



Texas Department of State Health Services

BUSINESS FILING AND VERIFICATION SECTION DEVICE MANUFACTURER MINOR AMENDMENT LICENSE APPLICATION

DEVICE MFG 2503

(Health and Safety Code, Chapter 431) Return both the completed application, and non-refundable check or money order made payable to: Texas Department of State Health Services, Food & Drug Licensing, PO Box 12008, Austin, Texas 78711

BUDGET: ZZ105 FUND: 091 LICENSE #:

Contact this office at (512)834-6727 for assistance with the application. Name Business is Conducted Under (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, In-vitro diagnostic, Sterile-Packaged, Tracked, Implantable, Software-driven

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.

Table with 2 columns: GROSS ANNUAL DEVICE SALES and FEE FOR MINOR AMENDMENT. Rows include LV1, LV2, and LV3 sales ranges and corresponding fees per facility.

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.

Exemption from license fee:

25 TAC 229.427 A person is exempt from the license fees required by this section if the person is a charitable organization, as described in the Internal Revenue Code of 1986, 501(c)(3), to a nonprofit affiliate of the organization, to the extent otherwise permitted by law.

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: <input type="checkbox"/> Owner <input type="checkbox"/> President <input type="checkbox"/> Partner <input type="checkbox"/> Corporate Designee / Agent
sign here ►	Date:

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 552.021, 552.023 and 559.004).

ALL SIX 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.texas.gov

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

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

Amendment of ownership name (this does not include an ownership change): This means the EIN/Taxpayer Numbers are remaining the same and the firm has submitted an amendment with the Secretary of State and the Comptroller's office. The current expire date remains in effect.

If change affects multiple licensed locations, contact us at 512-834-6727.

Previous name: _____

License number: _____ Effective date of change: _____

Amended DBA name or location: If change affects multiple licensed locations contact us at 512-834-6727 prior to submitting application. The current expiration date remains in effect for an amendment only.

Location change (previous location): _____

DBA Name Change (previous): _____

Other: _____

Current license number: _____

Effective date of change: _____

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 will be issued. **Note** – if you are submitting an amendment with the renewal, call our office prior to submitting the application. The renewal and amendment carry separate fees that will be due.

Notice that this firm is out of business. Date: _____

Not required to license – reason: _____

Sign & date page 1 and return.

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

Date of birth

Residence address

Driver's license number

BUSINESS HOURS OF OPERATION _____ **to** _____

WEBSITE/INTERNET ADDRESS: _____

MAILING ADDRESS INFORMATION (The license and/or courtesy renewal notice will be sent to the address below).

Mailing name: _____

Mailing address: _____

City, State, Zip code: _____

Name of application preparer (**contact person**): _____

Telephone number of contact person: _____

Email address of contact person: _____

Fax number for contact person: _____

LICENSE HOLDER INFORMATION: Please enter the 11-digit State Tax Payer's Identification number on file with the Texas Comptroller of Public Accounts. Enter the 9-digit Federal Employee Identification Number (**EIN**).

Taxpayer number

EIN number

Please note: Only for 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 and include a copy of the driver's license with the application.

For the information below, complete the **box** that applies to the ownership of the license. **In addition, where stated below, residence address, driver's license number, and date of birth are required.**

Sole Owner / Proprietorship

Name of sole owner: _____

Residence address _____ DLN _____ DOB _____

Association **State Agency**

Name of Association / State Agency: _____

Address: _____

Contact person: _____

Residence address _____ DLN _____ DOB _____

Contact person: _____

Residence address _____ DLN _____ DOB _____

Partnership **LP** **LLP** **LTD**

Name of partnership: _____

Address of partnership: _____

Effective date of partnership: _____

(partnership information continued on next page)

Partner name: _____

Residence address _____ DLN _____ DOB _____

Partner name: _____

Residence address _____ DLN _____ DOB _____

Partner name: _____

Residence address _____ DLN _____ DOB _____

Corporation **LLC**

Effective date of Incorporation: _____

Corporation Name: _____

Corporation Address: _____

President: _____

Residence address _____ DLN _____ DOB _____

Officer: _____

Residence address _____ DLN _____ DOB _____

Officer: _____

Residence address _____ DLN _____ DOB _____

Registered Agent: _____

Residence address _____ DLN _____ DOB _____