



### EU DECLARATION OF CONFORMITY

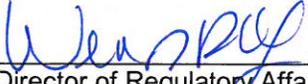
Manufacturer Name	Streck
Manufacturer Address	7002 S. 109 <sup>th</sup> Street La Vista, NE 68128 USA
SRN (Single Registration Number)	US-MF-000013009
Authorized Representative Name	MEDIMARK® Europe
Authorized Representative Address	11 rue Emile Zola, BP2332 38033 Grenoble Cedex 2, France
Basic UDI-DI:	08445090UPCENV
Name of the Device:	Streck® Urine Preserve CE
Intended Purpose:	Streck® Urine Preserve CE is a liquid reagent intended to stabilize nucleic acid targets in urine for up to 7 days when stored from 6°C to 37°C. Each single use container (5mL) is intended to stabilize one urine sample. The preservative is capable of stabilizing 25mL to 100mL or urine.
Product code(s):	230632 Streck Urine Preserve CE 120 x 5.0 mL 230631 Streck Urine Preserve CE 12 x 5.0mL
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

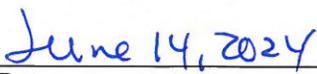
This declaration is issued under the sole responsibility of Streck. We hereby declare that the medical device specified above meet the provisions of Regulation (EU) IVDR 2017/746 for in vitro diagnostic medical devices. This declaration is supported by the Quality System approval issued by BSI Group. All supporting documentation is retained at the location of the manufacturer.

Signature

Place and Date of Issue of Declaration

Place: Streck  
7002 S. 109<sup>th</sup> Street  
La Vista, NE 68128

  
\_\_\_\_\_  
Director of Regulatory Affairs (or Designee)

  
\_\_\_\_\_  
Date