

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 2347938-1
Certificate Holder: MONLAB, S.L.
Cobalto, 74
08940 Cornellà de Llobregat
Spain

Scope: Design and development, manufacture and distribution of in vitro diagnostic test kits and related control materials, including rapid tests, intended for professional use in clinical chemistry, immunology and infectious diseases; used in the diagnosis and detection of transmissible agents, protein metabolism, autoimmune status, drugs of abuse and fertility testing. Distribution, installation and service of medical devices and in vitro diagnostic medical devices instruments.

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.: 92829733-30
Effective date: 2025-05-02
Expiry date: 2028-05-01
Issue date: 2025-04-23
Replaces certificate SX 2347938-1 issued 2023-10-09

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


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