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 Name	MEDIMARK® Europe
Authorized Representative Address	11, rue Emile Zola, BP 2332 38033 Grenoble Cedex 2, France
Basic UDI-DI	0844509012+MH
Name of the Device	Para 12® Plus
Intended Purpose	Para 12® Plus is an assayed hematology control for evaluating the accuracy and precision of hematology instruments that provide a white blood cell differential.
Product code(s)	218903 Para 12 Plus 3x3.0ml LNH 218907 Para 12 Plus 6x3.0ml LNH 218913 Para 12 Plus 12x3.0ml LNH 218914 Para 12 Plus 4x3.0ml Normal 218924 Para 12 Plus 4x3.0ml Low 218934 Para 12 Plus 4x3.0ml High
Classification	Class B
Certified 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 B: EU conformity declaration according to Annex VIII, Rule 6
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 Regulatory Affairs
(or Designee)

Place and Date of Issue of Declaration
Place: Streck
7002 S. 109th Street
La Vista, NE 68128

April 15, 2024
Date