

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Streck LLC
also doing business as Streck
7002 S. 109th Street
La Vista
Nebraska
68128
USA

Facility ID Number: F005094

Holds Certificate No:

MDSAP 791844

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2023-10-12

Effective Date: 2024-12-10

Expiry Date: 2027-12-09



BSI Group America Inc. is an MDSAP recognised auditing organization

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...making excellence a habit.™

Certificate No: **MDSAP 791844**

Registered Scope:

Design, development, manufacture, and distribution of in-vitro diagnostic analyzers and in-vitro diagnostic quality controls, calibrators and test kits (including sterile sample collection containers) used in the diagnosis and management of cancer screening, immune status, disease status, blood analyses, and blood components, including near-patient in-vitro diagnostic devices.



Original Registration Date: 2023-10-12 Effective Date: 2024-12-10

Expiry Date: 2027-12-09

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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

Certificate No: **MDSAP 791844**

Location

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Registered Activities

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Incoming inspection of raw material and commodities specific to blood collection tubes, labeling, inspection and release, warehousing and shipping.



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