



Florida Department of Environmental Protection

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Electronically Sent- Received Receipt Requested

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FINAL PERMIT

PERMITTEE

Tyco Healthcare Kendall (dba Covidien)
2010 International Speedway
DeLand, FL 32724-2010

Authorized Representative:
Ms. Lisa Young, Plant Manager

Air Permit No. 1270094-014-AC
Permit Expires: 01/31/2012
Site Name : DeLand Manufacturing Facility
Major Source Air Construction Permit
Project Name: Medivative Machine

This is the final air construction permit, which authorizes construction/installation of a Medivative machine that will be a source for volatile organic compounds (VOCs) and hazardous air pollutants (HAPs) in the facility's Building A. The proposed work will be conducted at the Deland Manufacturing Facility (Standard Industrial Classification No. 3841). The facility is located in Volusia County at 2010 International Speedway in DeLand, Florida. The UTM coordinates are Zone 17, 474.17 km East, and 3214.85 km North.

This final permit is organized by the following sections:

- Section 1. General Information
- Section 2. Administrative Requirements
- Section 3. Facility-wide and Emissions Unit Specific Conditions
- Section 4. Appendices

Because of the technical nature of the project, the permit contains numerous acronyms and abbreviations, which are defined in Appendix A of Section 4 of this permit.

This air pollution permit is issued under the provisions of: Chapter 403 of the Florida Statutes (F.S.) and Chapters 62-4, 62-204, 62-210, 62-212, 62-296 and 62-297 of the Florida Administrative Code (F.A.C.). The permittee is authorized to conduct the proposed work in accordance with the conditions of this permit. This project is subject to the general preconstruction review requirements in Rule 62-212.300, F.A.C. and is not subject to the preconstruction review requirements for major stationary sources in Rule 62-212.400, F.A.C. for the Prevention of Significant Deterioration (PSD) of Air Quality.

Upon issuance of this final permit, any party to this order has the right to seek judicial review of it under Section 120.68 of the Florida Statutes by filing a notice of appeal under Rule 9.110 of

the Florida Rules of Appellate Procedure with the clerk of the Department of Environmental Protection in the Office of General Counsel (Mail Station #35, 3900 Commonwealth Boulevard, Tallahassee, Florida, 32399-3000) and by filing a copy of the notice of appeal accompanied by the applicable filing fees with the appropriate District Court of Appeal. The notice must be filed within 30 days after this order is filed with the clerk of the Department.

Executed in Orange County, Florida

Caroline D. Shine 3/2/11
Caroline D. Shine Effective Date
District Air Program Administrator
Central District

CERTIFICATE OF SERVICE

The undersigned duly designated deputy agency clerk hereby certifies that this Final Air Permit package (including the Final Determination, the Final Permit and the Appendices) was sent by electronic mail (or a link to these documents made available electronically on a publicly accessible server) with received receipt requested before the close of business on March 3, 2011 to the persons listed below.

Ms. Lisa Young, Tyco Healthcare Kendall (dba Covidien) (lisa.young@covidien.com)
Ms. Sue Williams, Tyco Healthcare Kendall (dba Covidien) (sue.williams@covidien.com)
Ms. Suzanne Thomas-Cole, P.E., Aecom (suzanne.t.thomas@aecom)

Clerk Stamp

FILING AND ACKNOWLEDGMENT FILED, on this date, pursuant to Section 120.52(7), Florida Statutes, with the designated agency clerk, receipt of which is hereby acknowledged.

W. Agner 3/3/2011
(Clerk) (Date)

SECTION 1. GENERAL INFORMATION (FINAL)

FACILITY AND PROJECT DESCRIPTION

DeLand Manufacturing Facility

The facility consists of a needle manufacturing process that contains the following operations: needle lube mixing, grinding operations, needle assembly operations, sterilization, packaging, and prototypical equipment testing in Building B of the facility.

The existing facility consists of the following emissions units.

Facility ID No. 1270094	
ID No.	Emission Unit Description
009	Needle Manufacturing
010	Grinding Operations

Project Description and Proposed Emission Units

This project is for the construction/installation of a Medivative machine that will be a source for VOCs and HAPs in the facility's Building A. The Medivative machine will produce adult and pediatric needle cartridges for a hand held administration system.

This project will modify the following emissions unit.

