



DEVICE DETAILS

NAME OF DEVICE	Face Mask
ESTABLISHMENT NAME	DARREN DENTAL SUPPLY SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GA8145423-146360
BRAND NAME	International Orthodontic Services
MEDICAL DEVICE CATEGORY	DENTAL DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	A facemask is an appliance used in orthodontic treatment to correct cases with midfacial deficiency, CLP and similar cases.
DEVICE INTENDED PURPOSE	A dental device used in conjunction with extraoral traction anchored on the back of the head or neck, as a long metal bow that inserts intraorally into an orthodontic appliance. Generally used to move teeth or bones posteriorly or prevent their forward movement.
VALIDITY DATE OF REGISTRATION	29/08/2023 - 28/08/2028

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Face Mask Clear	16-111-100
2	Face Mask Blue	16-111-101
3	Face Mask Teal	16-111-102
4	Face Mask Pearl	16-111-103
5	Face Mask Red	16-111-104
6	Face Mask American Flag	16-111-105
7	Face Mask Hawaii	16-111-106
8	Face Mask Racin's Flames	16-111-107
9	Face Mask Tiger	16-111-108
10	Face Mask Pad Replacment - Clear	16-112-100
11	Face Mask Pad Replacment - American Flag	16-112-105
12	Face Mask Pad Replacment - Hawaii	16-112-106

NO	NAME OF DEVICE	IDENTIFIER
13	Face Mask Pad Replacment - Racin' Flames	16-112-107
14	Face Mask Pad Replacment - Tiger	16-112-108



MEDICAL DEVICE AUTHORITY