



COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
AIR QUALITY PROGRAM

STATE ONLY OPERATING PERMIT

Issue Date: January 25, 2017

Effective Date: February 1, 2017

Expiration Date: January 31, 2022

In accordance with the provisions of the Air Pollution Control Act, the Act of January 8, 1960, P.L. 2119, as amended, and 25 Pa. Code Chapter 127, the Owner, [and Operator if noted] (hereinafter referred to as permittee) identified below is authorized by the Department of Environmental Protection (Department) to operate the air emission source(s) more fully described in this permit. This Facility is subject to all terms and conditions specified in this permit. Nothing in this permit relieves the permittee from its obligations to comply with all applicable Federal, State and Local laws and regulations.

The regulatory or statutory authority for each permit condition is set forth in brackets. All terms and conditions in this permit are federally enforceable unless otherwise designated.

State Only Permit No: 15-00136

Federal Tax Id - Plant Code: 87-0447695-1

Owner Information

Name: MERIT MEDICAL
Mailing Address: 65 GREAT VALLEY PKWY
MALVERN, PA 19355-1302

Plant Information

Plant: MERIT MEDICAL/MALVERN
Location: 15 Chester County 15938 Malvern Borough
SIC Code: 3841 Manufacturing - Surgical And Medical Instruments

Responsible Official

Name: PETER RAPP
Title: MANAGING DIRECTOR
Phone: (610) 296 - 3000

Permit Contact Person

Name: PETER RAPP
Title: MANAGING DIRECTOR
Phone: (610) 296 - 3000

[Signature] _____
JAMES D. REBARCHAK, SOUTHEAST REGION AIR PROGRAM MANAGER

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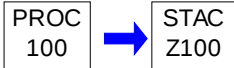
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100	PREP & CLEANING OPERATIONS	N/A	SOLVENT
Z100	PREP & CLEANING OPERATION FUGITIVES		

PERMIT MAPS

SECTION B. General State Only Requirements

#001 [25 Pa. Code § 121.1]

Definitions.

Words and terms that are not otherwise defined in this permit shall have the meanings set forth in Section 3 of the Air Pollution Control Act (35 P.S. § 4003) and in 25 Pa. Code § 121.1.

#002 [25 Pa. Code § 127.446]

Operating Permit Duration.

- (a) This operating permit is issued for a fixed term of five (5) years and shall expire on the date specified on Page 1 of this permit.
- (b) The terms and conditions of the expired permit shall automatically continue pending issuance of a new operating permit, provided the permittee has submitted a timely and complete application and paid applicable fees required under 25 Pa. Code Chapter 127, Subchapter I and the Department is unable, through no fault of the permittee, to issue or deny a new permit before the expiration of the previous permit.

#003 [25 Pa. Code §§ 127.412, 127.413, 127.414, 127.446 & 127.703(b)&(c)]

Permit Renewal.

- (a) The permittee shall submit a timely and complete application for renewal of the operating permit to the appropriate Regional Air Program Manager. The application for renewal of the operating permit shall be submitted at least six (6) months and not more than 18 months before the expiration date of this permit.
- (b) The application for permit renewal shall include the current permit number, a description of any permit revisions that occurred during the permit term, and any applicable requirements that were promulgated and not incorporated into the permit during the permit term. An application is complete if it contains sufficient information to begin processing the application, has the applicable sections completed and has been signed by a responsible official.
- (c) The permittee shall submit with the renewal application a fee for the processing of the application and an additional annual administrative fee as specified in 25 Pa. Code § 127.703(b) and (c). The fees shall be made payable to "The Commonwealth of Pennsylvania - Clean Air Fund" and shall be for the amount specified in the following schedule specified in 25 Pa. Code § 127.703(b) and (c).
 - (1) Three hundred dollars for applications filed during the 2000-2004 calendar years.
 - (2) Three hundred seventy-five dollars for applications filed for the calendar years beginning in 2005.
- (d) The renewal application shall also include submission of proof that the local municipality and county, in which the facility is located, have been notified in accordance with 25 Pa. Code § 127.413.
- (e) The application for renewal of the operating permit shall also include submission of supplemental compliance review forms in accordance with the requirements of 25 Pa. Code § 127.412(b) and § 127.412(j).
- (f) The permittee, upon becoming aware that any relevant facts were omitted or incorrect information was submitted in the permit application, shall promptly submit such supplementary facts or corrected information as necessary to address any requirements that become applicable to the source after the permittee submits a complete application, but prior to the date the Department takes action on the permit application.

#004 [25 Pa. Code § 127.703]

Operating Permit Fees under Subchapter I.

- (a) The permittee shall pay fees according to the following schedule specified in 25 Pa. Code § 127.703(b):
 - (1) Three hundred dollars for applications filed during the 2000-2004 calendar years.
 - (2) Three hundred seventy-five dollars for applications filed for the calendar years beginning in 2005.

