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9 *STERIS, INC.*

10 **BEFORE THE HEARING BOARD OF THE SOUTH COAST AIR**
11 **QUALITY MANAGEMENT DISTRICT**

12 In the Matter of

13 STERIS, INC.,

14 Petitioner,

15 v.

16 SOUTH COAST AIR QUALITY
17 MANAGEMENT DISTRICT,

18 Respondent.

CASE NO. 6297-1

FACILITY ID NO. 120829

**DECLARATION OF EVA MEJIA IN
SUPPORT OF STERIS, INC.'S
APPLICATION FOR A REGULAR
VARIANCE**

Date: October 20, 2026

Time: 9:30 AM

Location: 21865 Copley Drive
Diamond Bar, CA 91765

1 I, Eva Mejia, declare:

2 1. I am providing this declaration in support of the STERIS, Inc.'s, petition for a variance
3 in connection with operation of the facility located at 43425 Business Park Drive, Temecula,
4 California (the "Facility").

5 2. I am the Plant Manager of the Facility. I have served in this position since March 2024.
6 Among my responsibilities, I lead the site management team in the daily execution of handling and
7 processing customer products. My role encompasses overseeing all aspects of the Facility's day-to-
8 day operations and compliance with applicable safety, quality, and regulatory requirements.

9 3. I have held various operations management and supervisory roles with STERIS, Inc.,
10 and its affiliates, since November 2018. For example, from November 2018 and March 2021, I
11 worked at the Company's Ontario, California facility as an Operations Supervisor. In these past
12 roles, I have supervised facility operations, managed personnel, and coordinated budgets. Before
13 joining STERIS, I served in operations supervisor roles for several other companies in California.
14

15 4. I received a Bachelor of Business Administration from California State University, San
16 Bernadino, in 2018 and a Masters of Science in Leadership and Management from the University of
17 La Verne in 2022.

18 5. Through my position and responsibilities, I am familiar with the Facility's operations,
19 customers, sterilization processes, production capacity, staffing, regulatory obligations, and impacts
20 that a shutdown or curtailment of operations would have on the Facility and its customers.

21 **Facility Operations and Customers**

22 6. The Facility operates as a contract sterilization provider. Under contract with its
23 customers, the Facility provides ethylene oxide ("EtO") sterilization services for critical healthcare
24 products. EtO sterilization is a low temperature gaseous process widely used to sterilize a variety of
25 healthcare products, such as single-use medical devices. EtO sterilization can efficiently penetrate
26 surfaces of most medical devices and its lower temperature makes it an ideal process for a wide variety
27 of materials.
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1 7. The demand for sterilization services needed to ensure an uninterrupted supply of
2 sterilized medical devices to the healthcare market is very high and, as a result, the Facility operates
3 twenty-four hours a day, seven days a week.

4 8. The Facility utilizes a traditional three-step EtO sterilization process that takes place in
5 preconditioning rooms ("PCR"), sterilization vessels/chambers, and aeration rooms. In addition, the
6 Facility can perform "All-in-One" processing where preconditioning, sterilization, and aeration are
7 completed within the sterilization chamber itself. These capabilities provide flexibility to support
8 customer-specific validated sterilization processes while maintaining product safety, efficacy, and
9 regulatory compliance.

10 9. The Facility operates six sterilization chambers of varying capacities, including:

- 11 i. Two ten-pallet sterilization chambers;
- 12 ii. Two four-pallet sterilization chambers;
- 13 iii. One six-pallet sterilization chamber; and
- 14 iv. One two-pallet sterilization chamber.

15 The availability of multiple chamber configurations provides operational flexibility to accommodate
16 a broad range of medical devices and client needs.

17 10. Sterilization processes are validated on a facility-specific basis and depend upon factors
18 including chamber configuration, cycle parameters, process flow, environmental conditions, and
19 operational controls. As a result, many products sterilized at the Facility are validated specifically for
20 processing at this location.

21 11. Products utilizing either the Facility's traditional PCR/vessel/aeration processing or
22 All-in-One processing may require significant engineering, qualification, validation, and regulatory
23 activities before being transferred to an alternative sterilization facility.

24 12. Approximately 110 medical device manufacturers rely upon the Facility for
25 sterilization services related to a broad range of products utilized in patient diagnosis, treatment,
26 disease management, and surgical intervention. Products sterilized at the Facility, include devices used
27 in cardiovascular and structural heart procedures, orthopedic and trauma reconstruction, minimally
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1 invasive and robotic surgery, electrophysiology and cardiac mapping, ophthalmology, vascular access,
2 airway management, surgical instrumentation, and single-use procedural kits.

3 13. EtO sterilization remains an essential sterilization method within the medical device
4 industry due to its ability to effectively sterilize products with complex geometries, sensitive materials,
5 and packaged configurations that may not be compatible with alternative sterilization methods.
6 Estimates by the medical device industry indicate that approximately 50 percent (approximately 20
7 billion) of all single-use medical devices requiring sterilization are processed using EtO. This includes
8 many life-sustaining and life-saving medical devices that are designed, tested, validated, and
9 commercialized using EtO sterilization as an integral component of their manufacturing process.
10 Consequently, continued access to qualified EtO sterilization capacity is critical to the medical device
11 supply chain and healthcare delivery system.

