

State of Florida
Department of Business and Professional Regulation
Division of Drugs, Devices, and Cosmetics

Application for Permit as a Medical Gas Manufacturer
Form No.: DBPR-DDC-204

APPLICATION CHECKLIST – IMPORTANT – Submit all items on the checklist below with your application to ensure faster processing.

APPLICATION	APPLICATION REQUIREMENTS
<p>Application for Permit as a Medical Gas Manufacturer</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Submit fee of \$1,150.00, which includes \$1,000.00 application fee and \$150.00 initial application/on-site inspection fee. If the applicant is entitled to an exemption from inspection, the applicant would submit a fee of \$1,000.00. If establishment is applying for multiple manufacturing permits in the applicant's name and at applicant's address, you are only required to pay for the permit with the highest fee. <input type="checkbox"/> Make cashier's check, corporate or business check, or money order payable to the Florida Department of Business and Professional Regulation. <input type="checkbox"/> If you answer "Yes" to any question in Section IV, be sure to provide a detailed explanation along with any relevant documentation. <input type="checkbox"/> If you take possession of medical gases at your establishment, provide a photocopy of the establishment's current fire inspection report. <input type="checkbox"/> The label you provide must include the statement required by rule 61N-1.007(3)(a) or (b). For example, if the container is non-disposable and may be refilled, the label must bear the statement "federal law requires that this container be refilled with oxygen U.S.P. only by establishment registered as a drug producer in accordance with the Federal Food, Drug and Cosmetic Act." See rule 61N-1.007(3)(b), Florida Administrative Code. <input type="checkbox"/> Sign and date the Affidavit section of the application.
	<p>Submit the completed application with enclosures to: Department of Business and Professional Regulation 1940 North Monroe Street Tallahassee, FL 32399</p>

PLEASE NOTE:

Telephone, email, and fax contact information is used to quickly resolve questions with applications. If such information is not provided, questions regarding applications will be mailed to the application contact's mailing address and may take longer to resolve.

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Form No.: DBPR-DDC-204

If you have any questions or need assistance in completing this application, please contact the Department of Business and Professional Regulation, Division of Drugs, Devices and Cosmetics, at **850.717.1800**. For additional information see the instructions at the beginning of this application.

Section I – Application Type

CHECK ONE OF THE APPLICATION TYPES
<input type="checkbox"/> New Application [3330/1020]
<input type="checkbox"/> New Application due to change in ownership. If checked, provide legal documentation for the change of ownership (i.e. Bill of Sale, stock transfer, merger). [3330/1020] Current Permit Number: _____

Section II – Applicant Information

APPLICANT INFORMATION
TAXPAYER IDENTIFICATION NUMBER OR FEDERAL EMPLOYER IDENTIFICATION NUMBER
This is a unique nine-digit number assigned by the Internal Revenue Service (IRS) to business entities operating in the United States for the purposes of identification. When the number is used for identification rather than employment tax reporting, it is usually referred to as a Taxpayer Identification Number (TIN), and when used for the purposes of reporting employment taxes, it is usually referred to as the Federal Employer Identification Number (FEIN).
Applicant's TIN/FEIN: _____
FULL LEGAL NAME
The "full legal name" is the complete name of the business entity that will be operating the establishment. This is generally the name that is on the documents that establish the existence or formation of the business entity. For example, a corporation's full legal name would normally be the name that is found in the corporation's articles of incorporation.
Applicant's Full Legal Name: _____
FICTITIOUS, TRADE, OR BUSINESS NAME
If the applicant intends to operate the permitted establishment under a name that is different from the Applicant's Full Legal Name listed above – e.g. fictitious, trade, or business name (also commonly referred to as a "dba", "D/B/A", or "doing business as" name – this name must be registered with the Florida Department of State, Division of Corporations. This is the name that will appear on the permit issued to the applicant by the department and must be the name that the applicant uses on operational documents for permitted activities.
<input type="checkbox"/> The applicant WILL NOT operate the permitted establishment under a name that is different from the Applicant's Full Legal Name listed above.
<input type="checkbox"/> The applicant WILL operate the permitted establishment under the following fictitious, trade, or business name: _____
The fictitious, trade, or business name listed directly above, is registered with the Florida Department of State, Division of Corporations and the applicant has been issued the following registration number: _____

