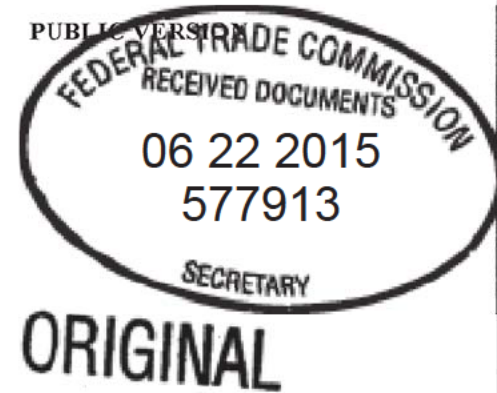


UNITED STATES OF AMERICA  
BEFORE THE FEDERAL TRADE COMMISSION  
OFFICE OF ADMINISTRATIVE LAW JUDGES



In The Matter of

Steris Corporation  
a corporation,  
  
and  
  
Synergy Health PLC  
a corporation.

Docket No. 9365

**ANSWER AND DEFENSES OF RESPONDENT**  
**SYNERGY HEALTH PLC**

Pursuant to Rule 3.12 of the Federal Trade Commission's ("Commission") Rules of Practice for Adjudicative Proceedings, Respondent Synergy Health plc ("Synergy"), by and through its attorneys, admits, denies, and avers as follows with respect to the Administrative Complaint ("Complaint") filed by the Commission as follows:

**INTRODUCTORY STATEMENT**

Synergy states that the premise of the Complaint – that, but for the merger between STERIS Corporation ("STERIS") and Synergy, Synergy would have constructed X-ray radiation sterilization plants in the United States, and that the merger is therefore anticompetitive – is erroneous both in fact and in its application of the U.S. antitrust laws. The Commission's challenge to the merger is based on a faulty factual premise and is contrary to well-established antitrust doctrine.

**I.**

**NATURE OF THE CASE**

1. Synergy admits the allegations contained in Paragraph 1, but specifically denies that "the world" is a relevant market for purposes of the Complaint. Synergy avers that it competes vigorously with a diverse group of competitors both in the U.S. and globally.

2. Synergy admits that it operates more than three dozen contract sterilization facilities globally, including gamma facilities outside the United States, and that, with respect to contract sterilization modalities it currently offers only e-beam and EO sterilization services in the United States. Synergy lacks sufficient knowledge to be able to admit or deny the allegations in Paragraph 2 pertaining to STERIS and Sterigenics. Synergy otherwise denies the allegations contained in Paragraph 2. Synergy avers that the Commission's selective quotation of unidentified written material offered without context is misleading as framed, and Synergy respectfully refers the Court to the quoted documents.

3. Synergy admits that gamma, e-beam, and EO are the three primary methods of sterilization currently used in the United States. Synergy also admits that gamma radiation sterilizes by exposure to Cobalt 60 and that EO is a non-radiation form of sterilization that exposes products to gas. Synergy lacks sufficient knowledge to admit or deny the allegations of Paragraph 3 concerning how customers choose sterilization modalities. Synergy denies the remaining allegations in Paragraph 3. Synergy avers that E-beam can and does compete with gamma radiation as a sterilization modality and that E-beam is an appropriate alternative sterilization method for most products being sterilized by gamma in the United States today.

4. Synergy admits the allegations contained in Paragraph 4 that X-ray is a substitute for gamma radiation offering comparable depth of penetration. Synergy otherwise denies the allegations contained in Paragraph 4 and avers that E-beam is a functional and economically viable alternative sterilization method to gamma for most applications. Synergy avers that the Commission's selective quotation of unidentified written material offered without context is misleading as framed, and Synergy respectfully refers the Court to the quoted documents.

5. Paragraph 5 contains legal conclusions to which no response is required. To the extent that Paragraph 5 contains factual allegations, Synergy denies the allegations contained in Paragraph 5. Synergy specifically denies that EO sterilization takes longer to complete than radiation sterilization and that EO gas leaves harmful residue on products.

6. Synergy admits that some medical device manufacturers with in-house sterilization facilities also utilize contract sterilization services. The rest of Paragraph 6 contains legal conclusions to which no response is required. To the extent that Paragraph 6 contains factual allegations, Synergy denies all other allegations contained in Paragraph 6. Synergy avers that it competes for medical device manufacturers' sterilization business against their use of existing in-house sterilization facilities and the threat of increased utilization or expansion of such facilities.

7. Synergy lacks sufficient information to respond to allegations regarding the concerns of unidentified customers about the availability and pricing of gamma sterilization. The rest of Paragraph 7 contains legal conclusions to which no response is required. To the extent that Paragraph 7 contains factual allegations, Synergy denies all other allegations contained in Paragraph 7. Synergy avers that E-beam is less expensive than gamma radiation and is an economical alternative for most products that are sterilized with gamma radiation.

