



DEVICE DETAILS

NAME OF DEVICE	EXTRAORAL ORTHODONTIC HEADGEAR
ESTABLISHMENT NAME	OSSTEM MALAYSIA SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GMD36787875018A
BRAND NAME	FACE MASK
MEDICAL DEVICE CATEGORY	DENTAL DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The FACEMASK series is orthodontic headgear. These headgears will be used for a complete orthodontic treatment. The series is fixed to the patient's neck or head by the band and holds patient's chin line comfortably by ergonomic design. The FACEMASK series has Air Vents to prevent humidity and release heat.
DEVICE INTENDED PURPOSE	This device is used for orthodontic treatment and supports the patient's forehead and jaw to align the teeth. When the upper jaw grows less than the lower jaw and the lower teeth cover the upper teeth (opposite bite), or when the lower jaw protrudes from the upper jaw (squeezing jaw), this is a device to improve the growth of the upper and lower jaws by using the growth of the children's jaws.
VALIDITY DATE OF REGISTRATION	26/11/2023 - 25/11/2028



LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Orthodontic Headgear_FACEMASK	801-71
2	Orthodontic Headgear_FACEMASK	801-72
3	Orthodontic Headgear_FACEMASK	801-73
4	Orthodontic Headgear_FACEMASK	801-74
5	Orthodontic Headgear_BK Mask	801-76