ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ
ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ
ΣΤΗΝ ΥΓΕΙΑ Α.Ε.
NATIONAL EVALUATION CENTER
OF QUALITY & TECHNOLOGY
IN HEALTH S.A.

EC CERTIFICATE

FULL QUALITY ASSURANCE SYSTEM

We hereby certify that the under mentioned manufacturer has established and maintains a full quality assurance system according to the requirements of Directive 93/42/EEC, Annex II (with the exemption of section 4) and its transposition in Greek legislation, for the design, manufacture and final inspection of the products mentioned in this certificate.

The certificate is subject to terms and conditions overleaf.

Any significant changes in design or manufacture may render this certificate invalid.

Certificate Number: 301001521

Manufacturer:	**OMNIA SPA**
Facility:	**VIA FRANCESCO DEL NEVO 190-FIDENZA PARMA ITALY**
Products:	**AS LISTED IN ANNEX I**
Devices Classification:	**AS LISTED IN ANNEX I**
Current issue date:	**26/07/2016**
Valid until:	**24/10/2017**
Audit report:	**200011521**

Χ. Παπαδάκης, Πρόεδρος & Διευθύνων Σύμβουλος
H. Papadakis, President & Managing Director

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ANNEX I No. 301001521 CERTIFICATE.

- **Classification IIb**

1. NON ABSORBABLE SURGICAL SUTURES	1. SILK, POLYAMID

- **Classification III**

1. ABSORBABLE SURGICAL SUTURES	1.1. PGA, MONOFAST
2. NON ABSORBABLE SURGICAL SUTURES	2.1. PTFE, POLYESTER

Χ. Παπαδάκης, Πρόεδρος & Διευθύνων Σύμβουλος
H. Papadakis, President & Managing Director

TERMS & CONDITIONS

1. For class I sterile products, the certificate covers only the aspects of manufacture concerned with securing and maintaining sterile conditions.
2. For Class I devices with a measuring function the certificate covers only the aspects of manufacture concerned with the conformity of the products with metrological requirements.
3. For class III products an additional Design Examination certificate is required according to the requirements of Annex II 93/42/EEC (section 4).
4. The certificate is valid only for the products and the facilities mentioned.
5. Periodical surveillance as referred in 93/42/EEC will be held in order to verify that the manufacturer maintains and applies the quality system.
6. When meeting with the terms and conditions above, the manufacturer may draw up an EC declaration of conformity and legally affix the CE 0653 mark.