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 38100 Grenoble, France
MediMark Europe SRN (Single Registration Number)	FR-AR-000000182
Basic UDI-DI:	08445090CY93
Name of the Device:	Streck Cell Preservative™
Intended Purpose:	Streck Cell Preservative™ is a solution formulated to preserve the white blood cells in peripheral blood samples without reducing the activity of antigenic sites. Samples treated with Streck Cell Preservative can be maintained for up to 7 days prior to processing and analysis by flow cytometric methods.
Product code(s):	213350 Streck Cell Preservative 6x1.0ml 213355 Streck Cell Preservative 50x1.0ml 213358 Streck Cell Preservative 2x10ml vial
Classification:	Class A Non-Sterile
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 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

July 7, 2025
Date