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**UNITED STATES OF AMERICA  
FEDERAL TRADE COMMISSION  
OFFICE OF ADMINISTRATIVE LAW JUDGE**

In the Matter of

GTCR BC HOLDINGS, LLC,  
a corporation;

and

SURMODICS, INC.,  
a corporation.

Docket No. 9440

**ANSWER AND DEFENSES OF RESPONDENT SURMODICS, INC.**

Pursuant to Rule 3.12 of the Federal Trade Commission (the “FTC” or the “Commission”) Rules of Practice for Adjudicative Proceedings, Respondent Surmodics, Inc. (“Surmodics”), by and through its attorneys, hereby admits, denies, and avers as follows with respect to the Administrative Complaint (the “Complaint”) filed by the Commission in the above-captioned matter relating to the proposed acquisition of Surmodics by GTCR BC Holdings, LLC (“GTCR”). To the extent not specifically admitted in the following paragraphs, the allegations in the Complaint are denied. Surmodics states that the introduction, headings, sub-headings, Notice, Notice of Contemplated Relief, and the image labeled “Figure 1” in the Complaint do not constitute well-pleaded allegations of fact and therefore no response is required. To the extent a response to those matters is deemed required, the allegations are denied. Surmodics reserves the right to amend and/or supplement this Answer.

**INTRODUCTION**

Surmodics denies the allegations and legal conclusions contained in the Commission’s unnumbered introductory paragraphs, except that Surmodics admits: (a) GTCR, through its

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corporate affiliates and their subsidiaries, and Surmodics entered into a Merger Agreement dated May 28, 2024, and (b) the FTC filed an administrative complaint on March 6, 2025, with an administrative proceeding on the merits currently scheduled to begin on August 6, 2025.

Surmodics further states that, contrary to the allegations in the Complaint, the proposed merger between GTCR and Surmodics is procompetitive and will not cause a substantial lessening of competition in any relevant antitrust market. In particular, the FTC's Complaint ignores the commercial and technical realities of Surmodics's UV-cured hydrophilic coatings and Biocoat's thermal-cured hydrophilic coatings, which are not close substitutes. Indeed, the evidence presented at trial will show that there is vanishingly little head-to-head competition between Surmodics's UV-cured hydrophilic coatings and Biocoat's thermal-cured hydrophilic coatings, such that the proposed merger will not threaten to substantially lessen competition.

#### **SPECIFIC RESPONSES TO THE FTC'S ALLEGATIONS**

1. As to the first sentence, Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and it denies them on that basis. As to the second sentence, Surmodics admits only that GTCR proposes to acquire it. The remaining allegations in this paragraph purport to state conclusions of law to which no response is required. To the extent a response is required, Surmodics denies the remaining allegations in this paragraph.

2. As to the first sentence, Surmodics admits that hydrophilic coatings are applied to interventional devices, that catheters and guidewires are types of interventional medical devices, and that neurological, cardiovascular and peripheral vascular procedures are some of the types of procedures where interventional medical devices are used. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and it denies them on that basis.

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3. As to the first sentence, Surmodics admits that original equipment manufacturers (“OEMs”) are among the purchasers of hydrophilic coatings. Surmodics admits the allegations in the second sentence. Surmodics admits that hydrophilic coatings can and are manufactured by certain OEMs in-house, but lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in the third sentence, and it denies them on that basis.

4. Surmodics denies the allegations in this paragraph.

5. As to the first sentence, Surmodics admits that it and Biocoat are among the providers of hydrophilic coatings. Surmodics denies the remaining allegations in this paragraph.

6. Denied.

7. Surmodics denies the allegations of the first sentence. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence, and it denies them on that basis.

8. Surmodics denies the allegations in the first and second sentences. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the third and fourth sentences, and it denies them on that basis. The fifth and sixth sentences purport to quote selectively from documents, and Surmodics denies that the Commission’s characterizations of the documents are complete, accurate or provide the necessary context. Surmodics denies the allegations of the seventh and eighth sentences.

