

CERTIFICATEOF 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 changer, airway management products, breathing bags, test lungs, ventilator tubing, water traps, pressure monitoring products and the distribution only of sterile transtracheal catheter.

Certificate Number:

0079253-01

Initial Certification Date:

2018-08-06

Date of Certification Decision:

2021-08-03

Certification Effective Date:

2021-08-05

Certification Expiry Date:

2022-08-05





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