

CERTIFICATEOF REGISTRATION

This is to certify that the management system of:

Xtant Medical Holdings, Inc.

(FIN F006565)

Main Site: 664 Cruiser Lane, Belgrade, Montana, 59714, United States

Additional site1: 600 Cruiser Lane, Belgrade, Montana, 59714, United States

Additional site2: 732 Cruiser Lane, Belgrade, Montana, 59714, United States

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

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

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 821

The management system is applicable to:

The Design, Development, and Manufacture of Sterile and Non-Sterile Fixation/Motion Implants and Instrumentation for the Spinal and Skeletal System. Servicing of Instrumentation. Design and Process of Human Tissues for Transplant Including HCT/P Medical Devices.

Main site: Headquarters and Manufacturing

Additional site1: Design, Development and Manufacturing

Additional site2: Design, Development, Manufacturing and Servicing

Certificate Number:

0143449

Initial Certification Date:

2021-03-16

Certification Effective Date:

2023-03-15

Certification Expiry Date:

2026-03-15





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Calin Moldovean

President, Business Assurance

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