Facility ID No. 1270094	
ID No.	Emission Unit Description
009	Needle Manufacturing, including Medivative Machine

NOTE: Please reference the Permit No., Facility ID, and Emission Unit ID in all correspondence, test report submittals, applications, etc.

FACILITY REGULATORY CLASSIFICATION

- The facility is a major source of hazardous air pollutants (HAP).
- The facility has no units subject to the acid rain provisions of the Clean Air Act (CAA).
- The facility is a Title V major source of air pollution in accordance with Chapter 213, F.A.C.
- The facility is not a major stationary source in accordance with Rule 62-212.400(PSD), F.A.C.

PERMIT HISTORY/AFFECTED PERMITS

Modifies Permit No. 1270094-013-AV;

SECTION 2. ADMINISTRATIVE REQUIREMENTS (FINAL)

1. Permitting Authority: The permitting authority for this project is the Florida Department of Environmental Protection, Central District Air Resource Management Section. The Central District's mailing address and phone number is:

Florida Department of Environmental Protection
Central District Office
Air Resource Management Section
3319 Maguire Blvd., Ste. 232
Orlando, FL 32803-3767 Telephone: 407-894-7555

All documents related to applications for permits shall be submitted to the above address.

2. Compliance Authority: All documents related to compliance activities such as reports, tests, and notifications shall be submitted to the Central District Air Resource Management Section (see above mailing address and phone number) or Local Air Program Name. The mailing address and phone number of the Local Air Program is: Address and Phone Number.
3. Appendices: The following Appendices are attached as part of this permit:
 - a. Appendix A. Citation Formats and Glossary of Common Terms;
 - b. Appendix B. General Conditions;
 - c. Appendix C. Common Conditions; and
 - d. Appendix D. Common Testing Requirements.
4. Applicable Regulations, Forms and Application Procedures: Unless otherwise specified in this permit, the construction and operation of the subject emissions units shall be in accordance with the capacities and specifications stated in the application. The facility is subject to all applicable provisions of: Chapter 403, F.S.; and Chapters 62-4, 62-204, 62-210, 62-212, 62-213, 62-296 and 62-297, F.A.C. Issuance of this permit does not relieve the permittee from compliance with any applicable federal, state, or local permitting or regulations.
5. New or Additional Conditions: For good cause shown and after notice and an administrative hearing, if requested, the Department may require the permittee to conform to new or additional conditions. The Department shall allow the permittee a reasonable time to conform to the new or additional conditions, and on application of the permittee, the Department may grant additional time.
[Rule 62-4.080, F.A.C.]
6. Modifications: Unless otherwise exempt by rule, the permittee shall not initiate any construction, reconstruction, or modification at the facility and shall not install/modify any pollution control device at the facility without obtaining prior authorization from the Department. Modification is defined as: Any physical change or changes in the method of operations or addition to a facility that would result in an increase in the actual emissions of any air pollutant subject to air regulations, including any not previously emitted, from any emission unit or facility.
[Rules 62-210.200 - Definition of "Modification" and 62-210.300(1)(a), F.A.C.]
7. Annual Operating Report: On or before **April 1** of each year, the permittee shall submit a completed DEP Form 62-210.900(5), "Annual Operating Report for Air Pollutant Emitting Facility" (AOR) for the preceding calendar year. The report may be submitted electronically in accordance

SECTION 2. ADMINISTRATIVE REQUIREMENTS (FINAL)

with the instructions received with the AOR package sent by the Department, or a hardcopy may be sent to the Compliance Authority.

[Rule 62-210.370(3), F.A.C.]

8. Application for Title V Air Operation Permit: This permit authorizes construction or modification of the permitted emissions unit(s) and initial operation to determine compliance with Department rules. A Title V air operation permit is required for continued operation of the permitted emissions unit(s). The permittee shall apply for a Title V air operation permit at least 90 days prior to expiration of this permit, but no later than 180 days after commencing operation or commencing operation as modified. Commencing operation means setting into operation of any emissions unit for any purpose. To apply for a Title V air operation permit, the applicant shall submit the following:

- a. the appropriate permit application form (*see current version of Rule 62-210.900, F.A.C. (Forms and Instructions), and/or FDEP Division of Air Resource Management website at: <http://www.dep.state.fl.us/air/>*); and
- d. copies of the most recent two months of records/logs specified in Specific Condition No. A.6.

