



DEVICE DETAILS

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| 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 |
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| 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 |