CERTIFICATE

Number: 3820951

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Implantech Associates, Inc.

6025 Nicolle Street, Suite B Ventura, CA 93003 United States of America

Manufacturer Facility Identifier F003593

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

Brazil: RDC ANVISA N. 665/2022, 551/2021 and 67/2009 Canada: Medical Devices Regulations - Part 1- SOR 98/282

United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D, 21 CFR 820

Scope:

Design, development, production and distribution of surgical implants for body contouring and scar management products. In addition, design, development, production and distribution of OEM prosthetic and surgical appliances and supplies and proprietary surgical appliances and supplies.

Certificate expiry date: 2027-12-14
Certificate effective date: 2025-04-21
Certified since: 2018-12-14

This certificate is valid for the organization(s) and/or locations mentioned on the addendum

DEKRA Certification B.V.

B.T.M. Holtus Managing Director J.M. McKenzie

Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

The validation of the validity of this certificate can be checked through DEKRA's website using the following link: https://www.dekra-checkme.com/org

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



ADDENDUM

To certificate: 3820951

The management system of the organization(s) and/or location(s) of:

Implantech Associates, Inc.

6025 Nicolle Street, Suite B Ventura, CA 93003 United States of America

Certified organization(s) and/or locations:

Different scope

Implantech Associates, Inc. 6020 Nicolle St. Suite A Ventura, CA 93003 USA Facility Identifier F003593	Design, development of surgical implants for body contouring and scar management products. In addition, design, development of OEM prosthetic and surgical appliances and supplies and proprietary surgical appliance and supplies.
Implantech Associates, Inc. 6000 Leland St. Ventura, CA 93003 USA Facility Identifier F003593	Warehouse, shipping and receiving

Addendum expiry date: 2027-12-14 Addendum effective date: 2025-04-21