

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

Revision Level: 03

Initial Certification Date:

2019-02-19

Certification Effective Date:

2025-02-18

Certification Expiry Date:

2028-02-18



intertek

A handwritten signature in black ink, appearing to read "Rathin Grover", is written over a horizontal line.

Rathin Grover

President, Business Assurance

Intertek Testing Services NA, Inc.
4700 Broadmoor SE, Suite 200
Kentwood, MI, USA, 49512

