

CERTIFICATEOF REGISTRATION

This is to certify that the management system of:

Spiraltech Dental Implants

(FIN F001567)

Main Site: 875 North Michigan Avenue, Suite 3106,

Chicago, Illinois, 60611, United States

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D), 21 CFR Part 821

The management system is applicable to:

Design and manufacture of sterile dental implants, sterile orthodontic implants, and abutments.

Certificate Number:

0091231

Initial Certification Date:

2019-05-29

Certification Effective Date:

2019-05-29

Certification Expiry Date:

2022-05-28



Intertek

Calin Moldovean

President, Business Assurance

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