9. Denied.

10. This paragraph purports to state conclusions of law to which no response is required.

11. This paragraph purports to state conclusions of law to which no response is required.

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12. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

13. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

14. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

15. Surmodics admits the allegations of the first sentence. As to the second sentence, Surmodics admits that it offers hydrophilic coatings and related services to customers. As to the third sentence, Surmodics admits that it markets certain hydrophilic coatings under the brand names Serene™ and Preside™, but it denies that those are the only hydrophilic coatings that it commercializes. As to the fourth sentence, Surmodics admits that it markets certain interventional medical devices under the brand names Pounce™ and Sublime™.

16. Admitted.

17. Admitted.

18. Surmodics admits that, to the extent they are applied, hydrophilic coatings are a relatively small portion of the cost of a medical device, and that they increase the lubricity of interventional medical devices. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in the first and second sentences in this paragraph, and it denies them on that basis. Surmodics denies the allegations in the third sentence.

19. Surmodics admits that lubricity, particulate count, and durability are among the criteria for assessing a hydrophilic coating's performance. Surmodics denies the remaining allegations in this paragraph.

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20. Surmodics denies the allegations in the first sentence. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the second and third sentence in this paragraph, and it denies them on that basis. Surmodics denies the remaining allegations in this paragraph.

21. Surmodics lacks knowledge or information sufficient to form a belief as to the first sentence, to the extent it refers to “most” hydrophilic coatings, and it denies them on that basis. Surmodics admits the remaining allegations in this paragraph insofar as they pertain to Surmodics’s two-coat hydrophilic coatings. Surmodics states that the image labeled “Figure 1” does not constitute well-pleaded allegations of fact and therefore no response is required. Surmodics denies the remaining allegations in this paragraph.

22. Admitted.

23. Surmodics denies the allegations in the first sentence. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second and third sentence, and it denies them on that basis. Surmodics denies the allegations in the fourth and fifth sentences. To the extent hydrophilic coatings are used, Surmodics admits that UV-curing may not be suitable to cure the coating on the inner diameter of medical devices, and thermal curing may not be suitable for medical devices that react poorly to high temperatures. The remaining allegations of the fifth sentence of this paragraph are denied.

24. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

25. As to the first sentence, Surmodics admits that it works with OEMs to optimize the performance of Surmodics’s coatings on the OEMs’ devices. Surmodics lacks knowledge or

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information sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and it denies them on that basis.

26. As to the first sentence, Surmodics admits that it offers a range of services to help OEMs prepare to launch their coated medical devices. Surmodics admits the allegations of the second and third sentences. As to the fourth sentence, Surmodics admits that some OEMs purchase coating reagents; otherwise, Surmodics denies the allegations on the grounds that some OEMs manufacture their own coating in-house. Surmodics admits the allegations of the fifth sentence. As to the sixth sentence, Surmodics admits that the FDA, in evaluating for approval a medical device that uses a Surmodics hydrophilic coating, may reference Surmodics's Master File for the hydrophilic coating on the device; otherwise, Surmodics denies the allegations insofar as they suggest Surmodics's coating is subject to "FDA approval."

27. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence insofar as they contain generalizations about other hydrophilic coating providers, and it denies them on that basis. As to the second sentence, Surmodics admits that medical devices may be sold on the market with the same hydrophilic coating for over a decade; otherwise, Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence insofar as they contain generalizations about other hydrophilic coating providers. As to the third sentence, Surmodics admits that it can earn revenue by selling reagents or by executing license agreements that provide for the payment of certain license fees, milestone payments, or royalties; otherwise, Surmodics denies the allegations regarding whether certain payments are "more important[]" than others; Surmodics further responds that it lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the third sentence insofar as they contain generalizations about other

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hydrophilic coating providers. As to the fourth sentence, Surmodics admits that royalty payments for Surmodics's hydrophilic coatings may be set a fixed rate per unit sold or at a percentage of the average sales price of the medical device; otherwise, Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the fourth sentence insofar as they refer to additional payments to other hydrophilic coating providers.

28. Denied.

29. Surmodics denies the allegations of the first and second sentences. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and it denies them on that basis.

30. Denied.

31. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph insofar as they contain generalizations regarding hydrophilic coatings, OEMs, and the cost of medical devices, and it denies them on that basis.

32. Surmodics denies the allegations of the first and second sentences. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the third and fourth sentences, and it denies them on that basis.

