



Certificate Number 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

Dun & Bradstreet D-U-N-S identification number : 54-090-2124

has been audited against the criteria stated below and found to conform to those criteria
for the scope contained in this certificate

MDSAP(ISO 13485:2016)

Australia:
Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)
– Full Quality Assurance Procedure [including design]
Brazil:
RDC ANVISA n. 16/2013 / RDC ANVISA n. 23/2012 / RDC ANVISA n. 67/2009
Canada:
Medical Devices Regulations – Part 1 SOR 98/282

For the following activities and devices

**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: 2020-03-25 until Expiry Date: 2023-03-24
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 2023-02-27
Issue 1. Certified since 2020-03-25

Authorised by J Hall
Business Manager

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