



America

CERTIFICATE

No. QS6 112727 0003 Rev. 01

Certificate Holder:

VIRCELL,S.L.

Parque Tecnológico de la Salud, Avicena 8
18016 Granada
SPAIN

Certification Mark:



Scope of Certificate:

**Design, Development, Production and Distribution of
In-Vitro Diagnostic Reagents for Infectious Diseases
and of In-Vitro Diagnostic Generic Use Consumables;**

**Design, Development, Production, Installation, Servicing
and Distribution of In-Vitro Diagnostic Instruments for
Infectious Diseases**

Standard(s):

ISO 13485:2016

Regulatory Authority(ies):

**Health Canada, USA FDA. See attached for listing of
specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:QS6 112727 0003 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:QS6_112727_0003_Rev.01)

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID:

F007207

Report No.:

ITA200220006988

Effective Date:

2025-07-17

Expiry Date:

2028-07-16

Page 1 of 2

Date of Issue: 2025-07-17

(Renee Walker)
Director, US Certification Body, MHS



America

CERTIFICATE

No. QS6 112727 0003 Rev. 01

Regulatory Requirements: Audit/Certification Criteria

Canada

- Medical Device Regulations – Part 1- SOR 98/282

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies):

VIRCELL,S.L.

Parque Tecnológico de la Salud, Avicena 8, 18016 Granada, SPAIN

VIRCELL,S.L.

Polígono Industrial Dos de Octubre, Plaza Domínguez Ortiz 1, 18320 Santa Fe, Granada, SPAIN

Facility Scopes:

VIRCELL, S.L.

Parque Tecnológico de la Salud, Avicena 8, 18016 Granada, SPAIN

Design, Development, Production and Distribution of In-Vitro Diagnostic Reagents for Infectious Diseases and of In-Vitro Diagnostic Generic Use Consumables;

Design, Development, Production, Installation, Servicing and Distribution of In-Vitro Diagnostic Instruments for Infectious Diseases
REPs Facility ID: F007207

VIRCELL, S.L.

Polígono Industrial Dos de Octubre, Plaza Domínguez Ortiz 1, 18320 Santa Fe, Granada, SPAIN

Production of In-Vitro Diagnostic Reagents for Infectious Diseases and In-Vitro Diagnostic Generic Use Consumables
REPs Facility ID: F008006

Page 2 of 2

Date of Issue: 2025-07-17

(Renee Walker)
Director, US Certification Body, MHS