33. As to the first sentence, Surmodics admits that it offers a range of services to help OEMs prepare to launch their coated medical devices; otherwise, Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding other hydrophilic coating providers and OEMs, and it denies them on that basis. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and it denies them on that basis.

34. Denied.

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35. Denied.

36. As to the first sentence, Surmodics admits that a hydrophilic coating may be a key feature of certain parts of certain medical devices; otherwise, it denies the allegations insofar as medical devices may be uncoated and meet performance requirements. The second sentence purports to state conclusions of law to which no response is required; to the extent a response is required, admitted. Surmodics denies the allegations of the third sentence.

37. Denied.

38. Denied.

39. As to the first sentence, Surmodics admits that it believes that in 2023 it generated roughly the alleged amount of revenue in coating services, PreMix services, reagent sales, feasibility fees, license fees, and royalty revenue relating to hydrophilic coatings. As to the second sentence, Surmodics admits only that it enters license agreements with many of its customers that provide for the payment to Surmodics of certain royalties; otherwise, Surmodics denies the allegations of the second sentence of this paragraph insofar as the term “nearly all” is vague. Surmodics admits the allegations in the third sentence.

40. As to the first sentence, Surmodics admits that its hydrophilic coatings are cured with ultraviolet (UV) light, and that it markets certain hydrophilic coatings under the brand names Serene™ and Preside™; however, Surmodics denies that those are the only hydrophilic coatings that it sells. As to the second sentence, Surmodics admits only that it launched Preside in October 2023; otherwise, Surmodics denies the remaining allegations in the second sentence of this paragraph.

41. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.



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42. As to the first sentence, Surmodics admits that it understands Biocoat manufactures hydrophilic coatings sold under the brand name Hydak. As to the second, third, and fourth sentences, Surmodics admits that Robert Hergenrother was formerly employed by Surmodics; otherwise, Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding Mr. Hergenrother's title, his employment activities at Biocoat, or the effect thereof on Biocoat's ability to compete with other hydrophilic coating providers including Surmodics, and it denies them on that basis. Surmodics denies the remaining allegations of this paragraph.

43. As to the second sentence, Surmodics admits that it understands Harland sells UV-cured coatings under the brand names Lubricent and Tylicent. Surmodics lacks knowledge or information regarding the remaining allegations in this paragraph, and it denies them on that basis.

44. As to the first sentence, Surmodics admits that DSM sells hydrophilic coatings. Surmodics lacks knowledge or information regarding the remaining allegations in this paragraph, and it denies them on that basis.

45. Denied.

46. To the extent the allegations in this paragraph are a legal assertion, no response is required; otherwise, Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

47. To the extent the allegations in this paragraph are a legal assertion, no response is required; otherwise, Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

48. Denied.

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49. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

50. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

51. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

52. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

53. Denied.

54. Denied.

55. As to the first sentence, Surmodics admits that Biocoat is one of many hydrophilic coating providers with which Surmodics competes; Surmodics denies the remaining allegations in the first sentence. The second, third fourth, fifth, and sixth sentences purport to reference documents, and Surmodics denies that the Commission's characterizations of the documents are complete, accurate or provide the necessary context.

56. Surmodics denies the allegations of the first sentence. The second, third, fourth, fifth, and sixth sentences purport to reference documents, and Surmodics denies that the Commission's characterizations of the documents are complete, accurate or provide the necessary context.

57. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

58. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

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59. Surmodics denies the allegations in the first sentence. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and it denies them on that basis.

60. Denied.

- a. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.
- b. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.
- c. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis. To the extent that the allegations in this paragraph purport to reference documents, Surmodics denies that the Commission's characterizations of the documents are complete, accurate or provide the necessary context.
- d. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.
- e. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis. To the extent that the allegations in this paragraph purport to reference documents, Surmodics denies that the Commission's

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characterizations of the documents are complete, accurate or provide the necessary context.

f. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis. To the extent that the allegations in this paragraph purport to reference documents, Surmodics denies that the Commission's characterizations of the documents are complete, accurate or provide the necessary context.

g. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis. To the extent that the allegations in this paragraph purport to reference documents, Surmodics denies that the Commission's characterizations of the documents are complete, accurate or provide the necessary context.

