

## EU DECLARATION OF CONFORMITY

Manufacturer Name	Streck
Manufacturer Address	7002 S. 109 <sup>th</sup> Street La Vista, NE 68128 USA
SRN (Single Registration Number)	US-MF-000013009
Authorized Representative Name	MEDIMARK® Europe Sarl
Authorized Representative Address	11 rue Emile Zola, 38100 Grenoble, France
MediMark Europe SRN (Single Registration Number)	FR-AR-000000182
Basic UDI-DI	08445090BCTTZ
Name of the Device	Cyto-Chex® BCT
Intended Purpose	Cyto-Chex® BCT is intended for collection and storage of blood specimens for immunophenotyping of white blood cells by flow cytometry. Recovery of lymphocyte subset cell markers of the HIV panel can be accomplished over a 14-day period following collection.
Product code(s)	218980 Cyto-Chex BCT 2.0ml, 100 tube box 213559 Cyto-Chex BCT 2.0ml, 6 tube box 213361 Cyto-Chex BCT 5.0ml, 6 tube pack 213362 Cyto-Chex BCT 5.0ml, 25 tube box 213386 Cyto-Chex BCT 5.0ml, 100 tube box 230658 Cyto-Chex BCT 5.0ml Switz, 6 Tube Pack 230659 Cyto-Chex BCT 5.0ml Switz, 25 Box 230660 Cyto-Chex BCT 5.0ml Switz, 100 Box 230661 Cyto-Chex BCT 2.0ml Switz, 6 Tube Pack 230662 Cyto-Chex BCT 2.0ml Switz, 100 Box
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

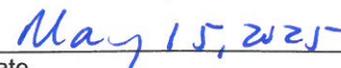
This declaration is issued under the sole responsibility of Streck. We hereby declare that the medical device specified above meets the provisions of Regulation (EU) IVDR 2017/746 for in vitro diagnostic medical devices. This declaration is supported by the Quality System approval issued by BSI Group.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

Signature

  
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Director of Regulatory Affairs  
(or Designee)

Place and Date of Issue of Declaration

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

  
\_\_\_\_\_  
Date