

Giấy chứng nhận đạt tiêu chuẩn quản lý chất lượng

Tài liệu được xác nhận bằng chữ ký số và có hiệu lực kể từ ngày ký.

Hà Nội, ngày 02 tháng 01 năm 2020

Người đại diện hợp pháp của cơ sở

**Giám đốc
Nguyễn Thị Minh Phương**

CERTIFICATE

Number: 3822111

The management system of:

Instrumentation Laboratory Company

180 Hartwell Road
Bedford, MA 01730

United States Of America

including the implementation meets the requirements of the standard:

ISO 13485:2016

Scope:

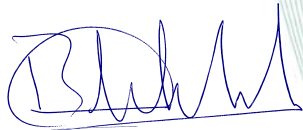
Design and Development, Manufacture, Distribution and Servicing of In Vitro Diagnostic Devices, Kits, Reagents, Analyzers/Software used in the Screening, Diagnosis and Management of Hemostasis, Fibrinolysis, Immunology, Chemistry, Blood Gas, CO-Oximetry, pH, Electrolytes, Glucose, Lactate and Blood Analytes, including Near Patient In Vitro Diagnosis Devices.

Certificate expiry date: 09 November 2021

Certificate effective date: 09 November 2018

Certified since: 09 November 2018

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



ADDENDUM 1/1

to Certificate 3822111

Concerning the Management System of:

Instrumentation Laboratory Company

List of certified locations

Location	Certification scope
Instrumentation Laboratory Company 18 Independence Drive Devens, MA 01434	Distribution (including warehousing) of In Vitro Diagnostic Devices, Kits, Reagents, Analyzers/Software used in the Screening, Diagnosis and Management of Hemostasis, Fibrinolysis, Immunology, Chemistry, Blood Gas, CO-Oximetry, pH, Electrolytes, Glucose, Lactate and Blood Analytes, patient and Blood Monitoring including Near Patient In Vitro Diagnosis Devices
Instrumentation Laboratory Co - NY 526 Route 303 Orangeburg, NY 10962	Design, Development and Manufacture of In Vitro Diagnostic Hemostasis Kits, Reagents, Controls and Calibrators; and the Manufacture of In Vitro Diagnostic Critical Care Kits, Reagents, Controls and Calibrators

Addendum Initial date: 09 November 2018

Addendum Effective date: 09 November 2018