

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Fabrication Enterprises, Inc.

(FIN F000819)

Main Site: 250 Clearbrook Road, Suite 240
Elmsford, New York, 10523, 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)

The management system is applicable to:

Manufacture of products for physical/occupational therapy and physical fitness, including Dynamometers, Inclinometers, Goniometers, Evaluation, Hot/Cold, Hydrotherapy, Pediatric Positioning, Aids to Daily Living, various exercise products, and similar items. Distribution of products for physical/occupational therapy and physical fitness including Dynamometers, Inclinometers, Goniometers, Evaluation Items, Models and Charts, Hot/Cold, Treatment Modalities, Hydrotherapy, Splint Material & Taping, Treatment Furniture, Aids to Daily Living, Durable Medicals Equipment, Splinting & Supports, and similar items.

Certificate Number:

0087352-02

Initial Certification Date:

2019-02-19

Date of Certification Decision:

2023-01-23

Certification Effective Date:

2023-01-23

Certification Expiry Date:

2025-02-18



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Calin Moldovean

President, Business Assurance

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