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

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. 03

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): **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 066267 0028 Rev. 03
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F001227**
Report No.: **ITA2086983**
Effective Date: **2023-06-29**
Expiry Date: **2026-06-28**

Date of Issue: 2023-07-31

(Renee Walker)
Director, US Certification Body, MHS

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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
- 21 CFR Part 821

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