8. Paragraph 8 contains legal conclusions to which no response is required. To the extent that Paragraph 8 contains factual allegations, Synergy denies the allegations contained in Paragraph 8.

9. As Synergy does not operate any gamma radiation facilities in the United States, Synergy lacks sufficient information to respond to the allegations contained in Paragraph 9 concerning customer purchases of gamma sterilization services domestically. Synergy admits that, in the past, it considered constructing X-ray facilities in the United States, including in the geographic areas identified. The rest of Paragraph 9 contains legal conclusions to which no response is required. To the extent that Paragraph 9 contains factual allegations, Synergy denies all other allegations contained in Paragraph 9.

10. Paragraph 10 contains legal conclusions to which no response is required. To the extent that Paragraph 10 contains factual allegations, Synergy denies the allegations contained in Paragraph 10. Synergy avers that the Merger Guidelines do not necessarily mirror, and do not substitute for, controlling case law.

11. Synergy admits that it has significant operations abroad and that it is a small contract sterilization provider in the United States offering E-beam sterilization services. Synergy avers that it also offers EO sterilization services in Florida. The rest of Paragraph 11 contains legal conclusions to which no response is required. To the extent that Paragraph 11 contains factual allegations, Synergy denies all other allegations contained in Paragraph 11.

12. [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED] Synergy denies all other allegations contained in Paragraph 12.  
[REDACTED]  
[REDACTED]  
[REDACTED]

13. Synergy admits the allegations contained in Paragraph 13 that its proposed merger with STERIS was announced on October 13, 2014. Synergy admits that its exploration of potential X-ray entry into the United States continued for some weeks thereafter. Synergy denies the remaining allegations in Paragraph 13.

14. Synergy admits that the FTC issued Second Requests to STERIS and Synergy in January 2015. Synergy denies all other allegations contained in Paragraph 14. Synergy avers that the Commission's selective quotation of unidentified written material or communications, offered without context, is misleading as framed, and Synergy respectfully refers the Court to the quoted documents, once identified, for a complete and accurate description of their contents. Synergy avers that insufficient customer support was, in fact, one of the reasons that Synergy terminated its United States X-ray entry plans.

15. Synergy lacks sufficient information to admit or deny the allegations in Paragraph 15 concerning customers' expectations. The rest of Paragraph 15 contains legal conclusions to which no response is required. To the extent that Paragraph 15 contains factual allegations, Synergy denies all other allegations contained in Paragraph 15. Synergy avers that the Commission's selective quotation of unidentified written material or communications, offered without context, is misleading as framed, and Synergy respectfully refers the Court to the quoted documents, once identified, for a complete and accurate description of their contents.

16. Synergy admits that it has global operations and a reputation as a quality service provider. The rest of Paragraph 16 contains legal conclusions to which no response is required. To the extent that Paragraph 16 contains factual allegations, Synergy denies all other allegations contained in Paragraph 16. Synergy avers that IBA is not the world's only supplier of commercially viable X-ray sterilization machines. Synergy further avers, on information and belief, that other domestic firms (including Nutek Corporation ("Nutek") and Iotron Industries Canada, Inc. ("Iotron")) are attempting to enter or are already offering X-ray sterilization services in the United States in competition with gamma sterilization.

17. Synergy admits that there is uncertainty regarding the future availability and pricing of Cobalt 60 and that Cobalt 60 is a regulated substance. The rest of Paragraph 17 contains legal conclusions to which no response is required. To the extent that Paragraph 17 contains factual allegations, Synergy denies all other allegations contained in Paragraph 17. Synergy avers that of the four sterilization modalities, E-beam is the least expensive to build and that the addition of E-beam capacity in the United States would reduce the cost of gamma sterilization for domestic customers.

18. Synergy lacks information sufficient to admit or deny the unspecified statements by an unidentified STERIS employee. Synergy avers that the Commission's selective quotation of unidentified written material or communications, offered without context, is misleading as framed, and Synergy respectfully refers the Court to the quoted documents, once identified, for a complete and accurate description of their contents. The rest of Paragraph 18 contains legal conclusions to which no response is required. To the extent that Paragraph 18 contains factual allegations, Synergy denies all other allegations contained in Paragraph 18.

## II.

### BACKGROUND

#### A.

#### Jurisdiction

19. Synergy admits the allegations contained in Paragraph 19.

20. Synergy admits the allegations contained in Paragraph 20, except to the extent that those allegations imply or assert that the Merger is or would be unlawful.

