



DEVICE DETAILS

NAME OF DEVICE	WIZARD FULL FACE MASK WITH HEADGEAR
ESTABLISHMENT NAME	ERIKG SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB10841721-76780
BRAND NAME	WIZARD
MEDICAL DEVICE CATEGORY	MD 0100 - GENERAL NON-ACTIVE, NON-IMPLANTABLE MEDICAL DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	Full face mask
DEVICE INTENDED PURPOSE	The Mask is intended to provide an interface for Continuous Positive Airway Pressure (CPAP) or bi-level therapy. These masks are intended for single-patient reuse in the home and multi-patient, multi-use in the hospital environment. These masks are to be used on patients greater than 30 kg for whom positive airway pressure (CPAP or bi-level system) has been prescribed.
VALIDITY DATE OF REGISTRATION	24/09/2021 - 23/09/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	WiZARD 320 Full Face Mask with Headgear	SM08003
2	WiZARD 320 Full Face Mask with Headgear	SM08002
3	WiZARD 320 Full Face Mask with Headgear	SM08001