Certificate

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

Registration No.:	SX 1973122-1
Certificate Holder:	CERTEST BIOTEC, S.L. Calle J Nº1 - Pol. Ind. Río Gallego II 50840 San Mateo de Gallego - Zaragoza Spain
Scope:	The design and development, production and distribution of *in vitro* diagnostic medical devices, including *in vitro* diagnostic reagents, test kits and their related calibrators and controls, intended for professional use in infectious disease testing, genetic testing, and immunochemistry. The design and development, production, distribution, installation and servicing of *in vitro* diagnostic medical device instruments for professional use in infectious disease testing, genetic testing, and immunochemistry. The design and development, production, distribution, installation and maintenance of *in vitro* diagnostic software for professional use used in the management of nucleic acid testing instruments for interpretation, data analysis and visualization of results

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.:	92878499 030, 92881185-20
Effective date:	2026-05-09
Expiry date:	2029-05-08
Issue date:	2026-04-29

Replaces certificate SX 1973122-1 issued 2023-05-09

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

Marta Trzpil
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

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