ANDERSEN PRODUCTS

Andersen Products, Inc.
Health Science Park
3202 Caroline Drive
Haw River, North Carolina 27258
Phone: 336 376-3000 Fax: 336 376-8153
SOP QAP004. Attachment 1 ECN #931

Supplier Survey Form

Company Surveyed		
Address		
City	State	Zip Code
Telephone	Fax	
Name of personnel	Designation	

Part I General Information

Years in Business	Privately owned	Subsidiary, division, Facility of

List Major Customers _____

_____

_____

Not Available ☐

Type of Contract Contract _____

_____

_____

Not Available ☐

Products for which Survey was performed _____

_____

1. *Is the Company ISO Certified?* YES ☐ NO ☐
(If 'YES' please enclose copy of the Certification)
2. Is there a defined program to review production records? YES ☐ NO ☐
3. Is there an internal Audit Program ? YES ☐ NO ☐
4. Does your company follow GMP/is facility clean and orderly? YES ☐ NO ☐
5. Do you have equipment maintenance logs ? YES ☐ NO ☐
6. Is all equipment used in calibration? YES ☐ NO ☐
7. Are there specifications for incoming material? YES ☐ NO ☐

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8. Has the manufacturer been inspected by any State or Federal agency within the last 2 years ? YES ☐ NO ☐

(If 'YES' give the Name of the Agency : _____)

Part II Purchasing

1. Is qualification based on written specifications and approval of supplier source YES ☐ NO ☐
2. Materials visibly marked as

Sampled ☐ Approved ☐ Rejected ☐ Not marked ☐

Part III Manufacturing

1. General housekeeping and environmental factors good YES ☐ NO ☐
2. Production equipment maint. and service records available YES ☐ NO ☐
3. Calibration records kept on periodic basis YES ☐ NO ☐
4. Production documents traceable by Lot # or Serial # YES ☐ NO ☐

Part IV Packaging

1. Under supervised control YES ☐ NO ☐
2. Are there written procedures for disposing of or reworking rejected items ? YES ☐ NO ☐

Part V Sterile Components (if applicable)

1. Are there procedures for establishing aseptic conditions ? YES ☐ NO ☐
2. Are there methods for routine auditing of sterile areas used? YES ☐ NO ☐

Part VI Others

1. Is the plant registered as a device manufacturer YES ☐ NO ☐
2. Is the product used tested prior to final release YES ☐ NO ☐
3. Are Quality control procedures in a formal written document YES ☐ NO ☐
4. Does quality control inspection group have full authority to withhold shipment or further production of rejected items YES ☐ NO☐