



# Certificate of Registration

OUALITY 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 invitro 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.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

CARDOL

Original Registration Date: 2023-10-16 Effective Date: 2024-12-10 Expiry Date: 2027-12-09

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Certificate No:

MD 791666

### Location

## Streck LLC also doing business as Streck 7002 S. 109th Street La Vista

Nebraska 68128 USA

## Streck LLC

also doing business as Streck

11710 Peel Circle

La Vista Nebraska 68128 USA

#### Registered Activities

Design, development, manufacture, and distribution of invitro 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 invitro diagnostic devices.

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



Original Registration Date: 2023-10-16 Latest Revision Date: 2024-11-26 Effective Date: 2024-12-10 Expiry Date: 2027-12-09

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