Certificate ES20/87484

The quality management system of

CERTEST BIOTEC S.L.

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
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Head of Notified Body 1639

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