61. Denied.

62. Denied.

63. Surmodics lacks knowledge or information sufficient to form a belief truth of the allegations in this paragraph, and it denies them on that basis.

64. Surmodics lacks knowledge or information sufficient to form a belief truth of the allegations in this paragraph, and it denies them on that basis.

65. Denied.

66. Surmodics denies the allegations in the first sentence. Surmodics lacks knowledge or information sufficient to form a belief truth of the allegations in the second sentence, and it

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denies them on that basis. Surmodics denies the allegations in the third sentence. To the extent the allegations in the fourth sentence purport to reference documents, Surmodics denies that the Commission's characterizations of the documents are complete, accurate or provide the necessary context. Surmodics denies the remaining allegations in the fourth sentence of this paragraph.

67. Surmodics denies the allegations in the first sentence. The allegations in the second sentence purport to reference documents, and Surmodics denies that the Commission's characterizations of the documents are complete, accurate or provide the necessary context. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and it denies them on that basis.

68. Surmodics lacks knowledge or information sufficient to form a belief truth of the allegations in this paragraph, and it denies them on that basis.

- a. Surmodics lacks knowledge or information sufficient to form a belief truth of the allegations in this paragraph, and it denies them on that basis.
- b. Surmodics lacks knowledge or information sufficient to form a belief truth of the allegations in this paragraph, and it denies them on that basis.
- c. Surmodics lacks knowledge or information sufficient to form a belief truth of the allegations in this paragraph, and it denies them on that basis.
- d. Surmodics lacks knowledge or information sufficient to form a belief truth of the allegations in this paragraph, and it denies them on that basis.

69. As to the first sentence, Surmodics admits that its hydrophilic coatings, including the coating that it markets under the brand name Serene, are cured with UV light. As to the second sentence, Surmodics admits that it has innovated and launched two next-generation products since

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launching Serene. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and it denies them on that basis.

70. As to the first sentence, Surmodics admits that it has launched two next-generation hydrophilic coating products since launching Serene. As to the second sentence, Surmodics admits that it first commercialized its latest-generation hydrophilic coating—marketed under the brand name Preside—in October 2023. As to the third sentence, Surmodics admits that Preside has demonstrated performance improvements compared to Surmodics’s legacy hydrophilic coatings, and admits that it competes with many hydrophilic coating providers for OEM customers commercializing medical devices for application in the neurovascular system of the brain. Surmodics denies the remaining allegations in this paragraph.

71. Denied.

72. Denied.

73. Surmodics denies the allegations in the first sentence. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and it denies them on that basis.

74. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the first, second, third, fourth, and fifth sentences insofar as they contain vague generalizations regarding product development, and it denies them on that basis. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the sixth sentence, and it denies them on that basis.

75. Surmodics denies the allegations in the first sentence. As to the second sentence, Surmodics admits that it launched Preside in October 2023; to the extent that this sentence purports

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to quote documents, Surmodics denies that the Commission's characterizations of the documents are complete, accurate or provide the necessary context.

76. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and it denies them on that basis.

77. The second and third sentences purport to state conclusions of law to which no response is required; to the extent a response is required, Surmodics admits that medical device manufacturers must obtain 510(k) clearance from the FDA prior to commercializing a device. Surmodics denies the remaining allegations in this paragraph.

78. The first sentence purports to state conclusions of law to which no response is required; to the extent a response is required, Surmodics admits that an OEM that changes the hydrophilic coating for a medical device that has obtained 510(k) clearance from the FDA may be required to obtain a "new" 510(k) clearance from the FDA for the device with the "new" coating; otherwise, Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this sentence, and it denies them on that basis. Surmodics admits the allegations of the second sentence. Surmodics denies the remaining allegations of this paragraph.

79. Surmodics denies the allegations in the first sentence. Surmodics lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and it denies them on that basis.

80. Denied.

81. Surmodics incorporates by reference its responses to Paragraphs 1 through 80.

82. Denied.

## DEFENSES

Without assuming the burden of proof that it would otherwise not bear under applicable law, Surmodics asserts the following defenses:

1. The FTC cannot satisfy its burden of demonstrating an entitlement to a preliminary injunction, which is an extraordinary equitable remedy.

