

**REGULATORY LICENSING UNIT
DEVICE DISTRIBUTOR**

**DEVICE DIST
2503**

Minor Amendment License Application

(Health and Safety Code, Chapter 431)

Return both the completed application, and non-refundable fee made payable to:
Texas Department of State Health Services, RLU, Food & Drug Licensing,
P.O. Box 12008, Austin, Texas 78711
For assistance in completing this application call (512) 834-6727

BUDGET: ZZ105
FUND 091

LICENSE #

If you are a device manufacturer, or a device distributor, who is also required to be licensed as a drug distributor or food wholesaler, contact this office at (512) 834-6727 for the correct application.

Name Under Which Business is Conducted (DBA): _____

Physical Address to be Licensed: _____

City, County, State, Zip Code: _____

Telephone # at address: (_____) _____

Type of Operation: (Check all that apply) Distributor Initial Distributor (Importer) Own-label Distributor Broker

Type of Device: (Check all that apply) Class I Class II Class III Prescription OTC
 Sterile-Packaged Tracked Implantable Software-driven In-vitro diagnostic

FEE SCHEDULE FOR DEVICE DISTRIBUTOR

License fees are based on **ALL** gross annual device sales at each licensed place of business. "Distributor" means a person who furthers the marketing of a finished domestic or imported device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user. The term includes an importer or an own-label distributor. The term does not include a person who repackages a finished device or who otherwise changes the container, wrapper, or labeling of the finished device or the finished device package. "Finished Device" means a device, or any accessory to a device, which is suitable for use, whether or not packaged or labeled for commercial distribution.

GROSS ANNUAL DEVICE SALES		FEE FOR MINOR AMENDMENT	
<input type="checkbox"/> LV1	\$ 0.00 - \$	499,999.99	= \$ 240.00 for each establishment
<input type="checkbox"/> LV2	\$ 500,000.00 - \$	9,999,999.99	= \$ 540.00 for each establishment
<input type="checkbox"/> LV3	\$ 10,000,000.00 - \$	Or more	= \$ 840.00 for each establishment


EXEMPTION FROM FEE:

- This place of business engages **ONLY** in the manufacture or distribution of radiation machines which are devices or the manufacture or distribution of devices which contain radioactive materials, and is currently licensed or registered with the Texas Department of State Health Services, Radiation Control under §289.252 or §289.226, 25 Texas Administrative Code.
- This place of business is a charitable organization as described in the Internal Revenue Code of 1986, §501(c)(3), or a nonprofit affiliate of the organization, to the extent otherwise permitted by law.

Late Fee - A person who files a renewal application after the expiration date must pay an additional \$100.00. **ANY RETURNED CHECKS RECEIVED AFTER EXPIRATION DATE WILL BE ASSESSED THE \$100.00 LATE FEE.**

VERIFICATION: I SWEAR OR AFFIRM THAT ALL INFORMATION IN THIS APPLICATION IS TRUE AND CORRECT. I FURTHER CERTIFY BY SIGNATURE HEREON, THAT I AM AUTHORIZED TO EXECUTE THIS DOCUMENT ON BEHALF OF THE CORPORATION AND AM ELIGIBLE TO RECEIVE A LICENSE. IF SIGNING THIS AS OWNER OF A SOLE PROPRIETORSHIP, I AM NOT DELINQUENT IN THE PAYMENT OF ANY CHILD SUPPORT OWED UNDER CHAPTER 232, FAMILY CODE. IF SIGNING AS A SOLE PROPRIETOR, I CERTIFY I HAVE FILED THE ASSUMED NAME CERTIFICATE IN APPROPRIATE COUNTIES PURSUANT TO BUSINESS AND COMMERCE CODE, CHAPTER 36. I FURTHER CERTIFY THAT I HAVE READ AND UNDERSTAND CHAPTER 431 OF THE HEALTH & SAFETY CODE, THE APPLICABLE PROVISIONS OF 25 TEXAS ADMINISTRATIVE CODE, CHAPTER 229, AND AGREE TO ABIDE BY THEM.

Print Name: _____ Title: Owner President
 Partner Corporate Designee / Agent

sign here  _____ Date: _____

LICENSE HOLDER INFORMATION: Please enter the 11 digit State Tax Payer's Identification number or Federal Identification number.

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****Please Note: For ONLY Drug, Device, and/or Certificate of Authority Applications:**

* Has the applicant, licensee, and/or managing officer(s) been convicted of a felony or misdemeanor? Yes No
(If yes, please attach a statement explaining the conviction.)

* Please include a copy of Driver's License with application.

* Applicants are required to fill in residence address, driver's license number, and date of birth below.

SOLE OWNER / PROPRIETORSHIP

Name of Sole Owner: _____
Residence Address DLN DOB

Partnership LP LLP LTD Effective Date of Partnership _____

Name of Partnership: _____

Partnership Address: _____ / _____ / _____ / _____
ADDRESS CITY ST ZIP

* Each of the Below Must Include: Name, Residence Address, Drivers License Number & Date of Birth:

Partner Name: _____
Residence Address DLN DOB

Partner Name: _____
Residence Address DLN DOB

Partner Name: _____
Residence Address DLN DOB

Association **State Agency**

Name of Association / State Agency: _____

Address: _____ / _____ / _____ / _____
ADDRESS CITY ST ZIP

* Each of the Below Must Include: Name, Residence Address, Drivers License Number & Date of Birth:

Name: _____
Residence Address DLN DOB

Name: _____
Residence Address DLN DOB

Corporation **LLC** Date and Place of Incorporation: _____

Corporation Name: _____

Corporation Address: _____ / _____ / _____ / _____
ADDRESS CITY ST ZIP

*Each of the Below Must Include: Name, Residence Address, Drivers License Number & Date of Birth:

President Name: _____
Residence Address DLN DOB

Officer's Name: _____
Residence Address DLN DOB

Officer's Name: _____
Residence Address DLN DOB

Name of Registered Agent: _____
Residence Address DLN DOB

