

Certificate ES20/87484

The quality management system of

CERTEST BIOTEC S.L.

SGS

C/ J, nº1, Polígono Industrial Río Gállego II, SAN MATEO DE GÁLLEGO, Zaragoza, 50840, Spain

Facility number: F004687

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System

Brazil: RDC ANVISA n. 16/2013 - Good Manufacturing Practices, RDC ANVISA n. 23/2012,
RDC ANVISA n. 67/2009 - Vigilance

Canada: Medical Device Regulations SOR/98-282, Part 1

Japan: MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW Ordinance No. 128 (2014) Articles 4 to 68 Japan
PMD Act (as applicable)

For the following activities

The design, development and manufacture of in-vitro diagnostic medical devices, in-vitro diagnostic reagents and in-vitro diagnostic test kits used in the identification and/or detection of transmissible agents and as aid in the diagnosis of diseases.

This certificate is valid from Effective date 2023-03-15 until Expiry date 2026-03-14 and remains valid subject to satisfactory surveillance audits.

Issue 3. Certified since 2020-03-25



Authorised by
Geoffrey De Visscher
Head of Notified Body 1639

SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 - www.sgs.com

SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com.



This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | [SGS](#). Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.

