APPLICATION FOR MEDICAL DEVICES INCLUDING DURABLE MEDICAL EQUIPMENT

Instructions to the Applicant – please complete this application in ink and answer all questions completely.

Attach extra sheets as necessary should you run out of space provided. An incomplete or illegible application cannot be processed. Completion of this application neither binds coverage nor guarantees that a policy will be issued.

Provide a fully completed application, signed and dated by the owner, partner, or officer not earlier than 45 days before the proposed effective date of coverage.

If a question is not applicable, then state "N/A".

The following information must be submitted with the completed application:

- Copy of your labels, brochures, marketing and instructions
- Copy of your current products liability insurance declarations page
- Copy of your current financial statement including balance sheet and income statement
- 5-year company loss runs, valued within the last 60 days

GENERAL INFORMATION

Applicant Name:_____

List of Any Previous Names or Organizations: _____

Date Established: _____ Website: _____

Mailing Address: _____

Additional Locations: _____

_____

_____

Applicant is: ☐ Corporation ☐ Partnership ☐ Joint Venture ☐ Not For Profit
☐ Limited Liability Company ☐ Individual ☐ Other

Audit Contact: _____ Phone Number: _____

Description of Operations: _____

_____

_____

_____

PRODUCTS AND OPERATIONS

1. Provide the following information for those products, goods and/or services the Applicant wants 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):_____

2. Annual Sales

	Gross Sales – United States	Gross Sales – Foreign	Total Gross Sales
Upcoming Year	_____	_____	_____
Current Year	_____	_____	_____
First Prior Year	_____	_____	_____
Second Prior Year	_____	_____	_____
Third Prior Year	_____	_____	_____
Fourth Prior Year	_____	_____	_____

3. Have you discontinued or are you considering discontinuing any product or service listed above: Yes ☐ No ☐
If Yes, provide details. _____
_____
4. Is the Applicant presently considering introducing any new product or service not listed above? Yes ☐ No ☐
If Yes, provide details. _____
5. Do you directly import any products or component parts? **If so, please list the products and provide the corresponding percentage of total sales, manufacturer, countries of origin and testing procedures.** Yes ☐ No ☐
_____
_____
6. Who designs your products? _____
7. Are your designs reviewed, tested and verified by others? Yes ☐ No ☐
8. Are all warning labels, instructions, operating manuals, warranties and advertising material reviewed by outside counsel? Yes ☐ No ☐
9. Does your product meet applicable government and/or industry standards? Yes ☐ No ☐

10. Have you, any of your products or any of your component parts ever been the subject of any investigation, enforcement action, or notice of violation of any kind by any governmental, administrative or regulatory body including the FDA or FTC? **If Yes, please provide details.** _____ Yes ☐ No ☐

_____

11. Do you have a formal written products recall procedure? Yes ☐ No ☐
12. Have you voluntarily or involuntarily recalled, or are you considering recalling, any known or suspected defective products from the market? **If yes, provide details:** _____ Yes ☐ No ☐

_____

_____

13. Do you comply with Good Manufacturing Practices (GMP)? Yes ☐ No ☐
14. Are you a member of any trade organization? **If yes, please list:** _____ Yes ☐ No ☐

_____

MANUFACTURERS

1. Do you manufacture, package or sterilize products for others under their name or label? Yes ☐ No ☐
   If so, provide details._____

   _____
2. Do you maintain formal written quality control and testing procedures? Yes ☐ No ☐
3. How long are quality control and testing records kept: _____
4. Do you maintain the following records:
   i. When and where your product was manufactured? Yes ☐ No ☐
   ii. To whom your product was sold and the date of sale? Yes ☐ No ☐
   iii. Who supplied the materials going into the product? Yes ☐ No ☐
   iv. Changes in design? Yes ☐ No ☐
   v. Changes in advertising material? Yes ☐ No ☐

   How long do you maintain these records? _____
5. Do you obtain Certificates of Product Liability Insurance from each of your suppliers? Yes ☐ No ☐
   i. Are you listed as an Additional Insured under each supplier's Product Liability Insurance? Yes ☐ No ☐
6. Have you attained ISO 9000, QS 9000 or similar Certification? Yes ☐ No ☐

DISTRIBUTORS

1. Do you distribute products under your name or label? Yes ☐ No ☐
2. If you contract the manufacturing of your product to others, do you have a formal written agreement with your subcontractors? Yes ☐ No ☐
3. Are you a manufacturer's representative? **If yes, attach the written agreement between you and the manufacturer.** Yes ☐ No ☐
4. Do you obtain Certificates of Insurance from all manufacturers/suppliers evidencing Product Liability insurance? Yes ☐ No ☐
   i. Are you included as an Additional Insured-Vendor under each manufacturer's/supplier's Product Liability insurance? Yes ☐ No ☐
   ii. What are the minimum limits of insurance required? _____
5. Please list each manufacturer and their location:

   _____

   _____

   _____

   _____

6. Percentage of equipment sold or leased/rented which is physician prescribed: _____%
7. Do you maintain the following records:
   i. When and where your product was manufactured? Yes ☐ No ☐
   ii. To whom your product was sold and the date of sale? Yes ☐ No ☐
   iii. Who manufactured the product? Yes ☐ No ☐
   vi. Changes in design? Yes ☐ No ☐
   vii. Changes in advertising material? Yes ☐ No ☐
   How long do you maintain these records? _____