**B.**  
**Respondents**

21. Synergy lacks information sufficient to admit or deny the allegations contained in Paragraph 21 regarding STERIS' revenues. On information and belief, Synergy admits all other allegations contained in Paragraph 21.

22. Synergy admits the allegations contained in Paragraph 22.

**C.**  
**The Merger**

23. Synergy admits the allegations contained in Paragraph 23 except that Synergy denies that the agreement currently has a termination date of July 12, 2015. Synergy avers that the termination date is now December 31, 2015.

**III.**

**THE RELEVANT PRODUCT MARKET**

24. Paragraph 24 contains legal conclusions to which no response is required. To the extent that Paragraph 24 contains factual allegations, Synergy denies the allegations contained in Paragraph 9.

**A.**  
**Background on Contract Radiation Sterilization Services**

25. Synergy admits the allegations contained in Paragraph 25, except to the extent that those allegations imply that in-house sterilization services are not part of the relevant market.

**Contract Gamma Sterilization Services**

26. Synergy admits the allegations contained in Paragraph 26.

27. Synergy denies the allegations contained in the first sentence of Paragraph 27. Synergy admits all the other allegations contained in Paragraph 27.

28. Synergy avers that STERIS' website speaks for itself and respectfully refers the Court to STERIS' website, once the cited portion is identified, for a complete and accurate description of its contents. Synergy denies the allegations contained in Paragraph 28 regarding the number of products that can only be sterilized using contract gamma sterilization services. Synergy avers that E-beam can be used cost-effectively to sterilize most products that are sterilized with gamma radiation.

### **Contract X-ray Sterilization Services**

29. Synergy admits that X-ray sterilization uses a high-powered electron beam machine to produce X-ray radiation and that IBA has developed equipment that can perform X-ray sterilization. Synergy denies all other allegations contained in Paragraph 29.

30. Paragraph 30 contains legal conclusions to which no response is required. To the extent that Paragraph 30 contains factual allegations, Synergy denies the allegations contained in Paragraph 30.

### **Contract E-beam Sterilization Services**

31. Synergy admits the allegations contained in Paragraph 31 except to the extent Paragraph 31 contains opinions or legal conclusions to which no response is required, and to the extent that Paragraph 31 implies that E-beam can only be used to sterilize small volumes of low-density, homogenous products. Synergy avers that E-beam can be used to sterilize most products that are sterilized with gamma radiation.

32. Synergy denies the allegations contained in Paragraph 32 that E-beam is not a cost-effective option for sterilizing denser products and that E-beam is not a cost-effective or practical substitute for sterilizing most products that are currently sterilized with gamma radiation. To the contrary, Synergy avers that E-beam can be used to sterilize most products that are sterilized with gamma radiation. Synergy lacks information sufficient to admit or deny the unspecified statements by unidentified customers. The rest of Paragraph 32 contains legal conclusions to which no response is required. To the extent that Paragraph 32 contains factual allegations, Synergy denies all other allegations contained in Paragraph 32. Synergy avers that the Commission's selective quotation of unidentified written material or communications, offered without context, is misleading as framed, and Synergy respectfully refers the Court to the quoted documents, once identified, for a complete and accurate description of their contents.

### **B.**

#### **The Market for Contract Radiation Sterilization Services**

33. Synergy admits that contract X-ray sterilization services, if offered in the United States, would compete with, among others, gamma and E-beam sterilization services. The rest of Paragraph 33 contains legal conclusions to which no response is required. To the extent that Paragraph 33 contains factual allegations, Synergy denies all other allegations contained in Paragraph 33. Synergy avers that E-beam can be used to sterilize most products that are sterilized with gamma radiation.

34. Synergy denies the allegations contained in Paragraph 34 that there is little switching between E-beam and gamma sterilization methods. Synergy lacks information sufficient to admit or deny the unspecified views of unidentified customers. Synergy avers that the Commission's selective summation of unidentified written material or communications, offered without context, is misleading as framed, and Synergy respectfully refers the Court to the summarized documents, once identified, for a complete and accurate description of their contents. [REDACTED]

35. Synergy lacks information sufficient to admit or deny the allegations contained in Paragraph 35 regarding STERIS' gamma sterilization capacity and future plans. Synergy also lacks information sufficient to admit or deny the unspecified statements by an unidentified STERIS employee. Synergy avers that the Commission's selective quotation of unidentified written material or communications from both Synergy and STERIS, offered without context, is misleading as framed, and Synergy respectfully refers the Court to the quoted documents, once identified, for a complete and accurate description of their contents. The rest of Paragraph 35 contains legal conclusions to which no response is required. To the extent that Paragraph 35 contains factual allegations, Synergy denies all other allegations contained in Paragraph 35.