The application shall be submitted to the Permitting Authority.

[Rules 62-4.030, 62-4.050, 62-4.220 and Chapter 62-213, F.A.C.]

SECTION 2. ADMINISTRATIVE REQUIREMENTS (FINAL)

This section of the permit addresses the following emissions unit.

ID No.	Emission Unit Description
009	<p>Needle Manufacturing, including Medivative Machine</p> <p>Medivative Machine:</p> <p>The process will use a Loctite adhesive along with a hexane lubricant during manufacturing.</p> <p>The specific processes contained within the Medivative Machine include:</p> <ul style="list-style-type: none"> - Plasma Treater/Cannula - Deionizer/ Adhesive Introduction - UV Cure (Exhaust System) - Lube Injection (Exhaust System) - Occlusion Test <p>Two of the processes, UV Cure and Lube Injection, will exhaust to the atmosphere. An existing exhaust system (NL03) will be used for ventilation of the Lube Injection equipment. The UV Cure exhaust, the pathway for VOCs and HAPs from the Loctite to the atmosphere, will be a new exhaust system (Med-UV01). The plasma treater is an Enercon machine that will not release any pollutants.</p>

PERFORMANCE RESTRICTIONS

- A.1. Permitted Capacity: The maximum production rate for the medivative machine shall not exceed 1,800 parts per hour.
[Rule 62-210.200(PTE), F.A.C.]
- A.2. Restricted Operation: The hours of operation for the medivative machine are not limited (8760 hours per year).
[Rules 62-4.070(3) and 62-210.200(PTE), F.A.C.]

EMISSIONS STANDARDS

- A.3. Emission Limitations: The total facility-wide VOC and HAP emission operation limits are as follows:

Pollutant	Emission Limits (tons/any consecutive 12 month period)
Total Volatile Organic Compounds (VOCs)	94.0
Total Hazardous Air Pollutants (HAPs)	less than 94.0
Individual Hazardous Air Pollutants (HAPs)	less than 94.0

[Rules 62-210.200(PTE) and 62-210.300(2)(a)1, F.A.C.; FESOP 0090078-004-AF]

SECTION 2. ADMINISTRATIVE REQUIREMENTS (FINAL)

- A.4. General Visible Emissions (VE) Limitation: Visible emissions are limited to less than 20 percent opacity.
[Rule 62-296.320(4)(b)1., F.A.C.]

NOTIFICATION REQUIREMENTS

- A.5. Notification of Operation Commencement: The permittee shall notify the Compliance Authority in writing of the date of commencing operation of the Medivative Machine, no later than five (5) business days after that date. Commencing operation means setting into operation of any emissions unit for any purpose.
[Rule 62-4.070, F.A.C., and Rule 62-210.200, F.A.C., (Definition of Commence Operation)]

RECORDS AND REPORTS

- A.6. In order to demonstrate compliance with Specific Condition Nos. A.1. and A.3., the permittee shall maintain daily records of production and monthly records to support the VOC/HAP usage and emissions. At a minimum, the logs shall contain the following:

a. Daily Records

- 1) Date (Month/Day/Year);
- 2) Total daily quantity of needle cartridges produced;
- 3) Total daily hours of operation of the medivative machine; and
- 4) Daily average production rate of the medivative machine (parts/hour).

b. Monthly Records

- 1) Date (Month and Year);
- 2) The usage of all lubricants and adhesives containing VOCs and HAPs
- 3) The total VOC content and total HAP content of each lubricant and adhesive;
- 4) The total of VOC/HAP emissions for each month; and
- 5) The cumulative 12-month running total of VOC/HAP emissions to ensure the annual VOC/HAP emission limits are not exceeded.

Supporting documentation may consist of "As Supplied" sheets, MSDS sheets, EPA data sheets, purchase orders, waste shipment/disposal records, etc. that includes information to determine VOC and HAP emissions.

All records shall include the Facility Name, Facility ID No. (1270094), Emission Unit ID No. (e.g., EU 009 - Needle Manufacturing, **including Medivative Machine**), and the Date. Daily records shall be completed within three (3) business days. Monthly records shall be completed by the end of the following month.

[Rule 62-4.070(3), F.A.C.]

