



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 Name	MEDIMARK® Europe
Authorized Representative Address	11, rue Emile Zola, BP 2332 38033 Grenoble Cedex 2, France
Basic UDI-DI	0844509012EXT5Y
Name of the Device	Para 12® Extend
Intended Purpose	Para 12® Extend is an assayed hematology control for evaluating the accuracy and precision of hematology instruments that provide a white blood cell differential.
Product code(s)	218750 Para 12 Extend 18x2.5ml LNH 218755 Para 12 Extend 3x2.5ml LNH 218758 Para 12 Extend 6x2.5ml Normal 218993 Para 12 Extend 6x2.5ml Low 218994 Para 12 Extend 6x2.5ml High 218995 Para 12 Extend 6x4.5ml Normal 218770 Para 12 Extend 18x4.5ml LNH 218776 Para 12 Extend 3x4.5ml LNH
Classification	B
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 B: EU conformity declaration according to Annex VIII, Rule 6
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.

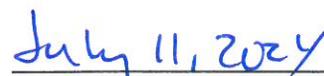
Signature



Director of Regulatory Affairs
(or Designee)

Place and Date of Issue of Declaration

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



Date