



**REGULATORY LICENSING UNIT
DEVICE MANUFACTURER
MINOR AMENDMENT LICENSE APPLICATION**

**DEVICE MFG
2503**

(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 distributor only (no manufacturing, fabricating, repackaging, relabeling, assembling, or processing of finished devices), 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) Manufacturer Contract Manufacturer Contract Sterilizer
 Remanufacturer Repackager and/or Relabeler Specification Developer Reprocessor of Single Use Devices

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 MANUFACTURER

License fees are based on gross annual sales of **ALL** devices sales at each licensed place of business. "Manufacturer" means a person who manufactures, fabricates, assembles, or processes a finished device. The term includes a person who repackages or relabels a finished device. The term does not include a person who only distributes a finished device. "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 place of business
<input type="checkbox"/> LV2	\$ 500,000.00 -	\$ 9,999,999.99	=	\$ 1,080.00 for each place of business
<input type="checkbox"/> LV3	\$ 10,000,000.00 -	\$ Or more	=	\$ 1,800.00 for each place of business

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 on file with the Texas Comptroller of Public Accounts.

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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

