Public Search

Malaysia Medical Device Register (MMDR)

DEVICE DETAILS

NAME OF DEVICE	AF531 ORO-NASAL EE FACE MASK
ESTABLISHMENT NAME	PHILIPS MALAYSIA SENDIRIAN BERHAD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB4408025-211606
BRAND NAME	PHILIPS RESPIRONICS
MEDICAL DEVICE CATEGORY	MD 0100 - GENERAL NON-ACTIVE, NON-IMPLANTABLE MEDICAL DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The AF531 Oro-Nasal EE Face Mask are devices that have only indirect clinical benefit in that they are used within device systems for the provision of non-invasive ventilation therapy. They do not, by themselves, deliver any therapeutic benefit to patients. The principles of operation and technology for the AF531 Oro-Nasal EE Face Mask have been in use for >35 years to aid treatment of sleep disordered breathing and respiratory insufficiency and failure, and the AF531 Oro-Nasal EE Face Mask detailed in this registration application have been on the market since 2008. The key difference between the Philips AF531 EE Leak 1 and EE Leak 2 elbows lies in the design of the exhalation port: EE Leak 1 (Clear) has a minimal, intentional leak, while EE Leak 2 (Orange) has a built-in leak port for use with specific circuits EE Leak 1: Features a minimal, intentional leak. Not sufficient to eliminate exhaled CO2 from the patient. EE Leak 2: Has a built-in leak port. Can be used without an additional exhalation port.
DEVICE INTENDED PURPOSE	Intended Use Medium and Large Size: The AF531 Oro-Nasal EE Leak 1 and 2 Face Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single use in the hospital/institutional environment only. The mask is to be used on patients (>30 kg) for whom CPAP or bi-level therapy has been prescribed. Small Size: The AF531 Oro-Nasal EE Leak 1 & 2 Face Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single use in the hospital/institutional environment only. The mask is to be used on patients 7 years or older (>20 kg) for whom CPAP or bi-level therapy has been prescribed.
VALIDITY DATE OF REGISTRATION	18/09/2025 - 17/09/2030

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	AF531 Oro-Nasal, Single-Use, Capstrap Headgear, EE, Leak 1, Small, 10 pk	1072627
2	AF531 Oro-Nasal, Single-Use, Capstrap Headgear, EE, Leak 1, Medium, 10 pk	1072628

NO	NAME OF DEVICE	IDENTIFIER
3	AF531 Oro-Nasal, Single-Use, Capstrap Headgear, EE, Leak 1, Large, 10 pk	1072629
4	AF531 Oro-Nasal, Single-Use, Capstrap Headgear, EE Leak 1/NE Elbow, Small, 10 pk	1072636
5	AF531 Oro-Nasal, Single-Use, Capstrap Headgear, EE Leak 1/NE Elbow, Medium, 10 pk	1072637
6	AF531 Oro-Nasal, Single-Use, Capstrap Headgear, EE Leak 1/NE Elbow, Large, 10 pk	1072638
7	AF531 Oro-Nasal, Single-Use, Four Point Headgear, EE, Leak 1, Small, 10 pk	1072621
8	AF531 Oro-Nasal, Single-Use, Four Point Headgear, EE, Leak 1, Medium, 10 pk	1072622
9	AF531 Oro-Nasal, Single-Use, Four Point Headgear, EE, Leak 1, Large, 10 pk	1072623
10	AF531 Oro-Nasal, Single-Use, Four Point Headgear, EE Leak 1/NE Elbow, Small, 10 pk	1072633
11	AF531 Oro-Nasal, Single-Use, Four Point Headgear, EE Leak 1/NE Elbow, Medium, 10 pk	1072634
12	AF531 Oro-Nasal, Single-Use, Four Point Headgear, EE Leak 1/NE Elbow, Large, 10 pk	1072635
13	AF531 Oro-Nasal, Single-Use, Capstrap Headgear, EE, Leak 2, Small, 10 pk	1100390
14	AF531 Oro-Nasal, Single-Use, Capstrap Headgear, EE, Leak 2, Medium, 10 pk	1100391
15	AF531 Oro-Nasal, Single-Use, Capstrap Headgear, EE, Leak 2, Large, 10 pk	1100392
16	AF531 Oro-Nasal, Single-Use, Four Point Headgear, EE, Leak 2, Small, 10 pk	1100393
17	AF531 Oro-Nasal, Single-Use, Four Point Headgear, EE, Leak 2, Medium, 10 pk	1100394
18	AF531 Oro-Nasal, Single-Use, Four Point Headgear, EE, Leak 2, Large, 10 pk	1100395
19	Philips Procedure 5 Pack, AF531 EE Leak 1 with FEP, S	1072639
20	Philips Procedure 5 Pack, AF531 EE Leak 1 with FEP, M	1072640
21	Philips Procedure 5 Pack, AF531 EE Leak 1 with FEP, L	1072641
22	Philips Procedure 5 Pack, AF531 EE Leak 1 with Capstrap headgear with FEP, S	1072642
23	Philips Procedure 5 Pack, AF531 EE Leak 1 with Capstrap headgear with FEP, M	1072643
24	Philips Procedure 5 Pack, AF531 EE Leak 1 with Capstrap headgear with FEP, L	1072644

NO	NAME OF DEVICE	IDENTIFIER
25	EE Leak 1 entrainment elbow	1072645
26	EE Leak 1 entrainment elbow	1072646
27	EE leak 1 elbow with NIVO port	1120967
28	EE leak 2 elbow with NIVO port	1120968