This fee schedule shall apply to the processing of an application for an operating permit as well as the extension,

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modification, revision, renewal, and re-issuance of each operating permit or part thereof.

(b) The permittee shall pay an annual operating permit administrative fee according to the fee schedule established in 25 Pa. Code § 127.703(c).

(1) Two hundred fifty dollars for applications filed during the 1995-1999 calendar years.

(2) Three hundred dollars for applications filed during the 2000-2004 calendar years.

(3) Three hundred seventy-five dollars for applications filed during the years beginning in 2005.

(c) The applicable fees shall be made payable to "The Commonwealth of Pennsylvania - Clean Air Fund".

#005 [25 Pa. Code §§ 127.450 (a)(4) and 127.464]

Transfer of Operating Permits.

(a) This operating permit may not be transferred to another person, except in cases of transfer-of-ownership that are documented and approved by the Department.

(b) In accordance with 25 Pa. Code § 127.450(a)(4), a change in ownership of the source shall be treated as an administrative amendment if the Department determines that no other change in the permit is required and a written agreement has been submitted to the Department identifying the specific date of the transfer of permit responsibility, coverage and liability between the current and the new permittee and a compliance review form has been submitted to, and the permit transfer has been approved by, the Department.

(c) This operating permit is valid only for those specific sources and the specific source locations described in this permit.

#006 [25 Pa. Code § 127.441 and 35 P.S. § 4008]

Inspection and Entry.

(a) Upon presentation of credentials and other documents as may be required by law, the permittee shall allow the Department or authorized representatives of the Department to perform the following:

(1) Enter at reasonable times upon the permittee's premises where a source is located or emissions related activity is conducted, or where records are kept under the conditions of this permit;

(2) Have access to and copy, at reasonable times, any records that are kept under the conditions of this permit;

(3) Inspect at reasonable times, any facilities, equipment including monitoring and air pollution control equipment, practices, or operations regulated or required under this permit;

(4) Sample or monitor, at reasonable times, any substances or parameters, for the purpose of assuring compliance with the permit or applicable requirements as authorized by the Clean Air Act, the Air Pollution Control Act, or the regulations promulgated under the Acts.

(b) Pursuant to 35 P.S. § 4008, no person shall hinder, obstruct, prevent or interfere with the Department or its personnel in the performance of any duty authorized under the Air Pollution Control Act or regulations adopted thereunder including denying the Department access to a source at this facility. Refusal of entry or access may constitute grounds for permit revocation and assessment of criminal and/or civil penalties.

(c) Nothing in this permit condition shall limit the ability of the EPA to inspect or enter the premises of the permittee in accordance with Section 114 or other applicable provisions of the Clean Air Act.

#007 [25 Pa. Code §§ 127.441 & 127.444]

Compliance Requirements.

(a) The permittee shall comply with the conditions of this operating permit. Noncompliance with this permit constitutes

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a violation of the Clean Air Act and the Air Pollution Control Act and is grounds for one or more of the following:

- (1) Enforcement action
- (2) Permit termination, revocation and reissuance or modification
- (3) Denial of a permit renewal application

(b) A person may not cause or permit the operation of a source which is subject to 25 Pa. Code Article III unless the source(s) and air cleaning devices identified in the application for the plan approval and operating permit and the plan approval issued for the source is operated and maintained in accordance with specifications in the applications and the conditions in the plan approval and operating permit issued by the Department. A person may not cause or permit the operation of an air contamination source subject to 25 Pa. Code Chapter 127 in a manner inconsistent with good operating practices.

(c) For purposes of Sub-condition (b) of this permit condition, the specifications in applications for plan approvals and operating permits are the physical configurations and engineering design details which the Department determines are essential for the permittee's compliance with the applicable requirements in this State-Only permit. Nothing in this sub-condition shall be construed to create an independent affirmative duty upon the permittee to obtain a predetermination from the Department for physical configuration or engineering design detail changes made by the permittee.

#008 [25 Pa. Code § 127.441]

Need to Halt or Reduce Activity Not a Defense.

It shall not be a defense for the permittee in an enforcement action that it was necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit.

#009 [25 Pa. Code §§ 127.442(a) & 127.461]

Duty to Provide Information.

(a) The permittee shall submit reports to the Department containing information the Department may prescribe relative to the operation and maintenance of each source at the facility.

(b) The permittee shall furnish to the Department, in writing, information that the Department may request to determine whether cause exists for modifying, revoking and reissuing, or terminating this permit, or to determine compliance with the permit. Upon request, the permittee shall also furnish to the Department copies of records that the permittee is required to maintain in accordance with this permit.

#010 [25 Pa. Code § 127.461]

Revising an Operating Permit for Cause.

This operating permit may be terminated, modified, suspended or revoked and reissued if one or more of the following applies:

- (1) The permittee constructs or operates the source subject to the operating permit so that it is in violation of the Air Pollution Control Act, the Clean Air Act, the regulations thereunder, a plan approval, a permit or in a manner that causes air pollution.
- (2) The permittee fails to properly or adequately maintain or repair an air pollution control device or equipment attached to or otherwise made a part of the source.
- (3) The permittee has failed to submit a report required by the operating permit or an applicable regulation.
- (4) The EPA determines that the permit is not in compliance with the Clean Air Act or the regulations thereunder.

