



GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF ENVIRONMENTAL QUALITY
LANSING



LIESL EICHLER CLARK
DIRECTOR

UPS NEXT DAY DELIVERY

ENFORCEMENT NOTICE

January 4, 2019

In the matter of:

Viant Medical, Inc.
520 Watson, S.W.
Grand Rapids, Michigan 49504

SRN: N0795; Kent County

ATTENTION: Mr. Bryan Curry, Senior Director Quality Assurance & Regulatory Affairs

This letter is to advise you of the commencement of escalated enforcement action against Viant Medical, Inc. (Company). This letter follows the August 23, 2017; July 25, 2018; and December 3, 2018, Violation Notices (VN) issued by the Michigan Department of Environmental Quality (MDEQ), Air Quality Division (AQD), which detailed violations of Part 55, Air Pollution Control, of the Natural Resources and Environmental Protection Act, 1994, PA 451, as amended (NREPA), MCL 324.5501 *et seq.*, and the following state and federal air quality violations:

- Failing to comply with the ethylene oxide (EtO) emission limits for EU-ETOSTERILIZERS established in Permit to Install (PTI) No. 605-89B;
- Failing to maintain a 99% emission reduction from the sterilization chamber vents and/or aeration room vents as required by the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide Emissions Standards for Sterilization Facilities, Title 40 of the Code of Federal Regulations (CFR), Part 63, Subpart O;
- Failure to maintain a minimum capture and destruction efficiency of 99.5% by weight for EtO as required by PTI No. 605-89B; and
- Failure to conduct performance testing by November 30, 2018 for EU-ETOSTERILIZERS as required by 40 CFR Part 63, Subpart O.

The AQD is providing the Company with an opportunity to formally resolve these violations through the entry of a legally enforceable agreement that will include a compliance program and payment of an appropriate monetary penalty pursuant to Section 5528 of Part 55 of NREPA, MCL 324.5528.

Be advised that failure to respond to this Enforcement Notice in a timely manner and adequately resolve or address the cited violations may result in further enforcement proceedings, including but not limited to, referral of the matter to the Michigan Department of Attorney General (MDAG) for commencement of civil litigation. This Enforcement Notice does not preclude or limit the MDEQ's ability to initiate any other enforcement action under federal or state law as appropriate.

Mr. Bryan Curry
Page 2
January 4, 2019

Please contact me at 517-284-6797, or by email at rathbunj1@michigan.gov, no later than January 18, 2019, to schedule a meeting to discuss the resolution of this matter.

STATE OF MICHIGAN
DEPARTMENT OF ENVIRONMENTAL QUALITY

By: Jenine Camilleri for
Jeff Rathbun
Air Quality Division, Enforcement Unit

Date: January 4, 2019

cc: Ms. Sarah Marshall, U.S. EPA, Region 5
Mr. Neil Gordon, MDAG
Ms. Heidi Hollenbach, MDEQ
Ms. Jenine Camilleri, MDEQ