



# CERTIFICATE



This is to certify that

## Sysmex Reagents America, Inc.

Two Sysmex Way  
Mundelein, IL 60060  
United States of America

has implemented and maintains a **Quality Management System**.

Scope:

The Contract Manufacture and Distribution of vitro diagnostic general reagents and diluents used in the analysis of hematology and urinalysis testing for home or point of care use.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

## ISO 13485 : 2016

Certificate registration no.	10018795 MP2016
Date of original certification	2003-09-08
Date of revision	2021-12-09
Date of certification	2022-01-16
Valid until	2025-01-15



**DQS Inc.**

Brad McGuire  
Managing Director