



# NSAI

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## QUALITY MANAGEMENT SYSTEM MEDICAL DEVICE AUDIT REPORT

|                              |  |  |   |  |
|------------------------------|--|--|---|--|
| <b>Details of Assessment</b> | Company Name / Address:<br>(Legal Manufacturer)  | Life Science Outsourcing Inc.<br>830 Challenger Street Brea, CA 92821  |   |  |
|                              |  | Multi-Site ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No   |   |  |
|                              | Address of Audited Site(s):  | Site 1 Address:  |   |  |
|                              |  | <input type="checkbox"/> Headquarter <input type="checkbox"/> Manufacturing / Support location<br>Site 2 Address: (Manufacturing / Support location) |   |  |
|                              | No. of employees   | 57 persons   |   |  |
|                              | Management Representative / Regulatory Correspondent   | Mireya Lozano  |   |  |
|                              | Position in Organisation   | Management Representative  |   |  |
|                              | Audit Criteria<br>(Standards, regulations assessed)  | <input checked="" type="checkbox"/> ISO 13485:2003<br><br><input type="checkbox"/> ISO 9001:2000   | <input type="checkbox"/> 93/42/EEC<br><input type="checkbox"/> 98/79/EC<br><input type="checkbox"/> 90/385/EEC<br><input type="checkbox"/> 2000/70/EEC<br><input type="checkbox"/> 2003/32/EC | <input type="checkbox"/> CMDR<br><br><input checked="" type="checkbox"/> Other |
|                              | NSAI Lead Auditor  | Stuart Campbell  |   |  |
|                              | NSAI team members  | n/a  |   |  |
| Date(s) of Assessment        | 07 – 10 Apr 2009   |  |   |  |
| Duration of Assessment       | 3.5 on-site auditor days   |  |   |  |
| QMS Scope                    | The contract Manufacturing, package testing, warehousing and distribution of non-active invasive and non-invasive surgical devices, diagnostic equipment and active electro-medical device including surgical and monitoring probes and contract moist heat sterilization services in accordance with ISO 17665-1:2006 |  |   |  |
| Type of Audit                | Re-assessment audit  |  |   |  |

*C L I E N T   C O N F I D E N T I A L*

This report is the property of NSAI and confidential to NSAI and the above-mentioned client.

Distribution:  NSAI  
 CLIENT

## AUDIT CONCLUSION:

This audit was conducted on-site using methodology including document review, interviews with management and operational staff, observation of processes and surroundings, review of records, and a comparison of the Quality Management System, as documented and implemented, with the requirements of the above referenced standard(s) and/or regulations.

The method of assessment sampled the organization's activities to assess these for conformance with:

- the effective interaction between all elements of the system;
- the overall effectiveness of the system in its entirety;
- demonstrated commitment to maintain the effectiveness of the system.
- compliance with all applicable regulatory requirements

Because the assessment is based on a sample of the organisation's activities, the findings reported do not purport to include all issues within the system.

Based on the audit and a review of available objective evidence, it is the conclusion of the Lead Auditor that the above named company is:

**RECOMMENDED:**

The company can be recommended for certification / continued certification to the above listed standards, and has been found in general compliance with the applicable regulatory requirements listed above.

**RECOMMENDED - Corrective Action Closure Required (Category 1 findings):**

The company may be recommended for certification / continued certification, based upon satisfactory closure of all category 1 findings, and if applicable, a satisfactory corrective action plan for all Category 2 findings as shown in this report.

- Corrective actions DO NOT require an on-site re-audit to verify effective implementation  
 Corrective actions require an on-site re-audit by NSAI to verify effective implementation

**RECOMMENDED - Corrective Action Plan Required (Category 2 findings only):**

The company may be recommended for certification / continued certification, based upon the acceptance of a satisfactory corrective action plan for all Category 2 findings as shown in this report. Effective implementation of corrective actions will be reviewed during the next surveillance audit.

**NOT RECOMMENDED AT THIS TIME:**

The company cannot be recommended for certification / continued certification at this time.

## Appeals

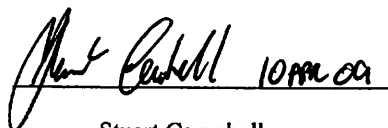
The attention of the Client is drawn to the existence of the NSAI Appeals Procedure.

