MEDICAL DEVICE MANUFACTURING LICENSE APPLICATION

All fields must be completed. Incomplete applications will result in delayed license issuance.

See Page 3 for Instructions

License Number (if not new): _____

☐ **NEW APPLICANT** ☐ **OWNERSHIP CHANGE**
☐ **RENEWAL APPLICANT** ☐ **RELOCATION**—Previous Address: _____

1. Name of Firm			6. Mailing Address (if different or P.O. Box number)		
2. DBA (Use other sheets as needed)			7. Mailing Address (continued)		
3. Facility Address (number, street)			8. Mailing City	State	ZIP Code
4. Facility Address (continued)			9. Country (if other than United States)		
5. Facility City	State	ZIP Code	10. Website (URL)		

Authorized Representatives:

11. Owner or Manager Name	12. Telephone Number	13. Emergency Number	14. E-Mail Address
15. Contact Name for Facility	16. Telephone Number	17. Alt Cell Phone Number	18. E-Mail Address

19. Interstate Commerce
☐ Product Shipped ☐ Product or Raw Materials Received ☐ N/A

20. Type ownership **(Please attach evidence of ownership)**
☐ Individual/Sole Proprietorship ☐ Partnership ☐ Corporation ☐ Limited Liability Company
☐ Nonprofit ☐ Other:

21. Corporate Name (if applicable)	State of Incorporation
22. Owner's and/or Corporate Officers' Names and Titles	Owner's and/or Corporate Officers' Names and Titles

23. Type of Manufacturing Business (Check all that apply)
☐ Manufacturer ☐ Contractor ☐ Component
☐ Specification Developer ☐ Other:

Business Information:
Size of Facility (square feet):
Number of Employees at this Facility:
Business Days and Hours:

24. Stage of Manufacture at Date of Application (Check all that apply)
☐ Manufacturing Products ☐ Design Development ☐ Design Validation
☐ Pre-Production Design Transfer ☐ Other

25. Intended Medical Device Destination (Check all that apply)
☐ Commercial Distribution ☐ Human Clinical Trials (Investigational Use) ☐ California Distribution Only
☐ U.S. Distribution ☐ Export Market

-Continue-

26. Check Each Product Area that Applies to Devices Manufactured

☐ 862 Clinical Chemistry and Toxicology	☐ 874 Ear, Nose and Throat	☐ 886 Ophthalmic
☐ 864 Hematology and Pathology	☐ 876 Gastroenterology/Urology	☐ 888 Orthopedic
☐ 866 Immunology and Microbiology	☐ 878 General and Plastic Surgery	☐ 890 Physical Medicine
☐ 868 Anesthesiology	☐ 880 General Hospital/Personal Use	☐ 892 Radiology
☐ 870 Cardiovascular	☐ 882 Neurological	
☐ 872 Dental	☐ 884 Obstetrical and Gynecological	

27. List the types of classified and/or unclassified medical devices manufactured in the spaces below. Use additional sheets if necessary.

Federal Classification and Title	**CLASSIFICATION (Check One)**		
	I	II	III
	☐	☐	☐
	☐	☐	☐

28. Identify the processes employed or planned in the manufacture of the devices listed above and if the activities will be done in-house or by contract. Use additional sheets if necessary.

Processes of Activities	**In-House**	**Contract**	**Processes of Activities**	**In-House**	**Contract**
Sterilization	☐	☐	Repackaging/Relabeling	☐	☐
Software Development	☐	☐	Remanufacturing/Refurbishing	☐	☐
Circuit Board Assembly	☐	☐	Tissue/Cell Culture	☐	☐
Lyophilization	☐	☐	Other (Specify):	☐	☐
Antigen/Antibodies	☐	☐			

29. Payment Code (Check all that apply)

A ☐ $4,616.00 Base Fee — Fee is due at the time application is submitted and is NON-REFUNDABLE

B ☐ $ 10.00 Late Fee — If over 30 days past license expiration date, see page 4.

$_____ TOTAL AMOUNT DUE — Payable to: CA Department of Public Health

30. If you meet one of the listed criteria below FDB can issue a license without first inspecting your facility. Check the appropriate box(es) and attach documentary evidence.

- ☐ A copy of a valid biologics license issued by the U.S. Food and Drug Administration (FDA).
- ☐ A copy of a valid establishment registration pursuant to Section 510 of the federal act and attestation that a federal inspection was completed within the last two years.
- ☐ A copy of documentation demonstrating compliance with audits conducted pursuant to International Organization for Standardization. (ISO) ISO standards (ISO 9000 series, ISO 13485:2003, ISO 15378:2006)
- ☐ A copy of approved investigational device exemption issued by the FDA.
- ☐ None of the above apply (Inspection will be required)

The Food and Drug Branch **MUST BE NOTIFIED IMMEDIATELY** of any changes in the above information as provided by California Health and Safety Code, Section 111630. Under penalties of perjury, I declare that the information included with this application and all attachments are true, correct, and complete. I also give permission for the below authorized representatives and/or signatories to speak about the application with CDPH.

