

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Streck LLC d/b/a Streck
7002 S. 109th Street
La Vista
Nebraska
68128
USA

Holds Certificate Number:

MD 791666

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

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

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2023-10-16

Latest Revision Date: 2025-11-05

Effective Date: 2024-12-10

Expiry Date: 2027-12-09

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...making excellence a habit.™

Certificate No: MD 791666

Location	Registered Activities
Streck LLC also doing business as Streck 7002 S. 109th Street La Vista Nebraska 68128 USA	Design, development, manufacture, and distribution of in-vitro diagnostic analyzers and in-vitro diagnostic quality controls, calibrators and test kits (including specimen preservation reagents and sterile sample collection containers) used in the diagnosis and management of cancer screening, immune status, disease status, fertility testing, blood analyses, and blood components, including near-patient in-vitro diagnostic devices.
Streck LLC also doing business as Streck 11710 Peel Circle La Vista Nebraska 68128 USA	Incoming inspection of raw material and commodities specific to blood collection tubes, labelling, inspection and release, warehouse and shipping.



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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact:

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