



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 revision | 2023-10-30 |
| Date of certification | 2022-01-10 |
| Valid until | 2025-01-09 |



DQS IS A MEMBER OF



DQS Inc.

Brad McGuire
Managing Director



Accredited Body: DQS Inc., 1500 McConnor Parkway, Suite 400, Schaumburg, IL 60173 USA
The validity of this certificate can only be verified by the QR-code.



**Annex to certificate
Registration No. 10016636 MP2016**

Sysmex America, Inc.

577 Aptakisic Road
Lincolnshire, IL 60069
United States of America

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, Pre-installation, Service, Repairs, 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.