



## EU DECLARATION OF CONFORMITY

|                                                                   |                                                                                                                                                                                                                                                                                                                                                                 |
|-------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Manufacturer Name                                                 | Streck                                                                                                                                                                                                                                                                                                                                                          |
| Manufacturer Address                                              | 7002 S. 109 <sup>th</sup> Street<br>La Vista, NE 68128 USA                                                                                                                                                                                                                                                                                                      |
| SRN (Single Registration Number)                                  | US-MF-000013009                                                                                                                                                                                                                                                                                                                                                 |
| Authorized Representative - EU                                    | MEDI <sup>MARK</sup> ® Europe Sarl                                                                                                                                                                                                                                                                                                                              |
| Authorized Representative Address - EU                            | 11 rue Emile Zola,<br>38100 Grenoble, France                                                                                                                                                                                                                                                                                                                    |
| MEDI <sup>MARK</sup> ® Europe SRN<br>(Single Registration Number) | FR-AR-000000182                                                                                                                                                                                                                                                                                                                                                 |
| 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<br>218997 Cell-Free DNA BCT CE, 100 tube EXPORT ONLY<br>230244 Cell-Free DNA BCT CE, 1000 cs EXPORT ONLY                                                                                                                                                                                                        |
| Classification                                                    | Clas A Sterile                                                                                                                                                                                                                                                                                                                                                  |
| Notified Body Certificate Number                                  | IVDR 791821                                                                                                                                                                                                                                                                                                                                                     |
| Notified Body Name                                                | BSI Group The Netherlands B.V.                                                                                                                                                                                                                                                                                                                                  |
| Notified Body Address                                             | Say Building<br>John M. Keynesplein 9<br>1066 EP Amsterdam, The Netherlands                                                                                                                                                                                                                                                                                     |
| Notified Body Identification Number                               | 2797                                                                                                                                                                                                                                                                                                                                                            |
| Conformity Assessment Route                                       | Conformity Assessment Route: Annex IX, Chapters I and III<br><br>Streck uses the following procedures for the CE-labeling of their products according to the Regulation IVDR 2017/746:<br><br>QA906A2 EU IVDR Requirements<br>QA906A3 EU Technical Documentation Creation and Control<br><br>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 Quality and Regulatory Affairs  
(or Designee)

Place and Date of Issue of Declaration

Place: Streck  
7002 S. 109<sup>th</sup> Street  
La Vista, NE 68128

15-SEP-2026

Date