



December 17, 2018

Via Email

April Lazzaro  
Senior Environmental Quality Analyst  
Air Quality Division  
Michigan Department of Environmental Quality  
350 Ottawa Avenue, NW, Unit 10  
Grand Rapids, MI 49503-2341  
(616) 558-1092



**RE: Violation Notice from Michigan Department of Environmental Quality to Viant Medical, Inc. on December 3, 2018**

Dear Ms. Lazzaro:

Viant Medical, Inc. (Viant) received a Violation Notice from the Michigan Department of Environmental Quality (MDEQ) dated December 3, 2018, for its facility located at 520 Watson SW, Grand Rapids, Michigan. The Violation Notice alleged the following Rule/Permit Condition Violated:

Process Description	Rule/Permit Condition Violated	Comments
Ethylene Oxide Sterilization Process	40 CFR Part 63, Subpart O (40 CFR 63.363)	Failure to conduct stack testing by November 30, 2018

In the Violation Notice, MDEQ requested that Viant submit a written response by December 17, 2018. This letter serves as Viant's response to that Violation Notice.

Response to Alleged Violation

MDEQ requested the stack testing referenced in the Violation Notice by MDEQ in a Violation Notice sent July 25, 2018 (July Violation notice). Following receipt of the July Violation Notice, Viant has been in regular contact with the MDEQ regarding this stack testing request, including discussion regarding the type of testing to be conducted and timing. As MDEQ has been aware, due to the timing to complete the test plan required for the stack testing, as well as the availability of the company who performed the stack testing (Stack Test Group), Viant was not able to schedule the stack testing by the end of November. Viant was able to schedule testing for December 5, 2018; however, at the request of MDEQ, Viant changed that date to accommodate the MDEQ's availability to be on-site during the testing. The testing was completed on December 6, 2018 with MDEQ representatives present; just four business days after November 30, 2018. Viant



has now satisfied MDEQ's request to conduct stack testing. Viant reserves its rights to provide further information related to this issue as communications with MDEQ and Viant proceed

MDEQ has also requested an update on any measures that Viant has taken to date to reduce emissions of ethylene oxide and requested that Viant provide the stack and fugitive emissions data for the months of September, October, and November 2018. Viant references MDEQ to its August 24, 2018 response to the July 25, 2018 Violation Notice as responsive to MDEQ's questions prior to August 24, 2018. Additionally (and as has been previously communicated to MDEQ), in November 2018, Viant eliminated the sterilization cycle that produced the majority of the fugitive ethylene oxide emissions from the facility. Viant provides the stack and fugitive emissions data for September, October and November as Attachment A, which evidences the reduction in ethylene oxide emissions based on Viant's actions to eliminate this sterilization cycle. This data shows that the removal of the cycle in question has been effective.

We believe that this should address all MDEQ's questions. If you have any further questions, please do not hesitate to contact me.

Sincerely,

Trish Albert  
Vice President and General Counsel  
Viant Medical, Inc.  
508-321-7507