CERTIFICATE

Number: 3821424

The management system of:

Jensen Industries, Inc.

50 Stillman Road
North Haven, CT 06473
United States Of America

Manufacturer DUNS 060018587

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure
Canada: Medical Devices Regulations - Part 1- SOR 98/282
Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68 and PMD Act
United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D, 21 CFR 820

Scope:
Design, Development, Manufacture and Distribution of precious and non-precious dental alloys and solders, dental ceramics and denture teeth for use by dental laboratories and dentists for fabrication of dental prostheses. Distribution including installation of dental software.

Certificate expiry date: 2022-04-26
Certificate effective date: 2020-05-08
Certified since: 2019-04-26

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

The validation of the validity of this certificate can be checked through DEKRA's website using the following link:
https:/www.dekra-product-safety.com/en/certified-organizations

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

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