



## DEVICE DETAILS

<b>NAME OF DEVICE</b>	Face Mask
<b>ESTABLISHMENT NAME</b>	DARREN DENTAL SUPPLY SDN BHD
<b>ROLE OF ESTABLISHMENT</b>	AUTHORIZED REPRESENTATIVE
<b>REGISTRATION NO</b>	GA8145423-146360
<b>BRAND NAME</b>	International Orthodontic Services
<b>MEDICAL DEVICE CATEGORY</b>	DENTAL DEVICES
<b>DEVICE GROUPING TYPE</b>	FAMILY
<b>DEVICE DESCRIPTION</b>	A facemask is an appliance used in orthodontic treatment to correct cases with midfacial deficiency, CLP and similar cases.
<b>DEVICE INTENDED PURPOSE</b>	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.
<b>VALIDITY DATE OF REGISTRATION</b>	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**