STRECK

EU DECLARATION OF CONFORMITY

Manufacturer Name	Streck
Manufacturer Address	7002 S. 109th Street La Vista, NE 68128 USA
SRN (Single Registration Number)	US-MF-000013009
Authorized Representative	MEDIMARK® Europe
Authorized Representative Address	11, rue Emile Zola, BP 2332 38033 Grenoble Cedex 2, France
Basic UDI-DI	08445090FC+S5
Name of the Device	CD-Chex Plus®
Intended Purpose	CD-Chex Plus® is intended to be used as a quality control material for evaluating monoclonal antibody binding by flow cytometry. CD-Chex Plus control cells possess surface antigens detectable with monoclonal antibodies. When these cells are stained with fluorescent antibodies and analyzed by flow cytometry they provide a reference for normal peripheral blood leukocytes. CD-Chex Plus is designed for use on the Becton Dickinson and Beckman Coulter flow cytometry systems.
Product code(s)	213323 CD-Chex Plus Plastic 1x3.0ml Normal 213324 CD-Chex Plus CD4 Low Plastic 1x3.0ml 213365 CD-Chex Plus Plastic 2x3.0ml Normal 213366 CD-Chex Plus CD4 Low Plastic 2x3.0ml 213367 CD-Chex Plus Plastic 5x3.0ml Normal 213368 CD-Chex Plus CD4 Low Plastic 5x3.0ml 213369 CD-Chex Plus Plastic 4x3.0ml Low,Normal 213370 CD-Chex Plus Plastic 10x3.0ml Low,Normal 213391 CD-Chex Plus Plastic 2x3.0ml Low,Normal
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: EC conformity declaration according to Annex VIII, Rule 3, subrule (h)
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 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

May 30, 2024
Date