



Certificate

No. Q5 112514 0001 Rev.

Holder of Certificate: **Systelab Technologies S.A.**

Av. Can Montcau 7
08186 Lliçà d'Amunt - Barcelona
SPAIN

Facility(ies): **Systelab Technologies S.A.**

Av. Can Montcau 7, 08186 Lliçà d'Amunt - Barcelona, SPAIN

See Scope of Certificate

Certification Mark:



Scope of Certificate:

Design and Development, Manufacturing and Servicing of Software as Medical Device for Anticoagulation Therapy and In-Vitro Diagnostic Software module for Laboratory Results Flagging.

The provision of Design and Development, Manufacturing and Servicing services for In-Vitro Diagnostic Laboratory Instrumentation Software.

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

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, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 112514 0001 Rev.

Report No.: ITA200220005005

Valid from: 2025-10-04

Valid until: 2028-10-03

Signature

Digitally signed by ELENA
RAJA PRADO / AS8333287
Date: 2025.01.13 07:45:50
+01'00

Elena Raja
Director of QA/RA for Digital Solutions

Date, [#ISU_DT#]

Christoph Dicks

Head of Certification/Notified Body