

DECLARATION OF CONFORMITY

Manufacturer Name	Streck
Manufacturer Address	7002 S. 109 th Street La Vista, NE 68128 USA
SRN (Single Registration Number)	US-MF-000013009
Authorized Representative - EU	MEDIMARK® Europe Sarl
Authorized Representative Address - EU	11 rue Emile Zola, 38100 Grenoble, France
MEDIMARK® Europe SRN (Single Registration Number)	FR-AR-000000182
Authorized Representative - Switzerland	MedEnvoy Switzerland
MedEnvoy Address	Gotthardstrasse 28 6302 Zug, Switzerland
MedEnvoy SRN (Single Registration Number)	CHRN-AR-20000310
Basic UDI-DI	08445090CFBCTCEBX
Name of the Device	Cell-Free DNA BCT® CE
Intended Purpose	Cell-Free DNA BCT® CE is a direct draw whole blood collection tube intended for collection, transport and storage of blood samples.
Product code(s)	218996 Cell-Free DNA BCT CE, 6 tube EXPORT ONLY 218997 Cell-Free DNA BCT CE, 100 tube EXPORT ONLY 230244 Cell-Free DNA BCT CE, 1000 cs EXPORT ONLY 230655 Cell-Free DNA BCT CE Switz, 6 Tube Pack 230656 Cell-Free DNA BCT CE Switz, 100 Box 230657 Cell-Free DNA BCT CE Switz, 1000 cs
Classification	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	2797
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: EU conformity declaration according to Annex VIII, Rule 5
Common Specifications (CS) applied	None

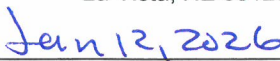
This declaration is the sole responsibility of Streck. We hereby declare that the medical device specified above meet the provision of Regulation (EU) IVDR 2017/746 for in vitro diagnostic medical devices. This declaration is supported by the Quality System approval issued by BSI Group. Supporting documentation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


Date