APPLICANT'S MAILING ADDRESS			
Street Address or P.O. Box:			
City:	State:	Zip Code (+4 optional):	
PHYSICAL ADDRESS OF ESTABLISHMENT TO BE PERMITTED (only if different from mailing address) Check <input type="checkbox"/> if not applicable			
Street Address:			
City:	State:	Zip Code (+4 optional):	
County (if located in Florida):	Country:		
E-Mail Address:	Phone Number:	Fax Number:	
APPLICATION CONTACT			
The application contact is the person that the department will contact if there are questions regarding the responses provided on, or the documentation submitted with, the application. The application contact is also the person that will receive all official communication from the department regarding the application.			
Last/Surname:	First:	Middle:	Suffix:
Address:			
City:	State:	Zip Code (+4 optional):	
Telephone Number:	Fax Number:		
E-Mail Address:			
EMERGENCY CONTACT			
The emergency contact is the person that the department will contact in the case of an emergency. During an emergency, the department will contact this person at times outside of the regular business hours listed below. The contact information provided should be sufficient for the department to actually reach and communicate with the person listed in the event of an emergency.			
Last/Surname:	First:	Middle:	Suffix:
Position/Title:			
Street Address:			
City:	State:	Zip Code (+4 optional):	
Phone Number:	E-Mail Address:		

OPERATING HOURS

List Operating Hours – minimum 10 total per week (M-F) between 8:00 a.m. and 5:00 p.m. Eastern Standard Time, and at least 2 consecutive hours on at least 1 day. REMEMBER to circle “a.m.” or “p.m.” for each time indicated below.

Mon ____:____ a.m./p.m. to ____:____ a.m./p.m.	Fri ____:____ a.m./p.m. to ____:____ a.m./p.m.
Tue ____:____ a.m./p.m. to ____:____ a.m./p.m.	Sat ____:____ a.m./p.m. to ____:____ a.m./p.m.
Wed ____:____ a.m./p.m. to ____:____ a.m./p.m.	Sun ____:____ a.m./p.m. to ____:____ a.m./p.m.
Thu ____:____ a.m./p.m. to ____:____ a.m./p.m.	

Section III – Ownership Information

TYPE OF OWNERSHIP

- | | | |
|---|--|---|
| <input type="checkbox"/> Publicly Held Corporation | <input type="checkbox"/> Closely Held Corporation | <input type="checkbox"/> Limited Liability Company |
| <input type="checkbox"/> Charitable Organization—501(c)(3) | <input type="checkbox"/> Sole Proprietorship | <input type="checkbox"/> Government |
| <input type="checkbox"/> Partnership – General | <input type="checkbox"/> Professional Corporation or Association | <input type="checkbox"/> Professional Limited Liability Company |
| <input type="checkbox"/> Partnership – Other, Including Limited Liability Partnership and Limited Partnership | <input type="checkbox"/> Other: _____ | |

List the state of incorporation or state of organization (except Partnership – General or Sole Proprietorship). Business entities organized under non-U.S. laws list the country of organization.
 N/A (Partnership – General or Sole Proprietorship)

State or Country:

List name and address of the applicant’s registered agent for service of process in Florida (except Sole Proprietorship or Partnership – General) and provide documentation, such as a print out from the Florida Department of State, Division of Corporations’ webpage, that the applicant’s registered agent is registered with the Florida Department of State, Division of Corporations.
 N/A (Partnership – General or Sole Proprietorship)

Name:

Address:

City:

State:

Zip Code (+4 optional):

List the name, position/title, social security number, date of birth and address of each owner, partner, member, manager, officer, director, chief executive, or other person who directly or indirectly controls the operation of the business entity, as applicable. For example, corporations would list officers and directors, limited liability companies would list members and managers, etc.

1.	Name & Title:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
2.	Name & Title:	Social Security #:	Date of Birth:	% of Ownership:

	Street Address:	City:	State:	Zip Code:
3.	Name & Title:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
4.	Name & Title:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
5.	Name & Title:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
6.	Name & Title:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
7.	Name & Title:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
8.	Name & Title:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
List the name, social security number, date of birth and address of each person who owns 10 percent or more of the outstanding stock or equity interest in the business entity.				
1.	Name:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
2.	Name:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:

3.	Name:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
4.	Name:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
5.	Name:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
6.	Name:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
7.	Name:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
8.	Name:	Social Security #:	Date of Birth:	% of Ownership:
	Street Address:	City:	State:	Zip Code:
List all trade or business names used by the applicant. Use additional sheet(s) if necessary. If the applicant does not use other trade or business names check this box <input type="checkbox"/> and write N/A on the lines below.				
Is the applicant a subsidiary of another company? (If yes, provide a listing of all parent companies with percentages of ownership, using additional sheet(s) if necessary). <u>Note</u> : A permit issued pursuant to this application is only valid for the applicant, and the applicant's name and address. (If no, please check this box <input type="checkbox"/> and write "N/A" in the lines below).				<input type="checkbox"/> Yes <input type="checkbox"/> No
Parent Company Name:		% of Ownership:		

