



# Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **09 100 89004**

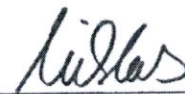
Certificate Holder: **SYSMEX CORPORATION**  
1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan  
including the locations according to annex

Scope: Development, design, production, sales and servicing of in-vitro diagnostic medical devices, laboratory equipment, reagents and laboratory information system, and development, design, production and sales of customized recombinant protein

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2021-08-01 until 2022-01-31.  
First certification 1998

2021-07-30



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln



# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization  
**SYSMEX EUROPE GmbH**  
**Bornbarch 1**  
**22848 Norderstedt**  
**Deutschland**

has established and applies a quality management system for medical devices  
for the following scope:

**see attachment**

Proof has been furnished that the requirements specified in

## EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

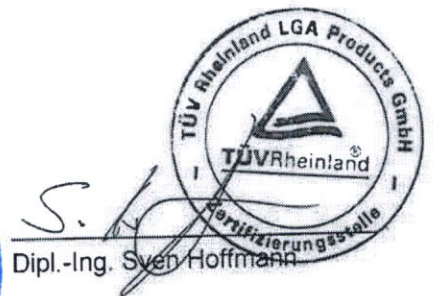
Effective Date: 2019-05-17  
Certificate Registration No.: SX 60137613 0001  
An audit was performed. Report No.: 21245244 005  
This Certificate is valid until: 2022-05-16

Certification Body



Date 2019-04-29

**TÜV Rheinland LGA Products GmbH · Tillystraße 2 · 90431 Nürnberg**  
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com http://www.tuv.com/safety



# Certificate

Standard **ISO 14001:2015**

Certificate Registr. No. **01 104 110072**

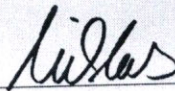
Certificate Holder: **SYSMEX EUROPE GmbH**  
Bornbarch 1  
22848 Norderstedt  
Germany

Scope: Sales, marketing and service of  
in-vitro diagnostic medical devices

Proof has been furnished by means of an audit that the  
requirements of ISO 14001:2015 are met.

Validity: The certificate is valid from 2020-07-25 until 2023-07-24.  
First certification 2011

2020-03-19

  
TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

www.tuv.com



Deutsche  
Akkreditierungsstelle  
D-ZM-16031-01-00





# EC Declaration of Conformity

## Application of Council Directive:

- 98/79/EC of 27 October 1998 on In Vitro Diagnostic Medical Devices

## Means of conformity:

The following products are in conformity with

- Directive 98/79/EC based on the conformity assessment procedures in accordance with Annex III,

## Product identification:

Product name: CUVETTE

Model name: SUC-400A

Classification: Other device (except Annex II and self-testing devices)

## List of Applied Standards:

- Harmonised Standards used for conformity assessment are listed in the technical documentation.

## Legal Manufacturer:

Name: SYSMEX CORPORATION

Address: 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan

Authorised officer: Hiroshi Yamane Date: 13 March 2018  
Hiroshi Yamane, Executive Vice President

## Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer: [Signature] Date: MARCOY 20<sup>th</sup> 2018  
Fernando Andreu, Chief Operations Officer

This declaration of conformity is issued under the sole responsibility of the manufacturer and is valid until 25.05.2022 or until a revised declaration is issued due to product modifications.

