Testing & Certification Australia

No 1127.0703

Certificate of Conformance

Issued To

Norwood Abbey Ltd
63 Wells Road
Chelsea Heights VIC 3196
Australia

for

Product:	Light-Assisted Anaesthetic Delivery (LAD) System
Model Number:	LAD-06
Manufacturer:	Norwood Abbey Ltd
Country of Origin:	Australia
ECRI Number:	18-839
ECRI Category:	Lasers, Er:YAG, Dermatologic

The electrical equipment described above and in the reference report/s, complies with the requirements of

AS/NZS 3200.1.0:1998

Including

AS/NZS 3200.2.22:1997

Exclusions: Clause 36 (EMC to AS/NZS 3200.1.2), 48 (Biocompatibility to ISO 10993-1) & 52.1 (Programmable Electronic Systems to AS/NZS 3200.1.4)

(TCA Report No. 43569.1 and 43569.2 are reference documents for this certificate)

Issued under the Rules of Certification of Testing & Certification Australia

Date of Issue 28/07/2003

This certificate indicates compliance with the requirements of type examination. Subject to exclusions and any additional regulation requirements, the product complies with the relevant Essential Principles and is suitable for inclusion in equipment management programs as described in AS/NZS 3551. The certificate is valid for a period of three years from the date of issue.

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Certificate of Compliance

EMC Technologies Report No: M030216_R
Issue Date: 7th April 2003

Test Sample:	Laser Aiming Device
Model Number:	LAD-06
Manufacturer:	Norwood Abbey Ltd
Tested for:	Norwood Abbey Ltd
Address:	63 Wells Road Chelsea Heights VIC 3196, Australia
Phone:	+61 3 9782 7333
Fax:	+61 3 9782 7338
Contact:	Yemon Chambers
Email:	ychambers@norwoodabbey.com.au

Test Standards:

IEC601-1-2: 1993 / AS/NZS 3200.1.2: 1995
Medical electrical equipment, Part 1: General requirements for safety Section 2. Collateral Standard: Electromagnetic compatibility - Requirements and tests
***IEC61000-3-2: 1995**
Limits for Harmonic Current Emissions (Equipment input current ≤ 16A).
***IEC61000-3-3: 1994**
Limitation of Voltage Fluctuations and Flicker in Low-Voltage Supply Systems for Equipment with Rated Current ≤ 16A.

Result of Test: **The test sample complied with the above listed Test Standards. Refer to Report M030216_R for full details.**

Test Dates: 19th to 25th February 2003

Test Officers:
Janath Gunasekera
Chieu Huynh

Authorised Signature:
Chris Zombolas
Technical Director
EMC Technologies Pty Ltd

*The Current Harmonics (IEC61000-3-2) and the Voltage Flicker (IEC61000-3-3) tests are not within the current cope of NATA accreditation.

Issued by EMC Technologies Pty. Ltd., 57 Assembly Dve., Tullamarine, Vic., 3043, Australia.
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SUMMARY

An *in vitro* biocompatibility study, based on the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 5: Tests for Cytotoxicity: *in vitro* Methods guidelines, was conducted on the test article, LAD-06 Single Use Disposable Tips, to determine the potential for cytotoxicity. A single extract of the test article was prepared using single strength Minimum Essential Medium supplemented with 5% serum and 2% antibiotics (1X MEM). This test extract was placed onto three separate confluent monolayers of L-929 mouse fibroblast cells propagated in 5% CO_2. Three separate monolayers were prepared for the reagent control, negative control and for the positive control. All monolayers were incubated at 37°C in the presence of 5% CO_2 for 48 hours. The monolayers in the test, reagent control, negative control and positive control wells were examined microscopically at 48 hours to determine any change in cell morphology.

Under the conditions of this study, the 1X MEM test extract showed no evidence of causing cell lysis or toxicity. The 1X MEM test extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity). The reagent control, negative control and the positive control performed as anticipated.

Study and Supervisory Personnel:

James R. Smith, Ph.D.
Cindy Cheung, B.S.
Marcia Mestre, B.S.
Suzy Schmidt, B.S.

Approved by:

Lubica Mikula, B.S.
Study Director, Toxicology

04-30-03
Date Completed

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SUMMARY

A guinea pig maximization test of LAD-06 Single Use Disposable Tips, was conducted to evaluate the potential for delayed dermal contact sensitization. This study was conducted based on the requirements of the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Sensitization.

The test article was extracted in 0.9% sodium chloride USP (SC) and cottonseed oil, NF (CSO). Each extract was intradermally injected and occlusively patched to ten test guinea pigs (per extract) in an attempt to induce sensitization. The vehicle was similarly injected and occlusively patched to five control guinea pigs (per vehicle). Following a recovery period, the test and control animals received a challenge patch of the appropriate test article extract and the reagent control. All sites were scored at 24, 48 and 72 hours after patch removal.

Under the conditions of this study, the SC and CSO test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig.

Study and Supervisory Personnel:

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Manager, Toxicology and *In Vitro*

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SUMMARY

The test article, LAD-06 Single Use Disposable Tips, was evaluated for primary skin irritation in accordance with the guidelines of the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Sensitization. Two 25 mm x 25 mm sections of the test article and contr article were topically applied to the skin of each of three rabbits and left in place for 24 hours. The sites were graded for erythema and edema at 1, 24, 48 and 72 hours after removal of the single sample application.

Under the conditions of this study, no erythema and no edema were observed on the skin of the rabbits. The Primary Irritation Index for the test article was calculated to be 0.0. The response of the test article was categorize as negligible.

Study and Supervisory Personnel:

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4-22-03
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