NEW ENGLAND EXCESS EXCHANGE

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MEDICAL DEVICES AND DURABLE MEDICAL EQUIPMENT SUPPLEMENTAL APPLICATION

COMPLETE IN ADDITION TO ACORD APPLICATIONS.

ATTACH ADDITIONAL SHEETS AS NECESSARY.

ANSWER ALL QUESTIONS. If not applicable, indicate N/A.

GENERAL INFORMATION

1)

Named Insured:	
Additional Named Insureds:	
Brokerage/Broker:	Agency/Agent:
Effective Date:	
Website:	

2)

Carrier:			
Limit of Insurance:			
Deductible:		Premium:	
Policy Term Dates:			
Offering renewal? Yes ☐ No ☐	Claims made? Yes ☐ No ☐	Retroactive date:	

Please attach copies of the following:

a) Currently valued five year loss runs, including claim detail for all losses open or exceeding $15,000

b) Your product brochure, catalog, or marketing materials if a website is not available

c) A copy of your current financial statement, including balance sheet and income statement

d) A copy of your expiring policy Declarations page for retroactive date and limits continuity

3) Mailing Address: _____

City: _____ State: _____ Zip Code: _____

4) Premise Address (if different from above): _____

City: _____ State: _____ Zip Code: _____

5) Are you a(n): ☐ Corporation ☐ Individual ☐ Partnership ☐ LLC
☐ Joint Venture ☐ Other: _____

6) Your enterprise is:
☐ For Profit ☐ Not for Profit ☐ Other: _____

7) Audit/Inspection contact: _____

a. Phone number: _____

b. Email: _____

OPERATIONAL INFORMATION

8) What are your operations? _____

_____

9) Please complete the below table regarding your sales:

Upcoming Year (est.):	Last 12 Months:	One Year Prior:	Two Years Prior:	Three Years Prior:

10) What percentage of your sales are outside of the United States? _____

11) What percentage of your sales (or rentals) are of physician prescribed equipment? _____

12) Provide the following information for those products, goods and/or services you want coverage for. Only those products, goods and services listed below will be considered for coverage.

Products and Services	Applicant Acts as a(n)					No. of Years	% of Gross Receipts	Products and Goods sold to:				
	M	**W**	**R**	**I**	**MR**			**M**	**W**	**R**	**C**	**O**

M: Manufacturer **W:** Wholesaler **R:** Retailer **I:** Importer **MR:** Manufacturer's Rep. **C:** Consumer Direct

O: Other (describe):_____

13) Are any new products to be introduced during the next year? Yes ☐ No ☐

a. If yes, please provide details: _____

14) Have you discontinued any products since last year? Yes ☐ No ☐

a. If yes, please provide details: _____

15) Do you directly import any products or component parts? Yes ☐ No ☐

a. If yes, please attach a complete list of imported products or parts including the percentage of total sales, manufacturer, and country of origin.

16) Do you obtain Certificates of Insurance including coverage for Products Liability from each of your suppliers? Yes ☐ No ☐

a. Are you listed as an Additional Insured on these policies, or do you require proof of a blanket Additional Insured – Vendor endorsement? Yes ☐ No ☐

b. What minimum limits do you require? _____

17) Do you design your products? Yes ☐ No ☐

a. If no, who designs your products? _____

18) Are designs reviewed, tested, and verified by an independent third party? Yes ☐ No ☐

19) Are all warning labels, instructions, and advertising material reviewed by outside counsel? Yes ☐ No ☐

20) Do your products meet applicable government or industry standards? Yes ☐ No ☐

21) Are you a member of any trade organizations? Yes ☐ No ☐

a. If yes, please list: _____

22) Do you have ISO 9000, QS 9000, or any similar certifications? Yes ☐ No ☐

23) Do you comply with Good Manufacturing Practices (GMP)? Yes ☐ No ☐

24) In the event that it becomes necessary to recall a product, do you have a recall plan in place? Yes ☐ No ☐

a. Do you have Product Recall insurance? Yes ☐ No ☐

b. What means would be used to secure the return and disposal of the product? _____

_____

25) Have you ever had a product recall event? Yes ☐ No ☐

a. If yes, supply the following details: Date of recall(s): _____

b. Voluntary? ☐ Ordered? ☐ By what agency? _____

c. Product(s) involved: _____

d. Reason for recall and how discovered: _____

e. What was the remedy for the problem? _____

f. What percentage of recalled goods were returned/repaired? _____

26) Are there any present situations that might give rise to an incident causing a product recall? Yes ☐ No ☐

