

Quaker Special RIsk 12 Christopher Way, Suite 201 Eatontown, New Jersey 07724

Medical Device Manufacturers

If a question in this application is not applicable to your business, please mark it NA. If you need more room to answer any question, please attach a separate sheet of paper with the question number clearly labeled.

Insured Name:

Internet Utilization

What is the extent of your Internet usage? Check all the apply:

Access: Company personnel access the Internet.

Presence: Company has published a Web site.

If so, provide the Internet address (URL):

E-Commerce: Company uses the Internet as a channel for commerce, sales and service.

If so, what percent of income is derived from Internet activities:

Income may derive from Internet related: sales of products or services, advertising revenues (incl. banner ads), subscription fees, licensing or franchise fees, or transaction fees.

Describe any planned changes in Online or other business operations in the next year:

Website Risk Management	(Complete only	/ if an Internet usage box is checked above.)	

a.	Do all employees' computers have anti-virus software?	🗌 Yes 🗌 No
	If so, does the company upgrade the software to latest versions?	🗌 Yes 🗌 No
b.	Are firewalls installed to prevent unauthorized access?	Yes No
c.	How regularly are your Web site and other business critical data backed up?	Daily Weekly Monthly Other
d.	Is the Web site back up copy maintained at a separate physical location?	Yes No
e.	Is all Web site content reviewed by legal counsel prior to posting?	Yes No

%

Your Business

Description of Products/Services		
Revenue Distribution	Estimated % of Total Revenue for Current Fiscal Year	Estimated % of Total Revenue for Next Fiscal Year
Medical Devices or Equipment Mfg.		
Research & Development	Use Payroll, if no product sales	
Medical Equipment Rental & Service		
Other		

1. Have you obtained any of the following Quality Registrations:				
		ISO		
9000	9001	13485	Other:	
9002	9003	15378	Other:	
If yes, please indicate:	Name of Product/Completed Operations Carrier			
	Limits of Liability			
	Effective Date of Policy			

2. Are you currently participating in any clinical trials?				🗌 Yes 🗌 No
If yes, please indicate:				
	# of Trials	Trial Length	Trial Location	Conducted by You/Subcontractor
Phase 1				
Phase 2				
Phase 3				
a. Could the trials be interrupted if there was a loss at your facility?			🗌 Yes 🔲 No	

Business Interruption

3. Do you have a written Business Continuity Plan?	🗌 Yes 🗌 No
a. Does it include contingencies for failure of key production equipment?	🗌 Yes 🗌 No
b. Does it include contingencies for failure of key facility systems (boiler, chillers, HVAC)?	🗌 Yes 🗌 No

4. Are FDA certification papers stored offsite?	🗌 Yes	🗌 No
5. How often do you back up electronic records?	☐ Daily ☐ Week ☐	ly
6. Are back up records stored in an off site facility?	🗌 Yes	🗌 No
7. How often do you send back up electronic records to the off site facility?	☐ Daily ☐ Week ☐	ly
8. Do you have a process to test stored back up data?	🗌 Yes	🗌 No
If yes, describe the process:		
9. How long would it take you to be fully restored to pre-loss income and/or research levels after a total loss?		Months

Property Information

10. Indicate ("	'X") all of the follow	ing that apply to	your business:
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	Please list class and size of each clean room:			
Clean Rooms	Class:	Size:	Square Fee	et
	Class:	Size:	Square Fee	et
a. Would a loss of clean roc systems result in a loss o	m integrity due to power interrup f product?	tion and/or failure of HVAC	□ Yes □] No
b. How long would it take to	resume operations due to a loss	s of clean room conditions?	N	Nonths
Metal Forming	Indicate square footage associa	ated with these operations:		
Glass Blowing	Indicate square footage associa	ated with these operations:		
11. Are all of your facilities prote	ected by an automatic sprinkler s	ystem?	□ Yes □	No
If no, describe facilities/areas not sprinklered:				
12. Are all of your facilities prote	ected by a fire detection system ((heat/smoke)?	Yes] No
If no, describe facilities/area	as not protected:			

13. Do you require security access for your premises?	Yes No
14. Are all of your facilities protected by a central station intrusion alarm?	🗌 Yes 🗌 No
If no, describe facilities/areas not protected:	
15. Do you have a patent for your product?	Yes No
16. What is the maximum amount of time it would take to replace raw materials used in research and/or manufacturing?	Months
17. Do you have a documented employee safety program?	Yes No

APPLICANT'S STATEMENT: I have read the above application and declare that to the best of my knowledge and belief all of the foregoing statements are true, and that these statements are offered as an inducement to the Company to issue the policy for which I am applying. (Kansas: This does not constitute a warranty.)

FRAUD STATEMENT - NEW YORK INSURANCE LAW. Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance containing any false information, or conceals, for the purpose of misleading, information concerning any fact material thereto commits a fraudulent insurance act, which is a crime.

Applicant's Signature

Producer's Signature

Date

Date