STRECK

EU DECLARATION OF CONFORMITY

Manufacturer Name	Streck
Manufacturer Address	7002 S. 109th Street La Vista, NE 68128 USA
SRN (Single Registration Number)	US-MF-000013009
Authorized Representative Name	MEDIMARK® Europe
Authorized Representative Address	11 rue Emile Zola 38100 Grenoble, France
MediMark Europe SRN (Single Registration Number)	FR-AR-000000182
Basic UDI-DI	08445090A1CR7
Name of the Device	A1c-Cellular®
Intended Purpose	A1c-Cellular® is a bi-level, whole blood based, assayed control material for evaluating the accuracy and precision of HbA1c procedures.
Product code(s)	211124 A1c-Cellular 6x2.0ml LV 1,2 211130 A1c-Cellular 2x2.0ml LV 1,2
Classification	C
Notified Body Certificate Number	IVDR 791821
Notified Body Name	BSI Group The Netherlands B.V.
Notified Body Address	Say Building John M. Keynesplein 9 1066 EP Amsterdam, The Netherlands
Notified Body Identification Number	2797
Conformity Assessment Route	Conformity Assessment Route: Annex IX Streck uses the following procedures for the CE-labeling of their products according to the Regulation IVDR 2017/746: QA906A2 EU IVDR Requirements QA906A3 EU Technical Documentation Creation and Control Class C: EU conformity declaration according to Annex VIII, Rule 3
Common Specifications (CS) applied:	None

This declaration is issued under the sole responsibility of Streck. We hereby declare that the medical device specified above meet the provisions of Regulation (EU) IVDR 2017/746 for in vitro diagnostic medical devices. This declaration is supported by the Quality System approval issued by BSI Group. All supporting documentation is retained at the location of the manufacturer.

Signature

Director of Regulatory Affairs (or Designee)

Place and Date of Issue of Declaration

Place: Streck
7002 S. 109th Street
La Vista, NE 68128

March 31, 2026
Date