If yes, please provide details: _____

_____

27) Do you offer any white labeling services (manufacturing of products which are then sold under another entity's brand name or label)? Yes ☐ No ☐

a. If yes, are all of your products sold white label? Yes ☐ No ☐

28) Are any products sold under your brand name or label produced by another entity under a white label agreement? Yes ☐ No ☐

a. If yes, do you utilize the same company for all subcontracted manufacturing? Yes ☐ No ☐

b. Please list companies: _____

29) Are batch or product records, serial numbers or copies of guarantee/warranty cards maintained that would facilitate tracing whereabouts of products? Yes ☐ No ☐

a. If yes, confirm how long these records are maintained: _____

b. Do these records include:

+ When and where the product was manufactured? Yes ☐ No ☐
+ To whom the product was sold and the date of sale? Yes ☐ No ☐
+ Who manufactured or supplied the product or ingredients? Yes ☐ No ☐
+ Changes in formula/formulation notes? Yes ☐ No ☐
+ Changes in advertising material/packaging notes? Yes ☐ No ☐

30) Do you have a formal written internal quality control and testing program? Yes ☐ No ☐

a. If yes, confirm how long these records are maintained: _____

MEDICAL DEVICES AND EQUIPMENT

31) Do you rent equipment? Yes ☐ No ☐

32) Do you buy, sell, or rent used equipment? Yes ☐ No ☐

a. If yes, what percentage of your revenues is from used equipment sales/rental? _____

b. Do you recondition or repair used equipment prior to resale or rental? Yes ☐ No ☐

33) Are Material Safety Data Sheets (MSDS) and Scheduled Maintenance Procedures (SMPs) issued to each customer? Yes ☐ No ☐

34) What is the percentage of your revenues (sales and rentals) for the following medical equipment/devices? Check all that apply:

Equipment/Device	Percentage of Revenues Last 12 Months	Estimated Percentage of Revenues Next 12 months	Equipment/Device	Percentage of Revenues Last 12 Months	Estimated Percentage of Revenues Next 12 months
☐ ADL Device	%	%	☐ Apnea Monitor	%	%
☐ Beds, Walkers, Crutches	%	%	☐ CPAP Device	%	%
☐ CPM Device	%	%	☐ Diabetic Supplies	%	%
☐ Defibrillators	%	%	☐ Disposables	%	%
☐ Endoscopes	%	%	☐ Lasers	%	%
☐ Latex Gloves (powdered)	%	%	☐ Latex Gloves (powder-free)	%	%
☐ Lift Chairs	%	%	☐ Motorized Scooters	%	%
☐ Motorized Wheelchairs	%	%	☐ Orthotics	%	%
☐ Oxygen Concentrators	%	%	☐ Oxygen Cylinders	%	%
☐ Parenteral Therapy	%	%	☐ PPE	%	%
☐ Prosthetics	%	%	☐ Safety Bars/ Harnesses	%	%
☐ Stair/Ceiling Lifts	%	%	☐ TENS Units	%	%
☐ Ventilators	%	%	☐ Wheelchairs	%	%
☐ Wheelchair Lifts	%	%	☐ Other: _____	%	%
☐ Other: _____	%	%	☐ Other: _____	%	%

35) What is your revenue for all FDA Class I medical devices? _____

a. What percentage of this revenue is rentals? _____

36) What is your revenue for all FDA Class II medical devices? _____

a. What percentage of this revenue is rentals? _____

37) What is your revenue for all FDA Class III medical devices? _____

a. What percentage of this revenue is rentals? _____

38) Please indicate what percentage of your devices are classified as the following:
   a. Implantable Devices: _____
   b. Orthopedic/Prosthetic: _____
   c. Dental: _____
   d. Pediatric: _____
   e. Durable Medical Equipment: _____
   f. Medical Instruments: _____

39) What percentage of your products contain silicone? _____

40) What percentage of your products contain latex? _____

41) Are any of your products currently being used in a clinical trial or any other tests involving human subjects? Yes ☐ No ☐
   a. If yes, please attach details about the trials, tests, or studies. ***If you are involved in the trials, tests, or studies and are seeking Professional Liability coverage for this exposure, please complete the Kinsale Allied Health Clinical Trials Supplemental Application.***

42) Do you promote your products for any off-label use? Yes ☐ No ☐
   a. If yes, please attach a description of the product(s), its approved use, the off-label use you are promoting, and supporting documentation of the acceptability of such off-label use.

