

## Fiscal Year 2020 CERTIFICATION OF REGISTRATION

This certifies that:

Pac-Dent, Inc. 670 Endeavor Circle, Brea, CA 92821, U.S.A.

has completed the FDA Establishment Registration (as manufacturer, initial importer) and Device Listing with the US Food & Drug Administration, through

U.S. Agent for FDA

PAC-DENT, INC.

Communications

670 ENDEAVOR CIRCLE,

BREA, CA 92821

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Owner/Operator Number: 2086043

**Device Listing#:** 

<b>Listing No</b>	Code	Device Name	Performance Testing/Approval
D382357	MSH	<ul> <li>iMask Premium Ear-Loop Face Mask ASTM level2</li> <li>iMask Premium KN95 Face Mask</li> <li>iMask Disposable Protective Mask</li> </ul>	<ul> <li>Meet ASTM F 1862 requirements for fluid resistance</li> <li>Meet ASTM F2101-01 and ASTM F2299 requirements for viral/bacterial filtration performance</li> <li>Meet ISO-10993-1 requirements for biocompatibility</li> </ul>

Pac-Dent, Inc. will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless such registration is terminated after issuance of this certificate. Pac-Dent, Inc. makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Pac-Dent, Inc. assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration doe not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Pac-Dent, Inc. is not affiliated with the U.S. Food and Drug Administration.



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Vicky Yang Regulatory Affairs Manager Issued: March. 25 2020 Cert. No. 20202086043-02

Expiration Date: Dec. 31 2020