



CERTIFICATE



This is to certify that

Sysmex America, Inc.

577 Aptakisic Road
Lincolnshire, IL 60069
United States of America

with the organizational units/sites as listed in the annex

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

Scope:

Design and development of customized decision support software for the clinical laboratory.
Distribution of in vitro diagnostics instruments and reagents and other IVD medical devices. Pre-installation, installation, servicing and repair of laboratory instruments. Corporate Administrative support for Regulatory, Quality, Clinical and Medical Affairs Activities.

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.	10016636 MP2016
Date of original certification	2018-08-07
Date of certification	2024-12-06
Valid until	2028-01-09



DQS Inc.

David Tellez
Managing Director

DQS IS A MEMBER OF





Annex to certificate
Registration No. 10016636 MP2016

Sysmex America, Inc.

577 Aptakisic Road
Lincolnshire, IL 60069
United States of America

Remote Location

Scope

10016637
Sysmex America, Inc.
One Sysmex Way
Mundelein, IL 60060
United States of America

The remote location at Mundelein, IL performs the following primary functions: Assay Lab, Services, Repairs, Calibration.

10016638
Sysmex America, Inc.
1701 Leider Lane
Buffalo Grove, IL 60089
United States of America

The remote location at Buffalo Grove, IL performs the following primary functions: Warehouse, Distribution, Incoming Verification.

10016945
Sysmex America, Inc.
1011 Woodlands Pkwy
Vernon Hills, IL 60061
United States of America

The remote location at Vernon Hills, IL performs the following primary functions: Customer, Field Service Training, Pre-installation, Service, Repairs, and Incoming Verification.