



America

# CERTIFICATE

No. QS6 17 10 66267 022

**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 13485:2003

**Regulatory Authority:** Health Canada, 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

<http://www.tuv-sud-america.com/us-en/resource-center/customer-support/certificate-finder>

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

**DUNS No:** 42-944-7667  
**Effective Date:** 2017-10-03  
**Expiry Date:** 2019-02-28

Manuel Bradaric  
MHS Certification Manager



Page 1 of 2



America

# CERTIFICATE

No. QS6 17 10 66267 022

## Audit/Certification Criteria

### Canada

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

### United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820
- 21 CFR Part 821

Effective Date: 2017-10-03  
Expiry Date: 2019-02-28

A handwritten signature in black ink, appearing to read 'Manuel Bradaric'.

Manuel Bradaric  
Certification Manager MHS

Page 2 of 2