

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	08445090CX8Z
Name of the Device	Cell-Chex®
Intended Purpose	<p>Cell-Chex® is an assayed control intended for monitoring total cell counts performed manually using a hemacytometer to validate quantitation of red and white blood cells in patient cerebrospinal fluid and body fluid samples including pleural, pericardial, peritoneal and synovial fluid. Level 1-UC contains monosodium urate crystals, and Level 1-CC contains Calcium Pyrophosphate Dihydrate (CPPD) crystals, which can be used to monitor the presence of crystals in synovial fluid. Cell-Chex is used by laboratory professionals.</p> <p>Cell-Chex is also intended for monitoring white blood cell differentiation (Mononuclear and Polymorphonuclear; Neutrophils, Eosinophils, Basophils, Lymphocytes and Monocytes) in body fluid samples performed using Cytospin smears.</p>
Product code(s)	212420 Cell-Chex 4x2.0ml L1-UC, L2 212424 Cell-Chex 6x2.0ml LV 2 212425 Cell-Chex 12x2.0ml L1-UC, L2 212429 Cell-Chex 2x2.0ml LV 1-CC 212430 Cell-Chex 6x2.0ml LV 1-CC 212431 Cell-Chex 3x2.0ml LV1-UC, LV1-CC, LV2 212432 Cell-Chex 6x2.0ml LV 1-UC
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	<p>Conformity Assessment Route: Annex IX, Chapters I and III</p> <p>Streck uses the following procedures for the CE-labeling of their products according to the Regulation IVDR 2017/746:</p> <p>QA906A2 EU IVDR Requirements QA906A3 EU Technical Documentation Creation and Control</p> <p>Class B: EU conformity declaration according to Annex VIII, Rule 6</p>
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.

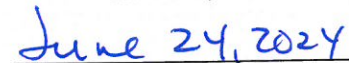
Signature

Place and Date of Issue of Declaration



Director of Regulatory Affairs (or Designee)

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



Date