GIẤY CHỨNG NHẬN ISO 13485:2016

Tài liệu được xác nhận bằng chữ ký số

Hà Nội, ngày 11 tháng 07 năm 2022

Người đại diện hợp pháp của cơ sở

GIÁM ĐỐC

M.S.D.N: 0305502875-C.T.T.N.H.H
CÔNG TY TNHH KỸ THUẬT NAM PHƯƠNG
Q. HOÀNG MAI - TP. HÀ NỘI

Nguyễn Thị Kim Chi

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CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Trinity Biotech

Primus Corporation dba Trinity Biotech

(FIN F000933)

Main Site: 4231 East 75th Terrace, Kansas City, Missouri 64132 USA

Additional site: 7545 Spruce Street, Kansas City, Missouri 64132 USA

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

Brazil: Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

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, installation and service of precision glycohemoglobin (A1c) and variant hemoglobin assay platforms, control materials and reagents, including service and monitoring of client instruments.

Additional site: Finished goods shipping, R&D

Certificate Number:
0084650-01

Initial Certification Date:
2018-12-09

Date of Certification Decision:
2021-12-08

Certification Effective Date:
2021-12-08

Certification Expiry Date:
2024-12-08

ISO 13485:2016 CERTIFICATION™

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

intertek

Calin Moldovean
President, Business Assurance

Intertek Testing Services NA, Inc.
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Lowell, MA, USA 01851