#011 [25 Pa. Code §§ 127.450 & 127.462]

Operating Permit Modifications

- (a) The permittee is authorized to make administrative amendments, minor operating permit modifications and

SECTION B. General State Only Requirements

significant operating permit modifications, under this permit, as outlined below:

(b) Administrative Amendments. The permittee shall make administrative operating permit amendments (as defined in 25 Pa. Code § 127.450(a)), according to procedures specified in § 127.450 unless precluded by the Clean Air Act or its regulations.

(c) Minor Operating Permit Modifications. The permittee shall make minor operating permit modifications (as defined 25 Pa. Code § 121.1) in accordance with 25 Pa. Code § 127.462.

(d) Permit modifications which do not qualify as minor permit modifications under 25 Pa. Code § 127.541 will be treated as a significant operating permit revision subject to the public notification procedures in §§ 127.424 and 127.425.

#012 [25 Pa. Code § 127.441]

Severability Clause.

The provisions of this permit are severable, and if any provision of this permit is determined by a court of competent jurisdiction to be invalid or unenforceable, such a determination will not affect the remaining provisions of this permit.

#013 [25 Pa. Code § 127.449]

De Minimis Emission Increases.

(a) This permit authorizes de minimis emission increases in accordance with 25 Pa. Code § 127.449 so long as the permittee provides the Department with seven (7) days prior written notice before commencing any de minimis emissions increase. The written notice shall:

(1) Identify and describe the pollutants that will be emitted as a result of the de minimis emissions increase.

(2) Provide emission rates expressed in tons per year and in terms necessary to establish compliance consistent with any applicable requirement.

(b) The Department may disapprove or condition de minimis emission increases at any time.

(c) Except as provided below in (d), the permittee is authorized to make de minimis emission increases (expressed in tons per year) up to the following amounts without the need for a plan approval or prior issuance of a permit modification:

(1) Four tons of carbon monoxide from a single source during the term of the permit and 20 tons of carbon monoxide at the facility during the term of the permit.

(2) One ton of NO_x from a single source during the term of the permit and 5 tons of NO_x at the facility during the term of the permit.

(3) One and six-tenths tons of the oxides of sulfur from a single source during the term of the permit and 8.0 tons of oxides of sulfur at the facility during the term of the permit.

(4) Six-tenths of a ton of PM₁₀ from a single source during the term of the permit and 3.0 tons of PM₁₀ at the facility during the term of the permit. This shall include emissions of a pollutant regulated under Section 112 of the Clean Air Act unless precluded by the Clean Air Act, the regulations thereunder or 25 Pa. Code Article III.

(5) One ton of VOCs from a single source during the term of the permit and 5.0 tons of VOCs at the facility during the term of the permit. This shall include emissions of a pollutant regulated under Section 112 of the Clean Air Act unless precluded by the Clean Air Act, the regulations thereunder or 25 Pa. Code Article III.

(6) Other sources and classes of sources determined to be of minor significance by the Department.

(d) In accordance with § 127.14, the permittee is authorized to install the following minor sources without the need for a plan approval or permit modification:

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(1) Air conditioning or ventilation systems not designed to remove pollutants generated or released from other sources.

(2) Combustion units rated at 2,500,000 or less Btu per hour of heat input.

(3) Combustion units with a rated capacity of less than 10,000,000 Btu per hour heat input fueled by natural gas supplied by a public utility or by commercial fuel oils which are No. 2 or lighter, viscosity less than or equal to 5.82 c St, and which meet the sulfur content requirements of 25 Pa. Code §123.22 (relating to combustion units). For purposes of this permit, commercial fuel oil shall be virgin oil which has no reprocessed, recycled or waste material added.

(4) Space heaters which heat by direct heat transfer.

(5) Laboratory equipment used exclusively for chemical or physical analysis.

(6) Other sources and classes of sources determined to be of minor significance by the Department.

(e) This permit does not authorize de minimis emission increases if the emissions increase would cause one or more of the following:

(1) Increase the emissions of a pollutant regulated under Section 112 of the Clean Air Act except as authorized in Subparagraphs (c)(4) and (5) of this permit condition.

(2) Subject the facility to the prevention of significant deterioration requirements in 25 Pa. Code Chapter 127, Subchapter D and/or the new source review requirements in Subchapter E.

(3) Violate any applicable requirement of this permit, the Air Pollution Control Act, the Clean Air Act, or the regulations promulgated under either of the acts.

(f) Emissions authorized under this permit condition shall be included in the monitoring, recordkeeping and reporting requirements of this permit.