2. The FTC cannot satisfy its burden of demonstrating a likelihood of ultimate success on the merits (*i.e.*, that the proposed transaction is likely to substantially harm competition under Section 7 of the Clayton Act and violate Section 5 of the FTC Act), including because:

- a. The Complaint fails to allege a valid product market;
- b. The Complaint fails to allege a valid geographic market;
- c. The Complaint fails to allege that the proposed transaction will plausibly harm consumers or competition; and
- d. The Complaint fails to account for alternative providers of hydrophilic coatings, and fails to account for new entry and expansion by competitors that is timely, likely, and sufficient.

3. The transaction will result in procompetitive benefits and efficiencies that outweigh any alleged anticompetitive effects.

4. Granting the relief sought is inequitable and contrary to the public interest.

5. The FTC seeks relief through an administrative process that violates Article I of the Constitution, which provides that “[a]ll legislative Powers herein granted shall be vested in a Congress of the United States.” U.S. Const. art. I, § 1. Among other things, FTC has total, unguided discretion to decide whether to bring an antitrust enforcement action in an administrative



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proceeding rather than in an Article III court, in violation of the Non-Delegation Doctrine under Article I.

6. The FTC seeks relief through an administrative process that violates Article II of the Constitution and separation of powers principles because, among other things, the FTC's Commissioners and Administrative Law Judges can only be removed for cause, and for-cause removal restrictions impermissibly restrict the President's removal powers—especially where, as here, an agency exercises substantial executive power. *See* Defs.' Notice of Change in Position at 1, *Express Scripts, Inc. v. FTC*, No. 4:24-cv-1549 (E.D. Mo. Feb. 15, 2025), ECF No. 57.

7. The FTC seeks relief through an administrative process that violates Article III of the Constitution by, for example, adjudicating private rights before a non-Article III body without meaningful review of the FTC's factual findings by an Article III court.

8. The FTC seeks relief through an administrative process that violates Surmodics's right to Equal Protection under the Fifth Amendment. Through a black box "clearance" process, the FTC and the Department of Justice ("DOJ") arbitrarily decide between them which agency will review a transaction. This transaction was reviewed by the FTC, which has the ability to judge the merits of its own case through an in-house proceeding that lacks the protections of an Article III court. By contrast, if the DOJ had reviewed the transaction and decided to challenge it, that challenge could *only* be brought in an Article III court with all the associated protections.

Surmodics furthermore adopts by reference any applicable defense not expressly set forth herein that is pled by GTCR in this action. Surmodics has not knowingly or intentionally waived any applicable defenses, and it reserves the right to assert and rely upon any other defenses that may become available or known to Surmodics throughout the course of this action, and to amend, or seek to amend, its answer or defenses.

**NOTICE OF CONTEMPLATED RELIEF**

Surmodics respectfully requests that the Commission:

- A. Dismiss the Complaint with prejudice;
- B. Deny the Commission's requested relief;
- C. Award to Surmodics the costs incurred in defending this action, including expert's

fees and reasonable attorney's fees;

- D. Provide any and all further relief as the Commission may deem just and proper.

Dated: March 18, 2025

/s/ Paul H. Saint-Antoine

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*Counsel for Respondent Surmodics, Inc.*

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**CERTIFICATE OF SERVICE**

I hereby certify that on March 18, 2025, I electronically filed a true and correct copy of the foregoing document using the FTC's E-Filing System, which will send a notice of electronic filing to:

April Tabor  
Secretary  
Federal Trade Commission  
600 Pennsylvania Avenue, NW, Rm. H-113  
Washington, D.C. 20580  
electronicfilings@ftc.gov

Office of Administrative Law Judges  
Federal Trade Commission  
600 Pennsylvania Avenue, NW, Rm. H-110  
Washington, D.C. 20580

I further certify that I caused the foregoing document to be served via email to:

Maia Perez (mperez@ftc.gov)  
600 Pennsylvania Ave., N.W.  
Washington, DC 20580  
Telephone: (202) 322-8971

*Counsel Supporting the Complaint*

/s Matthew Lechner  
Matthew Lechner