Section IV – Background Questions

BACKGROUND QUESTIONS			
1.	<input type="checkbox"/> Yes If yes, explain in detail in Section V	<input type="checkbox"/> No	Has the applicant or any “affiliated party” (defined below) been found guilty of (regardless of adjudication), or pled nolo contendere to, in any jurisdiction, a violation of law that directly relates to a drug, device, or cosmetic?
2.	<input type="checkbox"/> Yes If yes, explain in detail in Section V	<input type="checkbox"/> No	Has the applicant or any affiliated party (defined below) been fined or disciplined by a regulatory agency in any state (including Florida) for any offense that would constitute a violation of Chapter 499, F.S.?
3.	<input type="checkbox"/> Yes If yes, explain in detail in Section V	<input type="checkbox"/> No	Has the applicant or any affiliated party (defined below) been convicted (regardless of adjudication) of any felony under a federal, state (including Florida), or local law?
4.	<input type="checkbox"/> Yes If yes, explain in detail in Section V	<input type="checkbox"/> No	Has the applicant or any affiliated party (defined below) been denied a permit or license in any state (including Florida) related to an activity regulated under Chapters 456, 465, 499, or 893, F.S.?
5.	<input type="checkbox"/> Yes If yes, explain in detail in Section V	<input type="checkbox"/> No	Has the applicant or any affiliated party (defined below) had any current or previous permit or license suspended or revoked which was issued by a federal, state, or local governmental agency relating to the manufacture or distribution of drugs, devices, or cosmetics?
6.	<input type="checkbox"/> Yes If yes, explain in detail in Section V	<input type="checkbox"/> No	Has the applicant or any affiliated party (defined below) ever held a permit issued under Chapter 499, F.S. in a different name than the applicant’s name? (If yes, provide the names in which each permit was issued and at what address).

The term “affiliated party” includes all of the following that may apply: (i) the applicant's directors, officers, trustees, partners, or committee members; (ii) any person who manages, controls, or oversees the applicant's operations (does not have to be an employee), including the establishment manager and the next four (4) highest ranking employees responsible for prescription drug wholesale operations; and (iii) the five (5) individuals (natural persons) who own at least 5% of the applicant's stock ownership interest.

If you answered “YES” to any questions in Section IV, you must provide detailed explanations in Section V, including requirements for submitting supporting legal documents. If needed, explain on separate sheet(s).

Section V – Explanation(s) for “Yes” response(s) to background question(s) in Section IV

EXPLANATION

Section V (cont'd)

Section VI – Other Permits or Licenses

PERMITS OR LICENSES			
1.	Are there any other permits or licenses issued by any agency of the State of Florida that authorize the purchase or possession of prescription drugs at the applicant's establishment or address? (If no, please check this box <input type="checkbox"/> and write "N/A" in the lines below).		<input type="checkbox"/> Yes <input type="checkbox"/> No
1a.	Permit/License Name	Permit/License Type	Permit/License Number

Section VII – Medical Gas Manufacturing Activity

MANUFACTURING ACTIVITIES		
Identify the types of products the applicant will manufacture or distribute under this permit.		
<input type="checkbox"/> Oxygen	<input type="checkbox"/> Other Gases (Please list on separate sheet of paper.)	
Generally identify the applicant's intended customers, the persons and entities that will purchase or receive products from the applicant after permit issuance.		
<input type="checkbox"/> Manufacturers	<input type="checkbox"/> Wholesalers	<input type="checkbox"/> Pharmacies
<input type="checkbox"/> Hospitals	<input type="checkbox"/> Practitioners	<input type="checkbox"/> Clinics
<input type="checkbox"/> Veterinarians		
<input type="checkbox"/> Other (explain) _____		

Provide your Federal Food and Drug Administration (FDA) establishment registration number.