(g) Except for de minimis emission increases, installation of minor sources made pursuant to this permit condition and Plan Approval Exemptions under 25 Pa. Code § 127.14 (relating to exemptions), the permittee is prohibited from making changes or engaging in activities that are not specifically authorized under this permit without first applying for a plan approval. In accordance with § 127.14(b), a plan approval is not required for the construction, modification, reactivation, or installation of the sources creating the de minimis emissions increase.

(h) The permittee may not meet de minimis emission threshold levels by offsetting emission increases or decreases at the same source.

#014 [25 Pa. Code § 127.3]

Operational Flexibility.

The permittee is authorized to make changes within the facility in accordance with the regulatory provisions outlined in 25 Pa. Code § 127.3 (relating to operational flexibility) to implement the operational flexibility requirements provisions authorized under Section 6.1(i) of the Air Pollution Control Act and the operational flexibility terms and conditions of this permit. The provisions in 25 Pa. Code Chapter 127 which implement the operational flexibility requirements include the following:

(1) Section 127.14 (relating to exemptions)

(2) Section 127.447 (relating to alternative operating scenarios)

(3) Section 127.448 (relating to emissions trading at facilities with Federally enforceable emissions caps)

(4) Section 127.449 (relating to de minimis emission increases)

(5) Section 127.450 (relating to administrative operating permit amendments)

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(6) Section 127.462 (relating to minor operating permit modifications)

(7) Subchapter H (relating to general plan approvals and general operating permits)

#015 [25 Pa. Code § 127.11]

Reactivation

(a) The permittee may not reactivate a source that has been out of operation or production for at least one year unless the reactivation is conducted in accordance with a plan approval granted by the Department or in accordance with reactivation and maintenance plans developed and approved by the Department in accordance with 25 Pa. Code § 127.11a(a).

(b) A source which has been out of operation or production for more than five (5) years but less than 10 years may be reactivated and will not be considered a new source if the permittee satisfies the conditions specified in 25 Pa. Code § 127.11a(b).

#016 [25 Pa. Code § 127.36]

Health Risk-based Emission Standards and Operating Practice Requirements.

(a) When needed to protect public health, welfare and the environment from emissions of hazardous air pollutants from new and existing sources, the permittee shall comply with the health risk-based emission standards or operating practice requirements imposed by the Department, except as precluded by §§ 6.6(d)(2) and (3) of the Air Pollution Control Act [35 P.S. § 4006.6(d)(2) and (3)].

(b) A person challenging a performance or emission standard established by the Department has the burden to demonstrate that performance or emission standard does not meet the requirements of Section 112 of the Clean Air Act.

#017 [25 Pa. Code § 121.9]

Circumvention.

No person may permit the use of a device, stack height which exceeds good engineering practice stack height, dispersion technique or other technique which, without resulting in reduction of the total amount of air contaminants emitted, conceals or dilutes an emission of air contaminants which would otherwise be in violation of 25 Pa. Code Article III, except that with prior approval of the Department, the device or technique may be used for control of malodors.

#018 [25 Pa. Code §§ 127.402(d) & 127.442]

Reporting Requirements.

(a) The permittee shall comply with the applicable reporting requirements of the Clean Air Act, the regulations thereunder, the Air Pollution Control Act and 25 Pa. Code Article III including Chapters 127, 135 and 139.

(b) The permittee shall submit reports to the Department containing information the Department may prescribe relative to the operation and maintenance of any air contamination source.

(c) Reports, test data, monitoring data, notifications and requests for renewal of the permit shall be submitted to the:

Regional Air Program Manager
PA Department of Environmental Protection
(At the address given in the permit transmittal letter, or otherwise notified)

(d) Any records or information including applications, forms, or reports submitted pursuant to this permit condition shall contain a certification by a responsible official as to truth, accuracy and completeness. The certifications submitted under this permit shall require a responsible official of the facility to certify that based on information and belief formed after reasonable inquiry, the statements and information in the documents are true, accurate and complete.

(e) Any records, reports or information submitted to the Department shall be available to the public except for such

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records, reports or information which meet the confidentiality requirements of § 4013.2 of the Air Pollution Control Act and §§ 112(d) and 114(c) of the Clean Air Act. The permittee may not request a claim of confidentiality for any emissions data generated for the facility.

#019 [25 Pa. Code §§ 127.441(c) & 135.5]

Sampling, Testing and Monitoring Procedures.

(a) The permittee shall comply with the monitoring, recordkeeping or reporting requirements of 25 Pa. Code Chapter 139 and the other applicable requirements of 25 Pa. Code Article III and additional requirements related to monitoring, reporting and recordkeeping required by the Clean Air Act and the regulations thereunder including the Compliance Assurance Monitoring requirements of 40 CFR Part 64, where applicable.

(b) Unless alternative methodology is required by the Clean Air Act and regulations adopted thereunder, sampling, testing and monitoring required by or used by the permittee to demonstrate compliance with any applicable regulation or permit condition shall be conducted in accordance with the requirements of 25 Pa. Code Chapter 139.

