

# EC Declaration of Conformity

## Application of Directives:

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

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## Means of conformity:

The following product is in conformity with

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

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## Product identification:

Product name: SULFOLYSER

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

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## List of Applied Standards:

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

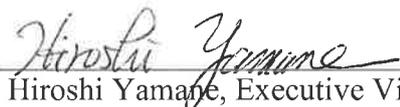
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## Legal Manufacturer:

Name: SYSMEX CORPORATION

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

Authorised officer:

  
Hiroshi Yamane, Executive Vice President

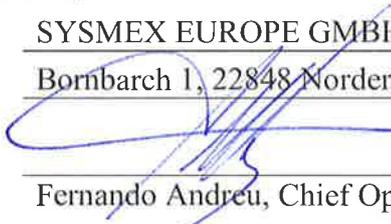
Date: 13 March, 2018

## Authorised representative:

Name: SYSMEX EUROPE GMBH

Address: Bornbarch 1, 22848 Norderstedt, Germany

Authorised officer:

  
Fernando Andreu, Chief Operations Officer

Date: MARCH 21<sup>st</sup> 2018

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.