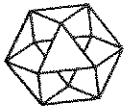
**NSAI**National Standards Authority of Ireland
Údarás Um Chaighdeán Náisiúnta na hÉireann20 Trafalgar Square Suite 603
Nashua, NH. 03063
Tel. (603) 882 4412 Fax (603) 882 1985**MEDICAL FLOWFORMA JOB NOTIFICATION****CSR: Diane Paz**

Company:	Life Science Outsourcing, Inc.	Certificate #:	MD19.4297
Division:		Cert Expiry:	6/30/2021
Accredited:	SCC	Date Registered:	8/23/2007
Contact:	Mireya Lozano	Status:	Registered
Phone:	(714)672-1090	Cell:	
E-Mail:	mlozano@lso-inc.com	DUNS #:	017149456
Site 1 Address: 830 Challenger Street Brea, CA			
Site 2 Address:			
SCOPE:	Contract Manufacture of Non-Active Invasive and Non-Invasive Surgical, and Active Electro-Medical Devices, and Distribution and Package Testing, Cleaning and Decontamination; Including Contract Moist Heat Sterilization and Validation Services in accordance with ISO 17665-1:2006 and Contract Ethylene Oxide Sterilization and Validation Services in accordance with ISO 11135:2014.		
Standard:	ISO 13485:2016	9k Cert Req: (AS/ MD only)	No
Headcount:	104	Profile Type:	Single
IAF Code:	14	Primary NANDO	MDS7006-R
Secondary IAF Code:		Secondary NANDO	MDS7006-E
		Tertiary NANDO	MDS7006-MH
ISO 13485 Exclusions:			
Audit Frequency:		# of Shifts:	1
CE Product:	N/A		
MDSAP:	Australia	United States	
	Schedule 3, Part 1	21 CFR Part 820	
	Schedule 3, Part 4	21 CFR Part 821	
	Japan	Canada	
	Brazil		

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ASSIGNMENT DETAILS			
Audit Type:	Surveillance	Start Date:	7/16/2019
Required additional documentation time (onsite)	.5 day Report Writing	Audit Days:	3 days total onsite (Includes Report Writing time)
File #s to be Audited:	MD19.4297		Auditor offsite time:
Lead Auditor Email:	Tiea Theurer	Tiea.Theurer@nsainc.com	.5 day Doc Prep .5 day Follow Up
Team Email(s):	N/A		

By accepting this project, the auditor confirms their availability and that the auditor has the required competence (EA Code/Nando Code) to accept the project. Additionally, the auditor does not have any conflict of interest with the above named company (e.g. training, consultancy, financial, personal or political) that would affect the integrity of the audit process and/or the recommended results. In the event a conflict is identified, NSAI is to be notified.

Next Audit Issue(s): None

Next Impartiality Issue(s): None

Office Comments:

POST AUDIT INFORMATION

Check NANDO Codes covered this audit:

MDS7006-R

MDS7006

MDS7006

-E

-MH

(Audit team must be qualified to cover NANDO)

Number of Majors

Number of Minors

Number of OFIs

MDSAP SPECIFIC AUDITS (Number of NC's Per Grade)

Grade 1s

Grade 2s

Grade 3s

Grade 4s

Grade 5s

If one or more **GRADE 5** non-conformities, or more than two **GRADE 4** non-conformities, or a public health threat, or any fraudulent activity or counterfeit product, NSAI will inform all participating Regulatory Authorities within **5 working days**.

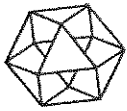
Nonconformity Corrective Action Plan due date:

Nonconformity implementation evidence due date:

(For Major and MDSAP Grade 4 and Grade 5 nonconformities)

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Nashua, NH. 03063
Tel. (603) 882 4412 Fax (603) 882 1985**Auditor Notes and Declaration:**

By my signature below, I am confirming that the audit was performed as listed above and all report documentation signature fields are affirmed and can be listed as "signature on file".

Lead Auditor: Tia Theurer

7/18/19

Signature

Date

Team Member(s):

Signature(s)

Date

CUSTOMER REPRESENTATIVE'S DECLARATION:

By my signature below, I am confirming to NSAI the audit activity has been completed, accepted the audit nonconformities, and understand the audit conclusions. Should I disagree, I understand my rights to request the NSAI appeal process and also agree to accept the decisions resulting from an independent review of this report.

All report documentation signature fields are affirmed and can be listed as "signature on file".

Client: Mireya Lozano

7/18/19

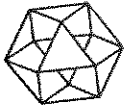
Signature

Date

Company:	Life Science Outsourcing, Inc.	Certificate #:	MD19.4297
Next Audit Type:	Surveillance	Next Audit Duration:	3 days
Next Audit Dates:	Due April 2020		

Note: Electronic copies of Non-conformance responses should be emailed to the Lead Auditor and copied to CARS@nsaiinc.com

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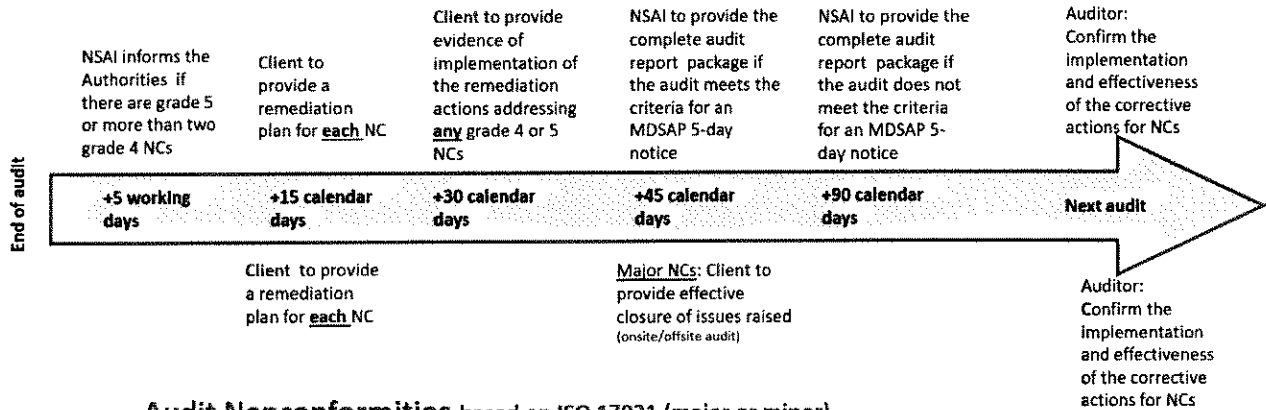
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Post Audit Timelines

*for MDSAP combined audits

Audit Nonconformities based on MDSAP grading (grade 1 through 5)



Audit Nonconformities based on ISO 17021 (major or minor)

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