#020 [25 Pa. Code §§ 127.441(c) and 135.5]

Recordkeeping.

(a) The permittee shall maintain and make available, upon request by the Department, the following records of monitored information:

- (1) The date, place (as defined in the permit) and time of sampling or measurements.
- (2) The dates the analyses were performed.
- (3) The company or entity that performed the analyses.
- (4) The analytical techniques or methods used.
- (5) The results of the analyses.
- (6) The operating conditions as existing at the time of sampling or measurement.

(b) The permittee shall retain records of any required monitoring data and supporting information for at least five (5) years from the date of the monitoring, sample, measurement, report or application. Supporting information includes the calibration data and maintenance records and original strip-chart recordings for continuous monitoring instrumentation, and copies of reports required by the permit.

(c) The permittee shall maintain and make available to the Department upon request, records including computerized records that may be necessary to comply with the reporting, recordkeeping and emission statement requirements in 25 Pa. Code Chapter 135 (relating to reporting of sources). In accordance with 25 Pa. Code Chapter 135, § 135.5, such records may include records of production, fuel usage, maintenance of production or pollution control equipment or other information determined by the Department to be necessary for identification and quantification of potential and actual air contaminant emissions.

#021 [25 Pa. Code § 127.441(a)]

Property Rights.

This permit does not convey any property rights of any sort, or any exclusive privileges.

#022 [25 Pa. Code § 127.447]

Alternative Operating Scenarios.

The permittee is authorized to make changes at the facility to implement alternative operating scenarios identified in this permit in accordance with 25 Pa. Code § 127.447.

SECTION C. Site Level Requirements

I. RESTRICTIONS.

Emission Restriction(s).

001 [25 Pa. Code §121.7]

Prohibition of air pollution.

No person may permit air pollution as that term is defined in the Air Pollution Control Act (35 P.S. Section 4003).

002 [25 Pa. Code §123.1]

Prohibition of certain fugitive emissions

No person may permit the emission into the outdoor atmosphere of fugitive air contaminant from a source other than the following:

- (a) construction or demolition of buildings or structures;
- (b) grading, paving and maintenance of roads and streets;
- (c) use of roads and streets. Emissions from material in or on trucks, railroad cars and other vehicular equipment are not considered as emissions from use of roads and streets;
- (d) clearing of land;
- (e) stockpiling of materials;
- (f) open burning operations, as specified in 25 Pa. Code § 129.14;
- (g) blasting in open pit mines. Emissions from drilling are not considered as emissions from blasting;
- (h) coke oven batteries, provided the fugitive air contaminants emitted from any coke oven battery comply with the standards for visible fugitive emissions in 25 Pa. Code §§ 123.44 and 129.15 (relating to limitations of visible fugitive air contaminants from operation of any coke oven battery; and coke pushing operations); and
- (i) sources and classes of sources other than those identified in (a)-(h), above, for which the permittee has obtained a determination from the Department that fugitive emissions from the source, after appropriate control, meet the following requirements:
 - (1) the emissions are of minor significance with respect to causing air pollution; and
 - (2) the emissions are not preventing or interfering with the attainment or maintenance of any ambient air quality standard.

003 [25 Pa. Code §123.2]

Fugitive particulate matter

A person may not permit fugitive particulate matter to be emitted into the outdoor atmosphere from a source specified in Condition #002(a) -- (i) (relating to prohibition of certain fugitive emissions) if such emissions are visible at the point the emissions pass outside the person's property.

004 [25 Pa. Code §123.31]

Limitations

A person may not permit the emission into the outdoor atmosphere of any malodorous air contaminants from any source in such a manner that the malodors are detectable outside the property of the person on whose land the source is being operated.

005 [25 Pa. Code §123.41]

Limitations

A person may not permit the emission into the outdoor atmosphere of visible air contaminants in such a manner that the opacity of the emission is either of the following:

- (a) Equal to or greater than 20% for a period or periods aggregating more than three minutes in any 1 hour.
- (b) Equal to or greater than 60% at any time.

006 [25 Pa. Code §123.42]

Exceptions

The limitations of Condition #005, of this Section, shall not apply to a visible emission in either of the following instances:

- (a) When the presence of uncombined water is the only reason for failure to meet the limitations.
- (b) When the emission results from the sources specified in Condition #002, of this Section.

007 [25 Pa. Code §129.14]

Open burning operations

No person may permit the open burning of material in the Southeast Air Basin except where the open burning operations result from:

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- (a) a fire set to prevent or abate a fire hazard, when approved by the Department and set by or under the supervision of a public officer;
- (b) any fire set for the purpose of instructing personnel in fire fighting, when approved by the Department;
- (c) a fire set for the prevention and control of disease or pests, when approved by the Department;
- (d) a fire set in conjunction with the production of agricultural commodities in their unmanufactured state on the premises of the farm operation;
- (e) a fire set for the purpose of burning domestic refuse, when the fire is on the premises of a structure occupied solely as a dwelling by two families or less and when the refuse results from the normal occupancy of the structure;
- (f) a fire set solely for recreational or ceremonial purposes; or
- (g) a fire set solely for cooking food.

