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

America

C E R T I F I C A T E

No. QS6 066267 0028 Rev. 02

Certificate Holder: **EUROSPITAL S.p.A.**
Via Flavia, 122
34147 TRIESTE
ITALY

Certification Mark:

Scope of Certificate: **Design and Development, Manufacturing and Distribution In-Vitro Diagnostic Medical Devices, including Self-Testing, for Diagnosis of Autoimmune, Diseases, Coeliac Disease, System Infections, Inflammatory Bowel Disease**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, 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. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **42-944-7667**

Effective Date: **2020-10-03**

Expiry Date: **2023-10-02**

Date of Issue: 2020-10-29

(Tina Israel)
Manager, US Certification Body,
Medical and Health Services

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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 066267 0028 Rev. 02

Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

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
- 21 CFR Part 821

Facility(ies): **EUROSPITAL S.p.A.**
Via Flavia, 122, 34147 TRIESTE, ITALY

Facility Scopes: Design and Development, Manufacturing and Distribution In-Vitro Diagnostic Medical Devices, including Self-Testing, for Diagnosis of Autoimmune, Diseases, Coeliac Disease, System Infections, Inflammatory Bowel Disease
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