- FDA Establishment Registration Number: _____
 or
 No FDA Establishment Number

1.	Are products to be distributed under this permit intended for export?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2.	Will all required records stored and maintained at applicant's physical address? (If no, provide the address of the establishments where all required records will be stored and maintained under question #2a.)	<input type="checkbox"/> Yes <input type="checkbox"/> No
2a.	Physical address where required records are to be stored: Street Address:	
	City:	State: Zip Code (+4 optional):
3.	Will the required records be computerized, automated or stored electronically? If yes, will you have a back-up procedure to be able to provide required records?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
4.	Is there a quarantine area at the applicant's establishment? Explanation included? <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
5.	Is the applicant's establishment equipped with an alarm system to detect entry after hours and a security system protecting against theft and diversion? (If yes, provide a written description of the alarm and security systems, that include: the type of system and how the system is monitored) Description included? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A (If no, provide a written explanation of why the establishment is not equipped with an alarm or security system.) Explanation included? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No
6.	Are you submitting a product registration application and labels of your products with this application? (If no, explain on a separate sheet providing accurate details). Note: You CAN NOT SELL a product that you manufacture at the establishment until that product has been registered with the department. Selling a product before it is registered with the division is the basis for application permit denial and enforcement action by the division. Explanation included? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No
7.	Do you have labels of your products ready for inspection?	<input type="checkbox"/> Yes <input type="checkbox"/> No
8.	Do you intend to comply with all Federal and State "Current Good Manufacturing Practices"?	<input type="checkbox"/> Yes <input type="checkbox"/> No
9.	Will you possess medical gases at your establishment? (If yes, attach a copy of your most recent fire inspection.)	<input type="checkbox"/> Yes <input type="checkbox"/> No
10.	Do you intend to handle gases not filled by you? (If yes, you must also be permitted by the division as a Medical Gas Wholesale Distributor.)	<input type="checkbox"/> Yes <input type="checkbox"/> No
11.	Do you intend to sell oxygen to patients? (If yes, you must be physically located in Florida and be permitted by the division as a Medical Oxygen Retail Establishment.)	<input type="checkbox"/> Yes <input type="checkbox"/> No
12.	Does the applicant have written policies and procedures to include: the receipt, security, storage, inventory, distribution/disposition of prescription drugs; distributing oldest approved stock first (FIFO); identifying, recording and reporting prescription drug losses and thefts; maintenance, retrieval and retention of required records; prescription drug recalls and withdrawals; natural	<input type="checkbox"/> Yes <input type="checkbox"/> No

	<p>disasters and other emergencies; segregation and destruction of outdated products; temperature and humidity monitoring?</p> <p>(If no, provide written explanation for lack of specific policy or procedure identified above).</p> <p style="text-align: center;">Explanation attached? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p> <p>(If yes, provide a copy of each policy and procedure. Label each policy and procedure specifically identifying the subject matter in the list above that is covered by the policy or procedure. For example, the policy or procedure for receipt, security, storage, inventory could be labeled or identified as "Policy and/or Procedure for receipt, security, storage, inventory" or in another manner similar to this example).</p> <p style="text-align: center;">Policies attached? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Policies labeled? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p>	
13.	<p>Does applicant intend to claim an exemption from inspection by the department? If applicant answered yes to this question applicant must provide: (a) proof applicant is registered with the United States Food and Drug Administration under s. 510 of the federal act, such as a copy of the Internet verification page; AND (b) proof of inspection by the Food and Drug Administration within the past 3 years that demonstrates substantial compliance with good manufacturing practices applicable to medical gases.</p> <p style="text-align: center;">Proof of FDA registration under s. 510 attached? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A FDA inspection within last 3 years attached? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
14.	<p>Provide the date the establishment will be ready and available for inspection if you are not eligible for an exemption authorized by section 499.93(3), Florida Statutes. <u>This is the earliest date the application may be deemed complete.</u></p>	<p>___/___/20___</p>

DRAFT

Section VIII – Affidavit

AFFIDAVIT

Pursuant to s. 559.79, F.S., each application for a license or renewal of a license issued by the Department of Business and Professional Regulation shall be signed under oath or affirmation by the applicant, or owner or chief executive of the applicant without the need for witnesses unless otherwise required by law.

Pursuant to s. 559.791, F.S., any license issued by the Department of Business and Professional Regulation which is issued or renewed in response to an application upon which the person signing under oath or affirmation has falsely sworn to a material statement, including, but not limited to, the names and addresses of the owners or managers of the licensee or applicant, shall be subject to denial of the application or suspension or revocation of the license, and the person falsely swearing shall be subject to any other penalties provided by law.

I UNDERSTAND THAT THE ISSUANCE OF A PERMIT BY THE DEPARTMENT ONLY AUTHORIZES THE APPLICANT TO CONDUCT REGULATED ACTIVITIES IN THE STATE OF FLORIDA UNDER THE NAME IN WHICH THE PERMIT IS ISSUED. IF THE PERMIT IS ISSUED IN THE NAME OF A DBA OR D/B/A THE APPLICANT MAY ONLY CONDUCT BUSINESS IN FLORIDA IN THE NAME OF THE DBA OR D/B/A.

I FURTHER UNDERSTAND THAT PROVIDING ADDITIONAL DBA OR D/B/A NAMES TO THE DEPARTMENT AS PART OF THE APPLICATION PROCESS IS NOT, UPON LICENSURE, AN AUTHORIZATION TO CONDUCT BUSINESS IN FLORIDA UNDER THE NAME OF THOSE ADDITIONAL DBA'S OR D/B/A'S.

I certify that I am empowered to execute this application as required by s. 559.79, F.S. I understand that my signature on this application has the same legal effect as if made under oath. To the best of my knowledge, all information contained on this application is true and correct. I understand the falsification of any information on this application may result in administrative action, including a fine, suspension, or revocation of the license.

Signature of Applicant, Owner or Chief Executive:	Date:
Print Name:	Title:

Mail completed application to:

Department of Business and Professional Regulation
1940 North Monroe Street
Tallahassee, FL 32399