II. TESTING REQUIREMENTS.**# 008 [25 Pa. Code §127.441]****Operating permit terms and conditions.**

- (a) If at any time the Department has cause to believe that air contaminant emissions from any source(s) listed in Section A, of this Permit, may be in excess of the limitations specified in this Permit, or established pursuant to, any applicable rule or regulation contained in 25 Pa. Code Article III, the permittee shall be required to conduct whatever tests are deemed necessary by the Department to determine the actual emission rate(s).
- (b) Such testing shall be conducted in accordance with the provisions of 25 Pa. Code Chapter 139, when applicable, and in accordance with any restrictions or limitations established by the Department at such time as it notifies the permittee that testing is required.

III. MONITORING REQUIREMENTS.**# 009 [25 Pa. Code §123.43]****Measuring techniques**

Visible emissions may be measured using either of the following:

- (a) A device approved by the Department and maintained to provide accurate opacity measurements.
- (b) Observers, trained and qualified to measure plume opacity with the naked eye or with the aid of any devices approved by the Department.

010 [25 Pa. Code §127.441]**Operating permit terms and conditions.**

- (a) The permittee shall monitor the facility, once per month, for the following:
 - (1) odors which may be objectionable (as per 25 Pa. Code §123.31);
- (b) Objectionable odors that are caused or may be caused by operations at the site shall:
 - (1) be investigated;
 - (2) be reported to the facility management, or individual(s) designated by the permittee;
 - (3) have appropriate corrective action taken (for emissions that originate on-site); and
 - (4) be recorded in a permanent written log.
- (c) The Department reserves the right to change the above monitoring requirements at any time, based on but not limited to: the review of the compliance certification (if applicable), complaints, monitoring results, and/or Department findings.

IV. RECORDKEEPING REQUIREMENTS.**# 011 [25 Pa. Code §127.441]****Operating permit terms and conditions.**

The permittee shall maintain a record of all monitoring of fugitive emissions, visible emissions and odors, including those that deviate from the conditions found in this permit. The record of deviations shall contain, at a minimum, the following

SECTION C. Site Level Requirements

items:

- (a) date, time, and location of the incident(s);
- (b) the cause of the event; and
- (c) the corrective action taken, if necessary, to abate the situation and prevent future occurrences.

012 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The permittee shall maintain records of all the facility's increases of emissions from the following categories:

- (a) De minimis increases without notification to the Department.
- (b) De minimis increases with notification to the Department, via letter.
- (c) Increases resulting from a Request for Determination (RFD) to the Department.
- (d) Increases resulting from the issuance of a plan approval and subsequent operating permit.

V. REPORTING REQUIREMENTS.

013 [25 Pa. Code §127.441]

Operating permit terms and conditions.

(a) The permittee shall, within two (2) hours of discovery of any occurrence, notify the Department, at (484) 250-5920, of any malfunction of the source(s) or associated air pollution control devices listed in Section A, of this permit, which results in, or may possibly result in, the emission of air contaminants in excess of the limitations specified in this permit, or of a regulation contained in 25 Pa. Code Article III.

(b) Malfunction(s) which occur at this facility, and pose(s) an imminent danger to public health, safety, welfare and the environment, and would violate permit conditions if the source were to continue to operate after the malfunction, shall immediately be reported to the Department by telephone at the above number.

(c) A written report shall be submitted to the Department within two (2) working days following the notification of the incident, and shall describe the following:

- (1) The malfunction(s).
- (2) The emission(s).
- (3) The duration.
- (4) Any corrective action taken.

014 [25 Pa. Code §127.441]

Operating permit terms and conditions.

(a) If required by Section 112(r) of the Clean Air Act, the permittee shall develop and implement an accidental release program consistent with requirements of the Clean Air Act, 40 CFR Part 68 (relating to chemical accident prevention provisions) and the Federal Chemical Safety Information, Site Security and Fuels Regulatory Relief Act (P.L. 106-40).

(b) The permittee shall prepare and implement a Risk Management Plan (RMP) which meets the requirements of Section 112(r) of the Clean Air Act, 40 CFR Part 68 and the Federal Chemical Safety Information, Site Security and Fuels Regulatory Relief Act when a regulated substance listed in 40 CFR § 68.130 is present in a process in more than the threshold quantity at a facility. The permittee shall submit the RMP to the federal Environmental Protection Agency according to the following schedule and requirements:

- (1) The permittee shall submit the first RMP to a central point specified by EPA no later than the latest of the following:
 - (i) Three years after the date on which a regulated substance is first listed under 40 CFR § 68.130; or,
 - (ii) The date on which a regulated substance is first present above a threshold quantity in a process.

(2) The permittee shall submit any additional relevant information requested by the Department or EPA concerning the RMP and shall make subsequent submissions of RMPs in accordance with 40 CFR § 68.190.

