


DECLARATION OF CONFORMITY

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| Manufacturer Name | Streck |
| Manufacturer Address | 7002 S. 109 th 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 |

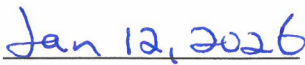
This declaration is issued under the sole responsibility of Streck. We hereby declare that the medical device specified above meet the provisions of Regulation (EU) IVDR 2017/746 for in vitro diagnostic medical device. This declaration is supported by the Quality System approval issued by BSI Group.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


Date