INSTALLATIONS *(complete this section only if you or someone on your behalf is installing/servicing equipment)*

43) Do you have any installation, service, or repair operations? Yes ☐ No ☐
   a. If yes, please describe: _____
   b. Do you hire subcontractors to perform any work on your behalf? Yes ☐ No ☐
   c. Do you collect certificates of insurance from all subcontractors prior to the beginning of work? Yes ☐ No ☐

44) Is all service and repair work performed by factory-trained personnel? Yes ☐ No ☐

45) Is all maintenance performed and documented according to the manufacturer's guidelines? Yes ☐ No ☐

46) What is the percentage of your revenues correlating to installation, service, or repair of the following medical equipment/devices? Check all that apply:

Equipment/Device Install, Service, or Repair	Percentage of Revenues Last 12 Months	Estimated Percentage of Revenues Next 12 months	Equipment/Device Install, Service, or Repair	Percentage of Revenues Last 12 Months	Estimated Percentage of Revenues Next 12 months
☐ Ceiling Lifts	%	%	☐ Elevators	%	%
☐ Grab Bars	%	%	☐ Ramps	%	%
☐ Stair Lifts	%	%	☐ Wheelchair Lifts	%	%
☐ Wheelchair Lifts in Autos	%	%	☐ Auto Hand Control Conversions	%	%
☐ Aquatic Lifts	%	%	☐ Other: _____	%	%
☐ Other: _____	%	%	☐ Other: _____	%	%

STAFF

47) Do you require all sales and service personnel to participate in a formal program that instructs them on all applicable company policies, procedures, and product training? Yes ☐ No ☐

48) Please complete the following for your staff:

	Number Employed		Number Contracted	
	Full-Time	Part-Time	Full-Time	Part-Time
Physician				
Physical Therapist				
Respiratory Therapist				
Service Technician				
Pharmacist				
RN, LPN				
CRNA				
X-Ray Technician				
Other: _____				

49) Are all of the individuals included in the table above licensed in accordance with applicable State and Federal regulations? Yes ☐ No ☐

50) Which of the following procedures do you use for hiring/screening employees? Check all that apply:

☐ Check of educational background
☐ Check of residency program
☐ Check of previous employers – In writing
☐ Check of previous employers – By telephone
☐ Criminal background check – State
☐ Criminal background check – Federal
☐ Driver's license verification
☐ MVR Check
☐ Drug screening
☐ Alcohol screening
☐ Abuse screening
☐ Reference verification
☐ Verification of license validity, suspensions, revocations, citations, or pending disciplinary actions
☐ Verification of any pending disciplinary actions by current or previous employers
☐ Other: _____

COVERAGE AND LOSS HISTORY

51) Have you been inspected by the FDA in the last five years? Yes ☐ No ☐

a. If yes, please list dates: _____

_____

b. Were you issued an FDA 483 form? *If yes, please attach copies as well as your response.* Yes ☐ No ☐

52) Have you received any customer complaints in the last five years? Yes ☐ No ☐

a. If yes, how many? _____

b. Please attach a description of product and complaint details, responses, investigations or testing, etc. in response to these complaints.

53) Have any adverse events concerning your products been reported to you or the FDA in the last five years? Yes ☐ No ☐

a. If yes, how many? _____

b. Please attach a description of product and adverse event details, responses, investigations or testing, etc. in response to these events.

54) Have you been cited by any regulatory agency for violations arising out of business activity involving your product(s)? If yes, please provide details: _____ Yes ☐ No ☐

_____

55) Have you had any Product Liability claims that were or were not covered by insurance? **If yes, please attach an explanation.** Yes ☐ No ☐

56) During the past five years, has any insurer ever canceled or non-renewed similar insurance to any applicant or has your insurance been canceled for nonpayment of premium by any insurance or finance company? **If yes, please attach an explanation.** Yes ☐ No ☐

57) Is your company aware of any occurrences, facts, circumstances, incidents, situations, damages or accidents arising out of or related to your operations that a reasonably prudent person might expect to give rise to a claim or lawsuit whether valid or not which might directly or indirectly involve the company? **If yes, please attach an explanation.** Yes ☐ No ☐

FRAUD WARNING

NOTICE TO ALABAMA, ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, CONNECTICUT, DELAWARE, GEORGIA, IDAHO, ILLINOIS, INDIANA, IOWA, KANSAS, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MISSISSIPPI, MISSOURI, MONTANA, NEBRASKA, NEVADA, NEW HAMPSHIRE, NORTH CAROLINA, NORTH DAKOTA, OREGON, RHODE ISLAND, SOUTH CAROLINA, SOUTH DAKOTA, TEXAS, UTAH, VERMONT, WASHINGTON, WEST VIRGINIA, WISCONSIN, AND WYOMING APPLICANTS: In some states, any person who knowingly, and with intent to defraud any insurance company or other person, files an application for insurance or statement of claim containing any materially false information, or, for the purpose of misleading, conceals information concerning any fact material thereto, may commit a fraudulent insurance act which is a crime in many states.

