. - INTENDED FOR SINGLE PATIENT RE-USE IN THE HOME ENVIRONMENT AND MULTI-PATIENT RE-USE IN THE HOSPITAL/INSTITUTIONAL ENVIRONMENT
VALIDITY DATE OF REGISTRATION	10/11/2021 - 09/11/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Quattro Air - SML - APAC	62717
2	Quattro Air - MED - APAC	62718
3	Quattro Air - LGE - APAC	62719
4	Quattro Air for Her - XSML - APAC	62772
5	Quattro Air for Her - SML - APAC	62773

NO	NAME OF DEVICE	IDENTIFIER
6	Quattro Air for Her - MED - APAC	62774
7	Quattro Air - XSML - ANZ	62724
8	Quattro Air - SML - ANZ	62725
9	Quattro Air - MED - ANZ	62726
10	Quattro Air - LGE - ANZ	62727
11	Quattro Air for Her - XSML - ANZ	62769
12	Quattro Air for Her - SML - ANZ	62770
13	Quattro Air for Her - MED - ANZ	62771
14	Quattro Air/Quattro Air for Her Cushion - SML	62737
15	Quattro Air for Her Cushion - XSML	62736
16	Quattro Air/Quattro Air for Her Cushion - MED	62754
17	Quattro Air Cushion - LGE	62739
18	Quattro Air for Her Frame System - XSML 	62752
19	Quattro Air/Quattro Air for Her Frame System - SML	62753
20	Quattro Air/Quattro Air for Her Frame System - MED	62754
21	Quattro Air Frame System - LGE	62755
22	Quattro Air Headgear - SML	62757
23	Quattro Air Headgear - STD	62756
24	Quattro Air/Quattro Air for Her Frame - XSML/SML	62760
25	Quattro Air/Quattro Air for Her Frame - MED/LGE	62762