



Product Service

Certificate

No. Q5 105329 0001 Rev. 02

Holder of Certificate: **iLine Microsystems S.L.**
Paseo Mikeletegi 69
20009 Donostia (Gipuzkoa)
SPAIN

Certification Mark:



Scope of Certificate: **Design and development, manufacture, servicing and distribution of in vitro diagnostic reagents and portable instruments for coagulation testing**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 105329 0001 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_105329_0001_Rev_02)

Report No.: 713275903

Valid from: 2023-03-21

Valid until: 2026-03-20

Date, 2023-03-15

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 105329 0001 Rev. 02

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): **iLine Microsystems S.L.**
Paseo Mikeletegi 69, 20009 Donostia (Gipuzkoa), SPAIN

Design and development, manufacture, servicing and distribution
of in vitro diagnostic reagents and portable instruments for
coagulation testing

iLine Microsystems S.L.
Paseo Mikeletegi 71, 20009 Donostia (Gipuzkoa), SPAIN

Manufacture, servicing and distribution of in vitro diagnostic
reagents and portable instruments for coagulation testing

/.