



**Criterion Tool & Die, Inc./Criterion Instrument
Quality System Questionnaire**

Part 1: Company Profile

Company Name: Criterion Tool & Die, Inc./Criterion Instrument

Address: 5349 West 161st Street, Brook Park, Ohio 44142

Years in Business: 59 years

Hours of Operation: Office Hours: 8:00 am to 4:30 pm EST.

Product/Service Provided: Contract Manufacturer/Precision Machine Shop

Total Plant Area: 20,000 sq. ft.

Employees: 27

Part 2: Company Management Representative

Name & Title: Tanya DiSalvo, President

Phone: 216-267-1733

Email Address: tdisalvo@criteriontool.com

Part 3: Quality System

	<u>Item</u>	<u>Yes</u>	<u>No</u>	<u>N/A</u>	<u>Remarks</u>
1.0	Organization & Quality Management System				
1.1	Do you have a company organization Chart?	X			
1.2	Do you have a Quality Policy?	X			
1.3	Do you have a Quality Manual?	X			
1.4	Is your company ISO Certified?	X			
	If yes, Which Quality System and assessment by which regulatory body?	X			ISO 9001:2008, SAI Global
	Please state date of certification, expiration date and attach a copy of the certification.				Expires: May 2015
	If no, do plans exist to obtain accreditation? If yes, by when?				
1.5	Has your facility been inspected by a government/ regulatory agency?	X			
	If yes, please state date and provide a copy of you latest registration.	X			FDA# 152 8668
1.6	Do you have employee job descriptions?	X			
1.7	Are employees formally trained in their respective jobs?	X			
1.8	If yes, is the training documented?	X			



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2.0 Others		Yes	No	N/A	Remarks
Item		Yes	No	N/A	Remarks
2.1	Do you have procedures or records to document & approve all changes made in manufacturing processes?	X			
2.2	Can certificates of material or processing certificates be traced back to the original results or supplier certifications?	X			
2.3	Do you retain quality records that pertain to the manufacturing, processing or services CTD? If so how long are your quality records affecting traceability retained?	X			Per customer requirements.
2.4	Are finished goods inspected and test results documented prior to delivery?	X			
2.5	Do you provide service/test reports upon completion of a manufacturing or service activity?	X			Per customer requirements.
3.0 Procedures		Yes	No	N/A	Remarks
Do you have written procedures for:					
		Yes	No	N/A	Remarks
3.1	Management Responsibility	X			
3.2	Quality Management System	X			
3.3	Order Processing & Review	X			
3.4	Design Control			X	
3.5	Control of Documents	X			
3.6	Control of Records	X			
3.7	Purchasing & Supplier Evaluation/Monitoring	X			
3.8	Control of Customer Supplied Product	X			
3.9	Product Identification & Traceability	X			
3.10	Control of Production & Service Provision	X			
3.11	QA inspection processes	X			
3.12	Control of Monitoring & Measuring devices	X			
3.13	Preventive Maintenance	X			
3.14	Control of Non-conforming product/material	X			
3.15	Corrective & Preventative Action	X			
3.16	Handling & Preservation of products	X			
3.17	Complaint Handling/Customer Satisfaction/Feedback	X			
3.18	Internal Audit	X			
3.19	Training/Development	X			
3.20	Installation & Servicing			X	
3.21	Risk Analysis			X	



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4.0		Records			
Do you maintain records for:					
		<u>Yes</u>	<u>No</u>	<u>N/A</u>	<u>Remarks</u>
4.1	Internal Audit	X			
4.2	Management Review	X			
4.3	Corrective/Preventative Action	X			
4.4	Order Processing & Review	X			
4.5	Design Control			X	
4.6	Purchasing & Supplier Evaluation Monitoring	X			
4.7	Control of Customer supplied product	X			
4.8	Product Identification & Traceability	X			
4.9	Control of Production & Service Provision	X			
4.10	QA inspection processes	X			
4.11	Housekeeping/Sanitation	X			
4.12	Control of Monitoring & Measuring Devices	X			
4.13	Preventative Maintenance	X			
4.14	Control of Non-Conforming Product/Material	X			
4.15	Handing & Preservation of Products	X			
4.16	Risk Analysis			X	
4.17	Training/Development	X			
4.18	Installation & Servicing			X	
4.19	Complaint Handling/Customer Satisfaction/Feedback	X			