(3) The permittee shall certify that the RMP is accurate and complete in accordance with the requirements of 40 CFR Part 68, including a checklist addressing the required elements of a complete RMP.

(c) As used in this permit condition, the term "process" shall be as defined in 40 CFR § 68.3. The term "process" means

SECTION C. Site Level Requirements

any activity involving a regulated substance including any use, storage, manufacturing, handling, or on-site movement of such substances or any combination of these activities. For purposes of this definition, any group of vessels that are interconnected, or separate vessels that are located such that a regulated substance could be involved in a potential release, shall be considered a single process.

(d) If this facility is subject to 40 CFR Part 68, as part of the certification required under this permit, the permittee shall:

- (1) Submit a compliance schedule for satisfying the requirements of 40 CFR Part 68 by the date specified in 40 CFR § 68.10(a); or,

- (2) Certify that this facility is in compliance with all requirements of 40 CFR Part 68 including the registration and submission of the RMP.

(e) If this facility is subject to 40 CFR Part 68, the permittee shall maintain records supporting the implementation of an accidental release program for five (5) years in accordance with 40 CFR § 68.200.

(f) When this facility is subject to the accidental release program requirements of Section 112(r) of the Clean Air Act and 40 CFR Part 68, appropriate enforcement action will be taken by the Department if the permittee fails to register and submit the RMP or a revised plan pursuant to 40 CFR Part 68.

015 [25 Pa. Code §135.3]

Reporting

If the permittee has been previously advised by the Department to submit a source report, the permittee shall submit by March 1, of each year, a source report for the preceding calendar year. The report shall include information from all previously reported sources, new sources which were first operated during the preceding calendar year, and sources modified during the same period which were not previously reported, including those sources listed in the Miscellaneous Section of this permit.

The permittee may request an extension of time from the Department for the filing of a source report, and the Department may grant the extension for reasonable cause.

VI. WORK PRACTICE REQUIREMENTS.

016 [25 Pa. Code §123.1]

Prohibition of certain fugitive emissions

A person responsible for any source specified in Condition #002, above, shall take all reasonable actions to prevent particulate matter from becoming airborne. These actions shall include, but not be limited to, the following

(a) use, where possible, of water or suitable chemicals, for control of dust in the demolition of buildings or structures, construction operations, the grading of roads, or the clearing of land.

(b) application of asphalt, water, or other suitable chemicals, on dirt roads, material stockpiles and other surfaces which may give rise to airborne dusts.

(c) paving and maintenance of roadways.

(d) prompt removal of earth or other material from paved streets onto which earth or other material has been transported by trucking or earth moving equipment, erosion by water, or by other means.

017 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The permittee shall ensure that the source(s) and air pollution control device(s), listed in Section A and Section G, where applicable, of this permit, are operated and maintained in a manner consistent with good operating and maintenance practices, and in accordance with manufacturer's specifications.

018 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The permittee may not modify any air contaminant system identified in this permit, prior to obtaining Department approval, except those modifications authorized by Condition #013(g), of Section B, of this permit.

019 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The permittee shall immediately, upon discovery, implement measures, which may include the application for the

SECTION C. Site Level Requirements

installation of an air cleaning device(s), if necessary, to reduce the air contaminant emissions to within applicable limitations, if at any time the operation of the source(s) identified in Section A of this permit, is causing the emission of air contaminants in excess of the limitations specified in, or established pursuant to, 25 Pa. Code Article III, or any other applicable rule promulgated under the Clean Air Act.

VII. ADDITIONAL REQUIREMENTS.

No additional requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements).

VIII. COMPLIANCE CERTIFICATION.

No additional compliance certifications exist except as provided in other sections of this permit including Section B (relating to State Only General Requirements).

IX. COMPLIANCE SCHEDULE.

No compliance milestones exist.

SECTION D. Source Level Requirements

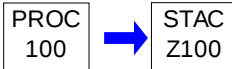
Source ID: 100

Source Name: PREP & CLEANING OPERATIONS

Source Capacity/Throughput:

N/A

SOLVENT

**I. RESTRICTIONS.****Emission Restriction(s).****# 001 [25 Pa. Code §127.441]****Operating permit terms and conditions.**

Total VOC emissions from the manufacturing processes shall not exceed 4.0 tons per year and 1.0 ton per month.

002 [25 Pa. Code §127.441]**Operating permit terms and conditions.**

Individual and total HAP emissions from the manufacturing processes shall not exceed 2.0 tons per year and 0.5 tons per month.

II. TESTING REQUIREMENTS.

No additional testing requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements).

III. MONITORING REQUIREMENTS.**# 003 [25 Pa. Code §127.441]****Operating permit terms and conditions.**

The permittee shall monitor the amount of chemicals and solvents added and removed from this source, on a monthly and 12-month rolling basis.