NOTICE TO COLORADO APPLICANTS: It is unlawful to knowingly provide false, incomplete or misleading facts or information to an insurance company for the purpose of defrauding or attempting to defraud the company. Penalties may include imprisonment, fines, denial of insurance and civil damages. Any insurance company or agent of an insurance company who knowingly provides false, incomplete or misleading facts or information to a policy holder or claimant for the purpose of defrauding or attempting to defraud the policyholder or claiming with regard to a settlement or award payable for insurance proceeds shall be reported to the Colorado Division of Insurance within the Department of Regulatory Agencies.

NOTICE TO DISTRICT OF COLUMBIA APPLICANTS: **WARNING:** It is a crime to provide false or misleading information to an insurer for the purpose of defrauding the insurer or any other person. Penalties include imprisonment and/or fines. In addition, an insurer may deny insurance benefits if false information materially related to a claim was provided by the applicant.

NOTICE TO FLORIDA APPLICANTS: Any person who knowingly and with intent to injure, defraud or deceive any insurance company files a statement of claim containing any false, incomplete or misleading information is guilty of a felony of the third degree.

NOTICE TO HAWAII APPLICANTS: For your protection, Hawaii law requires you to be informed that presenting a fraudulent claim for payment of a loss or benefit is a crime punishable by fines or imprisonment, or both.

NOTICE TO KENTUCKY APPLICANTS: Any person who knowingly and with intent to defraud any insurance company or other person files an application for insurance containing any materially false information or conceals, for the purpose of misleading, information concerning any fact material thereto commits a fraudulent insurance act, which is a crime.

NOTICE TO LOUISIANA APPLICANTS: Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to fines and confinement in prison.

NOTICE TO MAINE APPLICANTS: It is a crime to knowingly provide false, incomplete or misleading information to an insurance company for the purpose of defrauding the company. Penalties may include imprisonment, fines, or denial of insurance benefits.

NOTICE TO NEW JERSEY APPLICANTS: Any person who includes any false or misleading information on an application for an insurance policy is subject to criminal and civil penalties.

NOTICE TO NEW MEXICO APPLICANTS: Any person who knowingly presents a false or fraudulent claim for payment of a loss or benefit or knowingly presents false information in an application for insurance is guilty of a crime and may be subject to civil fines and criminal penalties.

NOTICE TO NEW YORK APPLICANTS: Any person who knowingly and with intent to defraud an insurance company or other person files an application for insurance or statement of claim containing any materially false information, or conceals, for the purpose of misleading, information concerning any fact material thereto, commits a fraudulent insurance act, which is a crime and shall also be subject to a civil penalty not to exceed $5,000 and the stated value of the claim for each such violation.

NOTICE TO OHIO APPLICANTS: Any person who, with intent to defraud or knowing that he/she is facilitating a fraud against an insurer, submits an application or files a claim containing a false or deceptive statement is guilty of insurance fraud.

NOTICE TO OKLAHOMA APPLICANTS: WARNING: Any person who knowingly, and with intent to injure, defraud or deceive any insurer, makes a any claim for the proceeds of an insurance policy containing any false, incomplete or misleading information is guilty of a felony.

NOTICE TO PENNSYLVANIA APPLICANTS: Any person who knowingly and with intent to defraud any insurance company, or other person, files an application for insurance or statement of a claim containing any materially false information or conceals for the purpose of misleading, information concerning any fact material thereto commits a fraudulent insurance act, which is a crime and subjects the person to criminal and civil penalties.

NOTICE TO TENNESSEE APPLICANTS: It is a crime to knowingly provide false, incomplete or misleading information to an insurance company for the purpose of defrauding the company. Penalties include imprisonment, fines and denial of insurance benefits.

NOTICE TO VIRGINIA APPLICANTS: It is a crime to knowingly provide false, incomplete or misleading information to an insurance company for the purpose of defrauding the company. Penalties include imprisonment, fines and denial of insurance benefits.

The Applicant acknowledges that the answers provided herein are based on a reasonable inquiry and/or investigation. The Applicant warrants that the above statements and particulars together with any attached or appended documents are true and complete and do not misrepresent, misstate or omit any material facts.

The Applicant agrees to notify us of any material changes in the answers to the questions on this questionnaire which may arise prior to the effective date of any policy issued pursuant to this questionnaire and the Applicant understands that any outstanding quotations may be modified or withdrawn based upon such changes at our sole discretion.

Completion of this form does not bind coverage. Applicant's acceptance of the company's quotation is required prior to binding coverage and policy issuance.

All written statements and materials furnished to the company in conjunction with this application are hereby incorporated by reference into this application and made a part of this application.

Applicant: _____ Title: _____

FEIN #: _____

Applicant's Signature: _____ Date: _____

Agent/Broker Name: _____