

Certificate

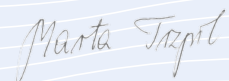
Quality Management System EN ISO 13485:2016 + AC:2018 + A11:2021 ISO 13485:2016

Registration No.: SX 1552211-1
Certificate Holder: SPINREACT, S.A.U.
Ctra. Santa Coloma 7
E-17176 Sant Esteve de Bas (Girona)
Spain

Scope: Design and development, manufacture and distribution of *in vitro* diagnostic (IVD) medical devices, including reagents, test kits, calibrators and controls for professional use, intended for the diagnosis and/or monitoring in the field of clinical chemistry, immunochemistry, haematology and infectious diseases.
Design and development, manufacture and distribution of *in vitro* diagnostic sample collection devices.
Manufacture, distribution, installation and servicing of *in vitro* diagnostic instruments for professional use, used in the field of clinical chemistry and haematology.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 92876765-040
Effective date: 2026-05-04
Expiry date: 2029-05-03
Issue date: 2026-04-02
Replaces certificate SX 1552211-1 issued 2025-05-21



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This certificate can be validated on <https://www.certipedia.com>