

CERTIFICATEOF REGISTRATION

This is to certify that the management system of:

BioPro Inc.

(FIN F007910)

Main Site: 2929 Lapeer Rd.

Port Huron, Michigan, 48060, 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, manufacture, and distribution of sterile and non-sterile orthopedic implants; sterile and non-sterile surgical instruments. The contract manufacture of sterile and non-sterile orthopedic implants; sterile and non-sterile surgical instruments

Organization was certified by another Certification Body before 11/22/2024.

Certificate Number:

0198699

Revision Level: 01

Initial Certification Date:

2019-12-13

Certification Effective Date:

2025-12-12

Certification Expiry Date:

2028-12-12





intertek

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