ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

America

CERTIFICATE

No. QS2 133177 0001 Rev. 00

Certificate Holder: **Sysmex Reagents America, Inc.**
Two Sysmex Way
Mundelein IL 60060
USA

Certification Mark:

Scope of Certificate: **Contract Manufacture and Distribution of In-Vitro Diagnostic Reagents and Diluents used in the Analysis of Hematology and Urinalysis Testing for Home or Point of Care Use**

Standard: **ISO 13485:2016**

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.: **721013846**

Effective Date: **2025-11-17**

Expiry Date: **2028-01-15**

Date of Issue: 2025-11-24

(Renee Walker)
Director, US Certification Body, MHS