31.Owner's Signature	Owner's Printed Name	Title Owner/	Date

-End of Application-

Please review your application to ensure all fields have been completed.

Do not write below this line. CDPH FDB use only.

License Number	Expiration Date	Date Received	Payment Type	Amount $

MEDICAL MANUFACTURING LICENSE APPLICATION INSTRUCTIONS

(Do not send instructions with completed application)

A separate application is required for each place of business. Please complete and/or amend this application as is most appropriate to your facility. Include the appropriate fee for each application and make payable to: **CA Department of Public Health**. The fee must accompany this application or it cannot be processed. Unsigned or incomplete applications cannot be processed. The following are further instructions on how to complete this application:

New Applicant: Place an (X) in the box next to New Applicant if your firm has not previously applied for a Medical Device Manufacturing License at this location while under the current ownership. **This license is non-transferable.** If your firm has changed location, ownership, or both, place an (X) in the appropriate box **and also** in the box next to New Applicant. For renewal applications, place an (X) in the box next to Renewal. For any section that does not apply to your company, please indicate with (N/A). **Do not leave any sections blank.**

1. **Name of Firm:** Enter full name of business, corporation, company, or organization applying for licensure.
2. **DBA:** Enter any other name(s) your company is doing business as.

3.–5. **Facility Address:** Enter the number, street, city, state, and ZIP code for this facility location.

6.-8 **Mailing Address:** Enter the full mailing address if different from the facility address or P.O. Box.

9. **Country:** Enter the country where your facility is located.
10. **Website:** Enter the website address for your business, if applicable.

11.-14. **Owner's/Manager's Contact Information:** Enter the owner's or manager of facility's telephone number, emergency number where the facility may be reached in the event of an emergency and e-mail address.

15.-18. **Facility Representative's Contact Information:** Enter the facility's representative's name, phone number, alternate cell phone number and e-mail address.

19. **Interstate Commerce:** Place an (X) in all appropriate boxes that correctly describe your business' receipt or distribution of products or materials through or into interstate commerce.
20. **Type of ownership:** Place an (X) in the box next to the appropriate legal description of the facility's ownership. Attach evidence of ownership.
21. **Corporate Name. State of Incorporation:** If applicable, enter the corporate name here.
22. **Owner's or Officers' Names and Titles:** List the business owner's or officers' names and titles. Use additional sheets if necessary.
23. **Type of Manufacturing Business:** Place an (X) in the box next to each type of manufacturing business conducted at this facility, size of facility, number of employees, and list business days and hours.
24. **Stage of Manufacture:** Place an (X) in the box next to the stage of manufacture your products are in at the time of application submission. Check all that apply.
25. **Intended Device Destination:** Place an (X) in the box adjacent to the destination(s) for your manufactured products. Check all that apply.
26. **Products Manufactured:** Place an (X) in the box adjacent to each product that applies to the devices manufactured or to be manufactured.
27. **Classified or Unclassified Products Manufactured:** For each medical device product, list the federal classification name and classification category (I, II, or III) as listed in 21 CFR, Sections 862 to 892.

28. **Manufacturing Processes:** Place an (X) in the column adjacent to any indicated processes to identify if they will be done in-house or contracted out. Leave line blank if the indicated process will not be used in the manufacture of listed devices. List additional processes or methods as needed herein or on additional sheets, if necessary.
29. **Payment Code:** Place an (X) in the box adjacent to each applicable fee.

Payment Type	*Fee*	*Description*	*Payment Code*
New, Relocation, Ownership Change, or Renewal	**$4,616**	Base fee, due at time of application	A
Late Fee	**$10**	Due if over 30 days past license expiration date	B

LICENSE FEES ARE NON-REFUNDABLE AND NON-TRANSFERABLE TO OTHER LOCATIONS OR ENTITIES

a. Enter license fee according to payment codes above. **(License valid for 2 years)**
b. Enter Total Payment Due by adding "A" and "B".

30. **Inspection Criteria:** Attach U.S. Food and Drug (FDA) or International Organization for Standardization (ISO) Standard Documents. Place an (X) in the appropriate box(es) for the items that you are submitting with the application. For more information regarding this requirement refer to the California Health and Safety Code Section 111635. If you meet any of the listed criteria on the application by providing documentary evidence, FDB may be able to issue a license without first inspecting your place of business. The documentary evidence must be valid for your current establishment. If no criteria are met, an inspection will be required.
31. **Owner's Signature:** Sign the application. Print the signer's signature, title, and indicate signature date. All signatures must be original.

Please make all checks payable to: **CA Department of Public Health** Mail Application and checks to:			
Regular Mail:	California Department of Public Health Food and Drug Branch – Cashier MS 7602 P.O. Box 997435 Sacramento, CA 95899-7435	Overnight Mail:	California Department of Public Health Food and Drug Branch – Cashier 1500 Capitol Avenue, MS-7602 Sacramento, CA 95814

If you have any questions about this application, please contact the FDB License Desk for Drug Manufacturing at (916) 650-6500, (800) 495-3232.