By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/746, Annex IX Chapter I and III

IVDR 791821 R000

Manufacturer: Streck

Address:
7002 S. 109th Street
La Vista
Nebraska
68128
USA

Single Registration Number: US-MF-000013009

EU Authorised Representative: MediMark Europe Sarl.

Address:
11 rue Emile Zola
38100 Grenoble
France

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/746, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class D devices, and self-test, near-patient test and companion diagnostic devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2023-12-18**

Current Issue Date: **2025-11-07**

Starting Validity Date: **2025-11-07**

Expiry Date: **2028-12-17**

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Device Schedule: Class D, C and B devices

Class C devices	Intended purpose
W0101 - **Clinical Chemistry** IVP 3002 - In vitro Diagnostic devices which require knowledge regarding biochemistry	Clinical chemistry controls intended to be used with reagents for confirmation, determination or monitoring of HbA1c as a physiological marker for diabetes.
W0103 - Haematology / Haemostasis / Immunohaematology / Histology / Cytology IVP 3006 - In vitro Diagnostic devices which require knowledge regarding flow cytometry	Flow cytometry controls intended to be used for screening, diagnosis, staging or monitoring of cancer.
W0104 - **Microbiology (Culture)** IVP 3011 - In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)	Microbiological controls intended to be used to evaluate the performance of nucleic acid tests for detection of infectious agents.
Class B devices	**Intended purpose**
IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers	Haematology calibrators and controls intended to be used for screening, determination or monitoring of physiological markers.
IVR 0607 - Devices intended to be used for detection of pregnancy or fertility testing	Haematology controls intended for monitoring sperm counts for male fertility testing.

Device Schedule: Class A sterile devices

Device(s)	Risk Classification
IVR 0803 - Sterile specimen receptacles	Class As
For Class A sterile devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2023-12-18	30000907	Issued
Current	30498910	Supplemented – Addition of Class B IVR 0607 Category and Class C Group W0104 + IVP 3011. Change of EU Authorised Representative address.

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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