MEDICAL DEVICES

1. Do you buy, sell or rent used equipment? Yes ☐ No ☐
   i. Percentage of total operations_____ %
   ii. Do you recondition/repair prior to resale? Yes ☐ No ☐
2. Do you repair or install your products? Yes ☐ No ☐
   i. Are you or your employees factory trained? Yes ☐ No ☐
   ii. Is maintenance performed and documented according to the manufacturer's guidelines? Yes ☐ No ☐
3. Do you subcontract repair or installation operations? Yes ☐ No ☐
   i. Do you obtain Certificates of Liability from your subcontractors? Yes ☐ No ☐
   ii. What are the minimum limits of insurance required? _____
   iii. What percentage of work do you subcontract to others? _____
4. Are Material Safety Data Sheets and Scheduled Maintenance Procedures issued to each customer? Yes ☐ No ☐
5. 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 ☐
6. When was your last FDA inspection? _____ Were you issued a FDA 483 form? Yes ☐ No ☐
   If yes, please attach the form and your response.
7. Are any of your products currently being used in a clinical trial or any other tests involving human subjects? Yes ☐ No ☐
   If yes, explain._____
   _____
8. Do you promote your products for any off-label use? Yes ☐ No ☐
   If yes, explain._____
   _____

9. Staff

Staff:	Full Time	Part Time	Contracted
MD/Physicians			
Service Technicians			
Physical Therapists			
Respiratory Therapists			
Nurses			
Pharmacists			
Sales Reps			
Other (specify)			
Other (specify)			

Check the hiring procedures that apply or are performed:

- ☐ Criminal Background Checks
- ☐ Drug, alcohol and sexual abuse screening or testing
- ☐ Verification of certification or professional licensing
- ☐ Reference Checks
- ☐ Questioning of employees in their previous involvement as defendants in professional malpractice litigation.

10. Indicate Product Revenues:

	Sales			Rental
FDA Class I:				
FDA Class II:				
FDA Class III:				
Indicate the following %:	Implantable Devices:	Silicone:	Latex:	Durable Medical Equipment:
	Orthopedic/Prosthetic:	Dental:	Pediatric:	Medical Instruments:

11. Durable Medical Equipment:

i. Sales/Rentals:

ADL Device	_____ %	Apnea Monitor	_____ %
Beds, Walkers, Crutches	_____ %	Braces	_____ %
CPAP Device	_____ %	CPM Device	_____ %
Diabetic Supplies	_____ %	Defibrillators	_____ %
Disposables	_____ %	Enteral Therapy	_____ %
Latex Gloves (powder)	_____ %	Latex Gloves (powder free)	_____ %
LAL Mattress	_____ %	Lift Chairs	_____ %
Motorized Scooters	_____ %	Motorized Wheelchairs	_____ %
Nebulizers	_____ %	Orthotics	_____ %
Oxygen Concentrators	_____ %	Oxygen Cylinder	_____ %
Parenteral Therapy	_____ %	Safety Bar/Harness	_____ %
Stair/Ceiling Lifts	_____ %	TENS Unit	_____ %
Ventilators	_____ %	Wheelchairs	_____ %
Wheelchair Lifts	_____ %	Other (describe)	_____ %
		_____	

ii. Installation:

Ceiling Lifts	_____ %	Elevators	_____ %
Grab Bars	_____ %	Ramps	_____ %
Stair Lifts	_____ %	Wheelchair Lifts	_____ %
Wheelchair Lifts in Autos	_____ %	Other Installation	_____ %

LOSS HISTORY

1. How many adverse events have been reported to you and/or the FDA concerning your products in the last 5 years?
   Please provide details. _____
   _____
   _____
2. How many customer complaints have you received concerning your products in the last 5 years? **Please provide details.**
   _____
   _____
   _____

3. Is any person or organization proposed for this insurance aware of any fact, incident, circumstance, situation, condition, defect or suspected defect which may result in a claim, such that would fall under the proposed insurance? Yes ☐ No ☐

If yes, please provide details.

_____

_____

4. Has any claim been made against any person or organization proposed for this insurance during the last five (5) years? Yes ☐ No ☐

If yes, please provide five (5) year loss history for all claims, including any predecessor. Attach a description of any loss greater than $10,000.

Year	No. of Claims	Total Amounts Paid	Amounts Reserved	Total Incurred	Date of Loss Info.

INSURANCE INFORMATION

1. Has any insurer declined, canceled, or nonrenewed any General Liability, Products Liability or similar insurance on behalf of any person or organization proposed for this insurance? Yes ☐ No ☐

If yes, please provide details. _____

2. Provide the following insurance information for the prior five (5) years:

Year	Limits of Liability	Deductible/SIR	Premium	Effective Dates	Retroactive Date

3. Indicate the limits of liability and deductible requested:
   i. General Liability Limits - $_____/$_____ Deductible - $_____
   ii. Products Liability Limits - $_____/$_____ Deductible -$_____
   iii. Professional Liability Limits - $_____/$_____ Deductible -$_____

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: _____