



**REGULATORY LICENSING UNIT  
DEVICE MANUFACTURER LICENSE APPLICATION  
(Health and Safety Code, Chapter 431)**

Return both the completed application and fee made payable to the  
TEXAS DEPARTMENT OF STATE HEALTH SERVICES in the envelope provided or mail to:  
Texas Department of State Health Services, PO Box 12008, Austin, Texas 78711.  
You may visit our website at: [www.dshs.state.tx.us](http://www.dshs.state.tx.us)

**DEVICE MFG**

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) 834-6626 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"/>	\$	0.00 -	\$	499,999.99	=	\$ 240.00 for each place of business
<input type="checkbox"/>	\$	500,000.00 -	\$	9,999,999.99	=	\$ 1,080.00 for each place of business
<input type="checkbox"/>	\$	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.

Signature \_\_\_\_\_  OWNER  PARTNER  PRESIDENT  CORPORATE DESIGNEE / AGENT

Printed Name & Title \_\_\_\_\_ Date \_\_\_\_\_

**PURPOSE OF THIS APPLICATION:** Mark appropriate box to indicate purpose of application, and/or any change in status of firm.

**New** - Start Date of Regulated Activity: \_\_\_\_\_

**Change of Ownership (Including legal entity)** [previous owner: \_\_\_\_\_ Effective Date: \_\_\_\_\_  
Change of ownership (including change of legal entity) requires submission of a new application and fee as listed on Page 1. The effective date of change becomes the new anniversary date.

**Amended** -  Change of Location [previous location: \_\_\_\_\_] } Enter the date the change  
 Change of Name [previous name: \_\_\_\_\_] } was effective  
 Other: \_\_\_\_\_ Date: \_\_\_\_\_

Any minor amendment including change of name or change in the location of a licensed place of business, requires submission of a new application and fee as listed on Page 1. The current expiration date remains in effect.

**Renewal** - Renewals are valid from the anniversary date. **Failure to submit the renewal fee before the expiration date will result in a delinquency fee for each location and must be remitted before the license or permit will be issued.**

**Notice that firm is out of business.** Date: \_\_\_\_\_  
Sign and date. Return for deletion from our records.

**Not required to license/permit**  
Reason: \_\_\_\_\_

**RESPONSIBLE INDIVIDUAL IN CHARGE AT PHYSICAL ADDRESS**

A license cannot be issued for manufacturing or holding of foods for distribution in any room used as living or sleeping quarters; or for the manufacturing, assembling, testing, processing, packing, holding or labeling of drugs and/or devices from any personal residence.

*\*Residence address, driver's license number, and date of birth are only required of drug and/or device applicants*

\_\_\_\_\_  
Name & Title \*Residence Address \*Driver's License Number \*Date of Birth

**BUSINESS HOURS OF OPERATION:** \_\_\_\_\_ m. to \_\_\_\_\_ m.

**WEBSITE/ INTERNET ADDRESS:** http://www. \_\_\_\_\_

**BILLING INFORMATION** (The license/permit and/or courtesy renewal notice will be sent to the following):

Billing Name: \_\_\_\_\_

Billing Address: \_\_\_\_\_

City, State, Zipcode: \_\_\_\_\_

Name of Application Preparer (Contact Person): \_\_\_\_\_

Telephone Number of Application Preparer (Contact Person): \_\_\_\_\_

Fax Number of Application Preparer (Contact Person): \_\_\_\_\_

E-mail Address of Application Preparer: \_\_\_\_\_

PRIVACY NOTIFICATION: With few exceptions, you have the right to request and be informed about information that the State of Texas collects about you. You are entitled to receive and review the information upon request. You also have the right to ask the state agency to correct any information that is determined to be incorrect. See <http://www.dshs.state.tx.us> for more information on Privacy Notification. (Reference: Government Code, Section 522.021, 522.023 and 559.004)

**ALL THREE PAGES OF THE APPLICATION FORM MUST BE COMPLETED BEFORE A LICENSE/PERMIT WILL BE ISSUED. Please allow 4-6 weeks for processing.**

For assistance in completing this application, call (512) 834-6626.

Please address any correspondence to: Texas Department of State Health Services, Regulatory Licensing Unit, Food and Drug Licensing Group, 1100 West 49<sup>th</sup> Street, Austin, Texas 78756.

**BE CERTAIN TO COMPLETE ALL PAGES OF THIS FORM  
PAGE 2 OF 3**

**LICENSE/PERMIT HOLDER INFORMATION:** Complete the required ownership information.

Legal name of company must be identical to the name on your State Tax Payer's Identification on file with the Texas Comptroller of Public Accounts.

Legal Name Tax Payer ID # or Charter # Outlet #

Mailing Address of Licensed Establishment City and State Zip

\* 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.)

**\*Residence address, driver's license number, and date of birth are required of drug and/or device applicants ONLY.  
INCLUDE A COPY OF YOUR DRIVER'S LICENSE**

**SOLE OWNER / PROPRIETORSHIP**

Name \*Residence Address \*Drivers License Number \*Date of Birth

**PARTNERSHIP**       **LP**       **LLP**       **LTD**

Name of Partnership Effective Date of Partnership

Name \*Residence Address \*Drivers License Number \*Date of Birth

Name \*Residence Address \*Drivers License Number \*Date of Birth

Name \*Residence Address \*Drivers License Number \*Date of Birth

**ASSOCIATION**

Name \*Residence Address \*Drivers License Number \*Date of Birth

Name \*Residence Address \*Drivers License Number \*Date of Birth

**CORPORATION**       **LLC**

Name of Corporation Date and Place of Incorporation

President's Name \*Residence Address \*Drivers License Number \*Date of Birth

Officer's Name \*Residence Address \*Drivers License Number \*Date of Birth

Officer's Name \*Residence Address \*Drivers License Number \*Date of Birth

Name of Registered Agent \*Residence Address Telephone Number