12 14. In addition to commercial sterilization processing, the Facility also supports customers
13 throughout the product lifecycle by performing validation studies, engineering (R&D) runs, process
14 development activities, and requalification work necessary for product commercialization and to
15 maintain regulatory compliance. These services are often required to introduce new medical devices
16 into the marketplace and to maintain existing product approvals. Interruption in the availability of EtO
17 sterilization by the Facility, therefore, could delay product launches, disrupt manufacturing schedules,
18 and adversely affect product availability to patients.

19 15. There are a limited number of medical sterilization facilities servicing Southern
20 California. Building a facility requires substantial regulatory oversight and approvals, including by the
21 U.S. Food and Drug Administration (“FDA”). As a result, the service provided by the Facility cannot
22 be supplemented by the construction of other sterilization facilities within the timeframe requested for
23 this variance.

24 16. Further, approximately 75 percent of the Facility’s customers rely on sterilization
25 processes that have been validated and qualified for performance at this specific Facility. For many
26 sterile medical devices, the FDA reviews premarket approval submissions to determine if the sterility
27 information – e.g., the method a manufacturer uses to sterilize their device and validation activities
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1 used to show that the device can be effectively sterilized – is in accordance with standards recognized
2 by the FDA. Many of these customers do not have a qualified alternative sterilization provider readily
3 available. Even where an alternative provider exists, transferring services typically requires
4 engineering assessments, process qualification, validation activities, regulatory review, and customer
5 approvals, which can take several months to a year to complete. For example, if a medical device
6 manufacturer changes the method, process, or the facility identified in its original premarket approval
7 submission, that manufacturer generally needs to submit a supplement to the FDA so that the agency
8 can review the changes and determine if they continue to meet recognized standards. Consequently,
9 due to limited alternatives for sterilization services and regulatory requirements, the Facility’s
10 customers are unlikely to be able to transition to alternative sterilization services within the timeframe
11 requested for this variance.

12 **Impacts of Facility Shut Down**

13 17. The Facility cannot perform EtO sterilization operations without its catalytic oxidizer.
14 This is because the catalytic oxidizer is an integral component of the Facility’s air pollution control
15 system required to treat EtO-containing exhaust streams from the sterilization chambers and associated
16 process areas.

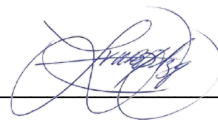
17 18. Operation of the catalytic oxidizer is mandated by the Facility’s South Coast Air
18 Quality Management District permit and the applicable requirements of Rule 1405. Specifically,
19 Permit Condition 5 requires that the air pollution control system be “in full use whenever drums
20 containing EtO are stored in the drum room and whenever the sterilization chambers and/or aeration
21 rooms are in operation.”

22 19. If the Facility were required to shut down because it was not allowed to operate its
23 catalytic oxidizer, the Company would lose approximately \$1.6 million per month. In addition to the
24 customer impacts identified in paragraphs 12-16, the Facility has approximately 30 employees across
25 operations, quality assurance, maintenance, validation services, customer support, and administrative
26 functions. These employees possess specialized knowledge and experience related to sterilization
27 operations, quality systems, regulatory compliance, validation activities, and customer-specific
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1 processing requirements. Prolonged interruption of operations could adversely affect workforce
2 stability and employee retention and could result in the loss of specialized technical expertise
3 developed through years of operational experience. Loss of this expertise could affect the Facility's
4 operational readiness and its ability to continue supporting customer requirements.

5 20. It is not feasible for the Facility to curtail or terminate operations as an alternative to
6 obtaining a variance. While short-term curtailment reducing operations by a percentage, running over
7 several days or a week, may be possible on an intermittent basis – e.g., when source tests are being
8 conducted or capital improvements are being undertaken – long-term curtailment would make it
9 impossible for the Facility to provide adequate capacity to sterilize customers medical devices. As
10 discussed above, the Facility provides the medical industry with critical sterilization services. The
11 demand for these services is substantial, generally requiring the Facility to operate 24 hours a day,
12 seven days a week. Many of the Facility's customers do not have an alternative contract sterilization
13 provider that has been validated by the FDA to sterilize their products. As a result, these customers
14 may be unable to maintain production if sterilization services at the Facility become unavailable, given
15 that validating an alternative sterilization provider can take several months to a year. As such, any
16 shut-down of the Facility, or material curtailment of operations, would likely have a material impact
17 on the healthcare industry in Southern California.

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20 I declare under penalty of perjury under the laws of the State of California that the foregoing
21 is true and correct. Executed this 14th day of October, 2026 at Temecula, California.

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24 EVA MEJIA
25 Plant Manager
26 43425 Business Park Drive
27 Temecula, California
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