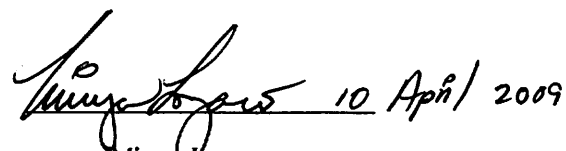
The following comprise this report

*These documents may be given to the client, on request.*

- |                                     |  |
|-------------------------------------|--|
| <input checked="" type="checkbox"/> | Audit Findings   |
| <input checked="" type="checkbox"/> | Audit Administrative Information   |
| <input checked="" type="checkbox"/> | Audit Details (Processes/Areas audited, Closure of previous findings)                              |
| <input type="checkbox"/>            | Database Information Sheet   |
| <input type="checkbox"/>            | Audit Plan for Next Visit (if not included, must be sent at least 10 days before next audit event. |
| <input type="checkbox"/>            | Checklist (if used)  |
| <input type="checkbox"/>            | Audit Trail  |
| <input type="checkbox"/>            | Other (please specify )  |

Signatures:

  
Stuart Campbell  
NSAI Lead Auditor

  
Mireya Lozano  
Audited Organization

# EXECUTIVE SUMMARY

Company overview

## Summary and Conclusion

Life Science Outsourcing Inc. with headquarters located at 830 Challenger Street Brea, CA 92821 (Administration, Purchasing, contract Manufacture, Warehouse, Distribution, Sterilization, calibration) the following products (multiple product families) for use in the area of (multiple areas as defined by the Customer who owns the product)

The following activities occur at these locations:

| Facility Address                     | Activities at location   | Products at location  |
|--------------------------------------|--|---|
| 830 Challenger Street Brea, CA 92821 | (Administration, Purchasing, contract Manufacture, Warehouse, Distribution, Sterilization, calibration.) | Customer Owned Products, ranging from complete assembly & sterilization to simple pouch and packaging |

### Outsourced processes:

The client does outsource critical processes.

Critical outsourced processes are described as follows:

| Outsourced Process             | Supplier Name / Address  | Certified by:                                   |
|--------------------------------|--|---|
| Offshore manufacturing         | [REDACTED]<br>Tijuana, Baja California                                 | TUV<br>[REDACTED]<br>ISO 9001:2000              |
| Biological & Microbial testing | Northview Laboratories<br>1880 Holste Road, Northbrook, Illinois 60062 | BSi for ISO 9001:2000<br>Certificate # FS 40654 |

Product conformity  
Critical Outsourced processes

Based upon a review of the client's management of the outsourced processes:

a.) The client's management of outsourced processes is sufficiently defined and controlled. Critical suppliers do not need to be visited as part of this audit.

### Sterilization:

The clients' products are supplied both sterile and non sterile.

Sterilization

| Device family             | Method | Sterilized by:  |
|---------------------------|--------|---|
| Various customer products | Gamma  | Steris Isomedix Services<br>1000 S.Sarah Dr., Ontario, CA 91761<br>BSi cert# MD 89745                 |
| Various customer products | Eto    | Centurion Sterilization Services<br>301 Catrell Drive, Howell, Michigan, 48843<br>BSi cert# MD 502195 |
| Various customer products | E beam | Nutek Corporation<br>30958 San Antonio St, Hayward, CA 94544<br>TUV cert# SD 60012963 0001            |

QMS documentation

Records related to the sterilization process were reviewed as part of this audit, and the sterilization process **does appear** to be in compliance with applicable sterilization standards and practices.

Internal audit process

The documented system is in place and documents were readily retrievable during the course of the audit.

Management Review

The internal audits show that they are being executed according to the programme and their effective role within the management system is demonstrated by the clear reports produced and audit schedule in place. A good degree of reliance can be placed on the internal audit process in monitoring system conformity and effectiveness.

Trends between audits

The last management review was held on 18 September 2008 & the next is currently scheduled to occur August 2009.

Continual improvement

The following trends were noted (relative to objectives and targets):

Competence

- 13% of Capa in 2008 did not meet the stated objective of having the investigation completed in ≤ 30 days
- 78 Customer complaints recorded in 2008 V's 18 YTD in 2009

Regulatory compliance / Effectiveness of QMS

The continual improvement process is performing adequately , the following example demonstrates this:

- Use of Just in Time process strategy in the purchasing process

Positive observations

A sample of the organisation's personnel have been audited and found to have evidence to demonstrate adequate competency for the process audited.

The appropriate regulatory requirements are being met, and the organisation's quality management system is systematically capable of meeting customer requirements. Please submit the corrective action plan for the category 2 findings to [REDACTED] and [REDACTED] by 10<sup>th</sup> May 2009.

Summary

The following positive observations were noted during the audit:

- Open positive approach to the audit throughout & good control & documentation evident in the training system.

Overall, the management system, with the exception of the findings noted on page 3 is compliant and its effectiveness has been