STRECK

DECLARATION OF CONFORMITY

Manufacturer Name	Streck
Manufacturer Address	7002 S. 109th Street La Vista, NE 68128 USA
Manufacturer's SRN (Single Registration Number)	US-MF-000013009
Authorized Representative	MEDIMARK® Europe
Authorized Representative's SRN (Single Registration Number)	FR-AR-000000182
Authorized Representative Address	11 rue Emile Zola, 38100 Grenoble, FRANCE
Basic UDI-DI	08445090CFBCTIVDLN
Name of the Device	Cell-Free DNA BCT®
Intended Purpose	Cell-Free DNA BCT® is a direct-draw venous whole blood collection device intended for the collection, stabilization, and transport of venous whole blood samples for use in conjunction with cell-free DNA next- generation sequencing liquid biopsy assays that have been cleared or approved for use with samples collected in the Cell-Free DNA BCT device.
Product code(s)	230469 Cell-Free DNA BCT, 6-tube (10.0 mL) 230470 Cell-Free DNA BCT, 100-tube (10.0 mL) 230471 Cell-Free DNA BCT, 1000-tube case (10.0 mL)
Classification	Class A, Sterile
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	2979
Conformity Assessment Route	Conformity Assessment Route: Annex IX, Chapters I and III 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 A Sterile: EU Conformity Declaration according to Annex VIII, Rule 5
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 device. 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

Jan 12, 2026
Date