

Certificate

Quality Management System EN 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
España

Scope Design, development, production and distribution on in-vitro diagnostic medical devices, in-vitro diagnostic reagents, in-vitro diagnostic test kits used in: the identification and/or detection of transmissible agents as aid in the diagnosis of diseases, the identification and/or detection of markers as aid in the diagnosis of pathologies or possible disorders and its controls and calibrators.
Design, development, production, distribution, installation and servicing on in-vitro diagnostic instruments involved in PCR systems.

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.

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