REGULATORY LICENSING UNIT
DEVICE MANUFACTURER
INITIAL / RENEWAL 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

DEVICE MFG
2503

BUDGET: ZZ105
FUND: 091

LICENSE #

NOTE: Do not submit a device manufacturer application if physical address of business is located outside of Texas.

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) G Manufacturer G Contract Manufacturer G Contract Sterilizer G Remanufacturer G Repackager and\or Relabeler G Specification Developer G Reprocessor of Single Use Devices

Type of Device: (Check all that apply) G Class I G Class II G Class III G Prescription G OTC G Sterile-Packaged G Tracked G Implantable G Software-driven G 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 INITIAL/RENEWAL LICENSE OR CHANGE OF OWNERSHIP
G LV1	$ 0.00	-	$ 499,999.99	=		$ 495.00 for each place of business
G LV2	$ 500,000.00	-	$ 9,999,999.99	=		$ 2,225.00 for each place of business
G LV3	$ 10,000,000.00	-	$ Or more	=		$ 3,708.00 for each place of business

EXEMPTION FROM FEE:

G 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.

G 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.

G **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:**

PURPOSE OF THIS APPLICATION: Mark appropriate box to indicate purpose of application, and/or any change in status of firm.
Please Note: Initial licenses will expire two years from date of payment receipt by the Department.

□ **New** - Start Date of Regulated Activity:_____

□ **Change of Ownership or Change of Legal Entity:** requires submission of an initial application and fee as listed on Page 1.

PLEASE NOTE: If change affects multiple licensed locations contact us at 512-834-6727 prior to submitting application.

□ Previous owner name _____

□ Previous legal entity name: _____

□ Effective Date of Change: _____

□ **Amended** - □ Change of Location [previous location: _____]
□ Change of Name [previous name: _____]
□ Other:

} Enter the date the change was effective:
Date:_____

Any minor amendment including change of name or change in the location of a licensed place of business requires submission of a minor amendment application and fee as listed on page 1 of that application. 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 out of business: _____**
Sign and date 1st page and return original license 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.

***Please Note:** **Only** drug, device, and/or certificate of authority applicants are required to fill in residence address, driver's license number, and date of birth.

_____

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 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. You may visit our website listed below for more information on the 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 WILL BE ISSUED. Please allow 4-6 weeks for processing.

Visit our website at: www.dshs.state.tx.us

Please address **correspondence only** to:
Texas Department of State Health Services
RLU, Food and Drug Licensing Group, MC 2835
PO Box 149347
Austin, Texas 78714-9347

BE CERTAIN TO COMPLETE ALL PAGES OF THIS FORM

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

BE CERTAIN TO COMPLETE ALL PAGES OF THIS FORM