

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Instrumentation Industries, Inc.

Main Site: 2990 Industrial Blvd.,
Bethel Park, Pennsylvania, 15102, United States (FIN F000850)

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:

The design, manufacture, and distribution of respiratory care products and accessories, including: one-way, exhalation and PEEP valves, breathing circuit adapters and connectors, oxygen instant flow valves, manual jet ventilators, endotracheal tube changers, airway management products, breathing bags, test lungs, ventilator tubing, water traps, pressure monitoring products, laryngoscope blades and distribution of sterile transtracheal catheters.

Certificate Number:

0079253-06

Initial Certification Date:

2018-08-06

Date of Certification Decision:

2024-07-22

Certification Effective Date:

2024-08-05

Certification Expiry Date:

2027-08-05



intertek

Calin Moldovean

President, Business Assurance

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