IV. RECORDKEEPING REQUIREMENTS.**# 004 [25 Pa. Code §127.441]****Operating permit terms and conditions.**

1. The permittee shall maintain records of the amount of chemicals and solvents added and removed from this source, on a monthly and 12-month rolling basis.

(a). Acceptable forms of documentation may include an invoice, bill of sale, certificate that corresponds to a number of sales, Material Safety Data Sheets (MSDS), or other appropriate documentation that is acceptable to the Department.

(b). Purchase records of the solvent to be used in this source shall indicate the name and address of the solvent supplier, the type of solvent including the product or vendor identification number, and the vapor pressure of the solvent measured in mmHg at 20°C (68°F).

2. The permittee shall maintain records of monthly and 12-month rolling VOC and HAP emissions.

V. REPORTING REQUIREMENTS.

No additional reporting requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements).

SECTION D. Source Level Requirements

VI. WORK PRACTICE REQUIREMENTS.

005 [25 Pa. Code §127.441]

Operating permit terms and conditions.

- (1) Immersion cold cleaning machines shall have a freeboard ratio of 0.50 or greater.
- (2) Immersion cold cleaning machines and remote reservoir cold cleaning machines shall:
 - (i) Have a permanent, conspicuous label summarizing the operating requirements in paragraph (3). In addition, the label shall include the following discretionary good operating practices:
 - (A) Cleaned parts should be drained at least 15 seconds or until dripping ceases, whichever is longer. Parts having cavities or blind holes shall be tipped or rotated while the part is draining. During the draining, tipping or rotating, the parts should be positioned so that solvent drains directly back to the cold cleaning machine.
 - (B) When a pump-agitated solvent bath is used, the agitator should be operated to produce a rolling motion of the solvent with no observable splashing of the solvent against the tank walls or the parts being cleaned.
 - (C) Work area fans should be located and positioned so that they do not blow across the opening of the degreaser unit.
 - (ii) Be equipped with a cover that shall be closed at all times except during cleaning of parts or the addition or removal of solvent.
- (3) Cold cleaning machines shall be operated in accordance with the following procedures:
 - (i) Waste solvent shall be collected and stored in closed containers. The closed containers may contain a device that allows pressure relief, but does not allow liquid solvent to drain from the container.
 - (ii) Flushing of parts using a flexible hose or other flushing device shall be performed only within the cold cleaning machine. The solvent spray shall be a solid fluid stream, not an atomized or shower spray.
 - (iii) Sponges, fabric, wood, leather, paper products and other absorbent materials may not be cleaned in the cold cleaning machine.
 - (iv) Air agitated solvent baths may not be used.
 - (v) Spills during solvent transfer and use of the cold cleaning machine shall be cleaned up immediately.

006 [25 Pa. Code §127.441]

Operating permit terms and conditions.

1. All VOC-containing materials shall be stored in closed, nonabsorbent, non-leaking containers when not being mixed or transferred to another container. Vessels are to be kept covered when not in use.
2. Cloth and paper, or other absorbent applicators, moistened with coatings, solvents or cleaning solvents, shall be stored in closed, nonabsorbent, non-leaking containers.
3. Dripping shall be kept at a minimum from the dipped parts when they are set for drying.
4. Spills shall be cleaned up immediately.
5. VOC and HAP emissions shall be calculated using a material balance method.

007 [25 Pa. Code §127.441]

Operating permit terms and conditions.

The permittee shall ensure that this source is operated and maintained in accordance with good operating practices and

**SECTION D. Source Level Requirements**

manufacturer's specifications.

VII. ADDITIONAL REQUIREMENTS.

No additional requirements exist except as provided in other sections of this permit including Section B (State Only General Requirements).



SECTION E. Alternative Operation Requirements.

No Alternative Operations exist for this State Only facility.

**SECTION F. Emission Restriction Summary.**

Source Id	Source Description
100	PREP & CLEANING OPERATIONS
Emission Limit	
0.500 Tons/Mth	Hazardous Air Pollutants
2.000 Tons/Yr	12-month rolling Hazardous Air Pollutants
1.000 Tons/Mth	VOC
4.000 Tons/Yr	12-month rolling VOC

Site Emission Restriction Summary

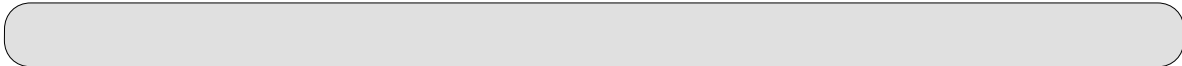
Emission Limit	Pollutant
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**SECTION G. Miscellaneous.**

#001. Previously issued Plan Approval 15-00136, issued on February 4, 2010, serves as the basis for certain terms and conditions set forth in this initial State Only Operating Permit.

#002. Administrative Amendment processed for a change of ownership and name change from Thomas Medical Products to Merit Medical. APS No. 806031; AUTH No. 966791.

#003. This permit is being renewed under APS No. 806031; AUTH No. 1141044.



***** End of Report *****
