

EU DECLARATION OF CONFORMITY

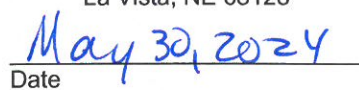
Manufacturer Name	Streck
Manufacturer Address	7002 S. 109 th Street La Vista, NE 68128 USA
SRN (Single Registration Number)	US-MF-000013009
Authorized Representative	MEDI [®] MARK Europe
Authorized Representative Address	11, rue Emile Zola, BP 2332 38033 Grenoble Cedex 2, France
Basic UDI-DI	08445090FC34F6
Name of the Device	CD-Chex CD34 [®]
Intended Purpose	CD-Chex CD34 [®] is a stabilized preparation of human blood to be used as a complete process control when evaluating CD34 positive cells. It is intended to be used with BD Biosciences ProCOUNT Progenitor Cell Enumeration Kit, BD Stem Cell Enumeration Kit, Beckman Coulter Stem-Kit, and with systems using the ISHAGE protocol for enumeration of CD34 cells.
Product code(s)	213337 CD-Chex CD34 2x1.0ml LV 1 213338 CD-Chex CD34 2x1.0ml LV 1,2 213339 CD-Chex CD34 4x1.0ml LV 1,2 213347 CD-Chex CD34 2x1.0ml LV 2 213383 CD-Chex CD34 2x1.0ml LV 3
Classification	C
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 C: EU conformity declaration according to Annex VIII, Rule 3
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 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


Director of Regulatory Affairs (or Designee)

Place and Date of Issue of Declaration

Place: Streck
7002 S.109th Street
La Vista, NE 68128

Date