



## American Global Standards Confidential Audit Report ISO 13485:2016

Organization:	Lonestar EMS, LLC. DBA Circuitronics, Inc.		
Location:	1900 Diplomat Drive Farmers Branch, Texas 75234 USA		
Type of Audit:	Medical Devices Management System		
Standard:	ISO 13485:2016: FDA QSR 21 CFR Part 820 cGMP		
Audit Dates:	November 04, 2025		
Management Rep. / E-mail:	Mary Sommer; Email: <a href="mailto:Marysommer@circuitronics.com">Marysommer@circuitronics.com</a>		
AGS Representative:	Jeff Porter : QMS & EMS Auditor		
Technical Expert / Trainee:	N/A		
Scope of Certification:	Providing World-Class Electronic Manufacturing Services for Commercial, Industrial, Medical (noninvasive), Mil-Aero and related markets; Capabilities including: PCBA, System Assembly and Test, NPI/Prototyping, Program Management, and Supply Chain services.		
No. of add'i sites / branches:	0		
No. of add'i sites audited:	0		
Results of the evaluation of the management documents and audits:	Y	The requirements of the standard on which the audit has been based have been satisfied, certificate award recommended	
	Y	Continuation of validity recommended.	
	n/a	Certificate expansion recommended.	
	N	Re-audit required (see Audit Nonconformities)	
	N	Submit new / additional documents.	
	N	Certificate suspension / withdrawal recommended.	
Environmental Aspect Complexity <i>(only for ISO 14001)</i>		Limited	Moderate
		Low	High
Re-Audit date: (corrective action)	N/A		
Audit Frequency	Annual		
Accreditation:	AIAO-BAR		



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### **1. Objective:**

*The objective of this audit was to:*

- Determine the extent of conformity of the Medical Devices Management System with the standard(s);
- Evaluate the capability of the Medical Devices Management System to ensure compliance with relevant statutory, regulatory and contractual requirements, as applicable;
- Evaluate the effectiveness of the Medical Devices Management System in meeting its specified objectives;
- Evaluate the operational control of processes, including internal audits and management review;
- Evaluate the management's responsibility for the company's policies
- Evaluate the links between the standard requirements and the Medical Devices Management System requirements.
- Identify areas for potential improvement of the Medical Devices Management System..

### **2. Company Information**

#### **2.1 General:**

The audit team reviewed and accepted the following clause exclusions to the standard:

- **6.12 Medical Device Risk Management, 7.5.2 Cleanliness of product, 7.5.3 Installation activities, 7.5.4 Servicing activities, 7.5.5 Requirements for sterile medical devices, 7.5.7 Requirements for validation of processes for sterilization and sterile barrier systems**

#### **3. Audit execution**

The practical implementation of the standard was evaluated and compared with the organization's Medical Devices Management System manual and supporting documents. The audit was conducted through discussions and interviews with personnel in various functions within organization.

The audit covered relevant documentation and processes / areas of the organization in order to obtain an overall understanding of the degree of Medical Devices Management System implementation. Although performed to reasonable depth, not every detail of the complete management system could be checked.

The processes and their associated areas of the organization were verified in accordance with the agreed audit plan, if applicable. Particular questions were used in support of the audit plan and audit question list.

Assessment of the audit results was made using the following categories:

**Nonconformities (N):** Corrective action is required before the decision to issue/continue certification.

**Opportunities for Improvement (I):** These are improvement possibilities of the management system. The overall requirements of the Standard are met.

**Positive remarks (P):** Comments made when a requirement was seen to be particularly well established and effective.



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**4. The following processes / clauses were audited:**

PROCESSES:	Cert / Repeat	Surveillance 1	CLAUSES:																					
			4.1	4.2	5.1	5.2	5.3	5.4	5.5	5.6	6.1	6.2	6.3	6.4	7.1	7.2	7.3	7.4	7.5	7.6	8.1	8.2	8.3	8.4
Documented Mgmt. Processes			X	X	X	X	X	X	X	X	X*	X	X	X	X	X	X	X*	X	X	X	X	X	X
Mgmt. Review			X	X	X	X	X	X	X	X*	X	X	X	X	X	X	X	X*	X	X	X	X	X	X
Documented Main Processes:			X	X	X	X	X	X	X	X*	X	X	X	X	X	X	X	X*	X	X	X	X	X	X
Support Proc.	See Document ID list																							
Internal Audits			X	X	X	X	X	X	X	X*	X	X	X	X	X	X	X	X*	X	X	X	X	X	X
Corrective Action			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Preventive Action			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



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### **5. Changes since the last audit:**

