ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

America

C E R T I F I C A T E

No. QS6 112727 0003 Rev. 00

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. 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. 00
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F007207**
Report No.: **ITA1482756756**
Effective Date: **2024-04-25**
Expiry Date: **2027-04-24**

Date of Issue: 2024-05-01

(Renee Walker)
Director, US Certification Body, MHS

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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

C E R T I F I C A T E

No. QS6 112727 0003 Rev. 00

Regulatory Requirements: **Audit/Certification Criteria**

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

Facility(ies): **VIRCELL,S.L.**
Parque Tecnológico de la Salud, Avicena 8, 18016 Granada, SPAIN

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

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