



Date:	
Company Name:	
Address:	
CITY, STATE, ZIP	
Product:	
Website:	
Telephone No:	
Fax No.:	

(Relevant copies, booklets and additional information material can be attached)

A. General Information

Manufacturer <input type="checkbox"/>	Distributor <input type="checkbox"/>	Service <input type="checkbox"/>	Consultant: <input type="checkbox"/>
Founding year:			
Form of organization:			
Product portfolio/ Core competencies:			
Manufacturing processes:			

Type of Company: Private Private Corporation Public Corporation

B. Key Personnel/Contacts

Dept.	Name	Title
Quality		
Development/Engineering		
Production Manager		
Financial		
Sales		
Customer Service		

C. Employees

Total # of Employees:		# of Shifts Being Worked:	
Total # of Production Employees:		Working hours per shift:	
Total # of part time/temp. Employees:		Union Representation:	
Total # of Development Employees:		Name of Union(s):	
Total # of Quality Employees:		Name of Unios(s)	



D. References/Customers (especially in medical technology)

Company	Contacts	Phone no.

All Manufacturers complete the following sections E, F, G, H, I, and J.1. If you are not an ISO Certified Manufacturing company you will also need to complete sections J.2, J.3, J.4 and J5.

All Distributors complete the following sections E, J.1. If you are not an ISO Certified Distributor you will also need to complete sections J.3

All Service providers complete the following section E, G, J.1.

All Suppliers complete section K as applicable.

E. Financial

Annual sales:		% of Medical Business:	
D & B Rating:			
Annual spend for innovation:			
Annual purchasing expenditures:			

NOTE: If company published an Annual Financial Report and information is generally available to the public, please attach and return with survey.

F. Facilities / Environmental

# of Buildings:		Production SF:	
Overall condition of Bldg (s):		Office SF:	
Age of building(s):		Warehouse SF:	
Building Construction Type:		Cleanroom(s) (incl. class):	
% Production-vs-Full Capacity:		Testlabor(s):	
Facility: <input type="checkbox"/> Owned <input type="checkbox"/> Leased <input type="checkbox"/> Rented			
Fire preventions:			
Is an environmental management system established?			Yes No
<i>Describe:</i>			
The compliance with all relevant legal requirements with respect to environmental aspects (air, water, hazardous waste generation and disposal...) is ensured and monitored.			Yes No
<i>Describe:</i>			



G. Equipment /: Provide equipment list if applicable.

Type of equipment:
Age of equipment:
Condition of equipment
Load factor of the equipment:
Preventive maintenance program: documented:
Equipment: : Owned: <input type="checkbox"/> Leased: <input type="checkbox"/> Customer owned: <input type="checkbox"/>

H. Engineering/Test- and measurement capabilities:

What software is used for CAD/CAM?
What kind of test and analysis methods can be performed in-house?
What test, measurement and analysis equipment is available?
Tooling department is available? Yes No
<i>Short description</i>
Prototype manufacturing is available? Yes No
<i>Short description</i>
The status of projects are regularly evaluated, changes documented and results are verified and validated against customer requirements Yes No
<i>Short description</i>

I. Process Controls:

Describe your process controls.



J. Quality assurance

1. Quality management system

How long are quality records retained?		
Certification accredited to	<input type="checkbox"/> ISO 9000 <input type="checkbox"/> ISO 9001 <input type="checkbox"/> ISO 13485 <input type="checkbox"/> none <input type="checkbox"/> others _____	
Certification expiry date:	Date: _____	Provide a copy of current Certification.
FDA Registration	<input type="checkbox"/> yes if yes, since when?: _____ <input type="checkbox"/> none FDA Registration number: _____	
Are you open to a Supplier Quality Audit? <input type="checkbox"/> Yes <input type="checkbox"/> No		
If not ISO Certified; provide evidence of a Documented Quality System (i.e. Quality Manual, List of Standard Operating Procedures...)		

2. Document control:

A structured document management system is established.	Yes	No
<i>Describe:</i>		
A defined document change and release procedure is established.	Yes	No
<i>Short description:</i>		
A complete description of the production process by means of working instructions, control plans etc. is prepared and available at the working stations.	Yes	No
<i>Short description:</i>		
Router/ Shop traveler has revision and Lot control.	Yes	No
<i>Short description:</i>		

3. Purchased material & and components:

A system exists to evaluate, select and monitor suppliers.	Yes	No
<i>Short description:</i>		
Documented shipping and receiving guidelines exist.	Yes	No
<i>Short description:</i>		
Material certs. on file with Lot traceability.	Yes	No
<i>Short description:</i>		
Material is properly identified and stored.	Yes	No
<i>Short description:</i>		



Paints, Inks, Adhesives, etc., are on a Shelf Life Program.	Yes	No
<i>Short description:</i>		
Tooling is properly identified and stored.	Yes	No
<i>Short description:</i>		
Processes or services that are conducted by subcontractors:		
<i>Short description:</i>		

4. Process Control

Full time Inspection staff.	Yes	No
<i>Short description:</i>		
Incoming material is inspected by QC using appropriate statistical sampling.	Yes	No
<i>Short description:</i>		
Dedicated inspection area is in place.	Yes	No
<i>Short description:</i>		
First samples are evaluated and approved in writing.	Yes	No
<i>Short description:</i>		
In-process controls are established and documented.	Yes	No
<i>Short description:</i>		
Process capabilities by means of statistical process control are monitored and reviewed.	Yes	No
<i>Short description:</i>		
Final inspections acceptable to customer requirements are performed.	Yes	No
<i>Short description:</i>		
Measurement and test devices are registered, monitored and capable.	Yes	No
<i>Short description:</i>		
Documented calibration program is in place:	Yes	No
<i>Short description:</i>		
The Ship-To-Stock procedure is applied with other customers (Skip of incoming inspections).	Yes	No
<i>Short description:</i>		
ESD Compliance is monitored (if applicable):	Yes	No
<i>Short description:</i>		



5. Quality control

Suppliers have documented quality systems.	Yes	No
<i>Evidences are?:</i>		
Quality authorities and responsibilities are defined in writing.	Yes	No
<i>Where?</i>		
Defect material is separated, analysed and corrective actions are defined.	Yes	No
<i>Short description:</i>		
Formal Corrective Actions are initiated and monitored.	Yes	No
<i>Short description:</i>		
Formal internal auditing system is in place.	Yes	No
<i>Short description:</i>		
Quality and defect data are monitored, evaluated on trends and appropriate improvement actions are defined.	Yes	No
<i>Short description:</i>		
Customer complaints are prioritized and promptly resolved.	Yes	No
<i>Short description:</i>		
The customer satisfactions is regularly measured and reviewed.	Yes	No
<i>Short description:</i>		
Customer is notified of all material / process changes.	Yes	No
<i>Short description:</i>		
The qualification/training of the employees is documented and maintained.	Yes	No
<i>Short description:</i>		

K. Other information about the company as enclosure