- Quality Manual System reviewed.
- All Policies & Procedures reviewed.
- Context of the Organization Process reviewed & approved.
- Leadership Process reviewed & approved.
- Planning Process reviewed & approved.
- Support Process reviewed & approved.
- Operation Process reviewed & approved.
- Performance Evaluation Process reviewed & approved.
- Improvement Process reviewed & approved.
- Internal Audits Summary: All requirements are Compliant, with zero (O) non-conformances observed.
- Nonconformities & Corrective Actions: For Year 2025, 6 open Incidents & 18 closed.
- Product On-time Delivery: No current issues to report.
- Customer Feedback: All positive feedback.
- Customer Complaints: No current customer complaints.
- Process Performance & Conformity of Products & Services: Did have issues with a new product 1st time build, but did end up shipping units to the customer - less than expected. Working major component issue now for next time run. Fast Photonics.
- Changes in External & Internal Issues: Testing out Artificial Intelligence (AI) to query component drawings. Investigating cost for AI, as well as other uses for AI.
- Monitoring & Measurement Results Processes: Ordering the new CAE 6-up Panel Selective Solder fixture to complete the remaining 4K+ order.
- Monitoring & Measurement Results Products: Received customer feedback regarding silver wire - strip insulation with solder iron & solder at the same time. This is not per IPC. PM & customer notified.
- On-time Delivery Suppliers: Strategic Suppliers increased but still under the threshold - Arrow & Digikey. All Receiving personnel will enter the date received as opposed to the date In-coming releases.
- Supplier Rejects: No current issues to report.
- Recommendations for Improvement: **1)** Making final adjustments regarding the shared FAI format document - anyone can edit at any time even if someone else is editing or has it open. **2)** Continuing to support the Selective Solder process. Procured 2 flux pots for the ANT regarding water soluble & no clean fluxes as well as additional fixtures. **3)** Keeping up with Incoming. Other than obtaining the needed documents, no other issues.

**Rev.: 3 – 05/23/2023**

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- Organization must notify the AGS Lead Auditor of all future significant changes made to the approved management system.

### **6. Summary**

The audit team was able to verify the effectiveness of the Medical Devices Management System in the audited areas by reviewing selected Medical Devices Management System documents and records.

- Management Meeting Minutes for 2025
- Internal Audit Reports dated November 03, 2025
- Reviewed & Approved on November 01, 2024
- ISO 13485:2016 Certificate Expires October 31, 2027

Departments audited are listed on the audit plan.



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**7. Audit results**

	yes	no	n/a
1. Correction and Corrective Action for Nonconformities identified during this audit were submitted and found to be acceptable.			X
2. The audit team evaluated the corrective action taken for all Nonconformities from the previous audit.	X		
3. The effectiveness of the Medical Devices Management System was assessed by Internal Audits and the results were supplied to Management Review.	X		
4. The auditors determined that the Medical Devices Management System is effective in ensuring that agreed requirements for any product or service supplied are met.	X		
5. Documentation contains a statement for Quality Policy, measurable goals and documented methods for their achievement.	X		
6. A central Management Review was carried out at least once annually.	X		
7. The central Management Review addresses the internal audit results from all locations. (multiple-site only).			X
8. The AGS auditors evaluated internal audit records for all locations under the scope of the certification. (multiple-site only).			X
9. A single quality management system exists for all locations. The Medical Devices Management System is managed centrally. (multiple-site only).			X
10. The organization has a method of collecting customer feedback, including customer complaints. The data is evaluated and corrective / preventive measures are taken.	X		
11. Minor nonconformities from the last audit were checked and the measures taken were seen to be effective.	X		
12. The auditors checked the use of the certification and AGS mark. (e.g., in marketing literature / internet). All uses are acceptable.	X		
13. The auditor(s) was/were convinced of the qualification and professional experience of those employees who were interviewed / whose records were supplied during the audit.	X		



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	yes	no	n/a
14. The authority and position of these employees were clearly defined.	X		
15. The organization provides resources for the improvement and maintenance of the Medical Devices Management System as well as for increased customer satisfaction.	X		
16. The organization ensures continual improvement of the Medical Devices Management System and customer satisfaction by measuring, analyses and actions.	X		
17. The organization's internal audit program can be relied upon to ensure that the Medical Devices Management System is effective and that requirements are being met.	X		
18. If a Repeat Audit, information over the past 3 years indicates positive trends and improvement in the Medical Devices Management System's effectiveness.	X		
19. When responding to AGS nonconformities the organization considered correction and corrective action for all sites and not just the site where the nonconformity was identified. (multiple-site only).			X

*Note: If any answer is "no", enter details below in Section 7 Action List*



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**Action List**

Clause Number	Process	N/C Type		Description of non-conformity MUST include: Requirement, Nonconformity Statement, and Objective Evidence	C/A Due Date(s)	Cause Analysis of the company Correction and Corrective Action (may reference attached internal corrective action)	N/C Corrected	C/A Plan Accepted	C/A Implemented
		Maj./Min.							
				<u>Requirement:</u>  <u>Description of N/C:</u>  <u>Supporting Audit Evidence:</u>					
				<u>Requirement:</u>  <u>Description of N/C:</u>  <u>Supporting Audit Evidence:</u>					

Date: November 04, 2025

AGS Rep.: Jeff Porter

Client Management Rep: Mary Sommer