



Osypka Medtec, Inc.

1804 Skyway Drive, Unit E,
Longmont, CO 80504

Is certified by **PLATINUM REGISTRATION** as a company that has developed, implemented and maintains a quality management system that conforms to the requirements of the following International Standards:

ISO 13485:2016

(Requirements not applicable: 7.5.3 Installation activities, 7.5.4 Serving activities, 7.5.5 Particular requirements for sterile medical devices, 7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems.)

The scope of this certification includes:

Contract manufacturing and packaging of active and non-active medical devices assemblies and components within controlled environments, including leads, neurostimulators, cardiac implants, and hearing implants, based upon customer requirements. Contract device design and contract design and development of related manufacturing processes.

Design, manufacture within a controlled environment, and sale of neurostimulator lead assemblies adaptable for connection o customer active impactable devices.

Certificate Number: 14143536

Certified Since: October 1, 2014*

Certificate Approval Date (Date Granted, Reduced, Extended, or Renewed): September 22, 2023

Current Certification Cycle Start Date: September 30, 2023

Current Certification Cycle Expiration Date: September 29, 2026

Rev: C

This certification is subject to the organization maintaining its management system to the requirements of ISO 13485:2016 as well as the requirements of Platinum Registration, Inc. This certificate is the property of Platinum Registration, Inc. and must be returned upon request. To verify this certificate please call 303-639-9001

**Transferred to Platinum Registration, Inc. on September 8, 2023*



PLATINUM REGISTRATION INC.

1040 South Gaylord Street, Suite 71, Denver, CO 80209

www.platinumregistration.com | info@platinumregistration.com