36. Synergy denies the allegations contained in Paragraph 36 to the extent that they imply that E-beam is not currently a competitive option for contract gamma customers. Synergy admits all other allegations contained in Paragraph 36, except to the extent that Paragraph 36 contains legal conclusions to which no response is required.

37. Synergy lacks information sufficient to admit or deny the allegations contained in Paragraph 37 concerning the unspecified views of unidentified customers. Synergy avers that the Commission's selective summation of unidentified written material or communications, offered without context, is misleading as framed, and Synergy respectfully refers the Court to the summarized documents, once identified, for a complete and accurate description of their contents. Similarly, Synergy avers that the Commission's selective quotation of unidentified written material or communications from Synergy personnel, offered without context, is misleading as framed, and Synergy respectfully refers the Court to the quoted documents, once identified, for a complete and accurate description of their contents. Synergy denies the remaining allegations contained in Paragraph 37.

#### **EO Sterilization Is Not a Substitute for Radiation Sterilization Services**

38. Synergy lacks information sufficient to admit or deny the allegations contained in Paragraph 38 concerning STERIS' purported views regarding the impact of nearby EO sterilization facilities and STERIS' marketing efforts. Synergy avers that the Commission's selective summation of unidentified written material or communications from STERIS personnel, offered without context, is misleading as framed, and Synergy respectfully refers the Court to the summarized documents, once identified, for a complete and accurate description of their contents. The rest of Paragraph 38 contains legal conclusions to which no response is required. To the extent that Paragraph 38 contains factual allegations, Synergy denies all other allegations contained in Paragraph 38.

39. Synergy denies the allegations contained in Paragraph 39 that EO sterilization takes significantly longer than other sterilization methods, and to the extent that they imply that EO sterilization is only "theoretical." To the contrary, Synergy avers that EO sterilization is widely used and is quicker than typical gamma sterilization. Synergy admits the other allegations contained in Paragraph 39.

### **In-House Sterilization Is Not a Viable Substitute for Most Customers**

40. Synergy lacks information sufficient to admit or deny the allegations contained in Paragraph 40 regarding the purported number of cubic feet of gamma-sterilized product annually required to justify in-house gamma sterilization, whether any in-house sterilizer in the continental United States sells excess sterilization capacity, and the percentage of gamma sterilization performed in-house. On information and belief, Synergy admits that most in-house gamma sterilization facilities are operated by large medical device manufacturers. Synergy further admits that its contract sterilization customers do not rely on in-house gamma sterilization facilities to satisfy all of their sterilization requirements. The rest of Paragraph 40 contains legal conclusions to which no response is required. To the extent that Paragraph 40 contains factual allegations, Synergy denies all other allegations contained in Paragraph 40.

41. On information and belief, Synergy admits the allegations contained in Paragraph 41 that there are regulatory barriers to establishing a gamma facility in the United States, that Sterigenics acquired Nordion, Inc. (“Nordion”) in 2014, that there are questions about the future availability and supply of Cobalt 60, and that Sterigenics sells gamma sterilization services. Synergy denies all other allegations contained Paragraph 41 and avers that there is a robust resale market for partially used Cobalt 60 pencils, which are available from suppliers other than Nordion, and that medical device manufacturers in the United States continue to add in-house radiation capacity, including E-beam capacity.

42. Synergy admits the allegations contained in Paragraph 42 that some customers with in-house sterilization capabilities use contract sterilization services as backup when their facilities are down and in areas where they do not have an in-house facility. The rest of Paragraph 42 contains legal conclusions to which no response is required. To the extent that Paragraph 42 contains factual allegations, Synergy denies all other allegations contained in Paragraph 42.

### **C.**

#### **The Market for Contract Gamma and X-ray Sterilization Services Sold to Targeted Customers**

43. Synergy lacks information sufficient to admit or deny the allegations contained in Paragraph 43 concerning STERIS’ presentation to the Commission. Synergy avers that the Commission’s selective summation of unidentified written material or communications from STERIS, offered without context, is misleading as framed, and Synergy respectfully refers the Court to the summarized documents, once identified, for a complete and accurate description of their contents. The rest of Paragraph 43 contains legal conclusions to which no response is required. To the extent that Paragraph 43 contains factual allegations, Synergy denies all other allegations contained in Paragraph 43.



44. Synergy lacks information sufficient to admit or deny the allegations contained in Paragraph 44 concerning STERIS' and Sterigenics' actual customer negotiations and negotiation strategies. The rest of Paragraph 44 contains legal conclusions to which no response is required. To the extent that Paragraph 44 contains factual allegations, Synergy denies all other allegations contained in Paragraph 44. Synergy avers that E-beam can be used to sterilize most products that are sterilized with gamma radiation

45. Synergy admits the allegations contained in Paragraph 45 that customers could switch some portion of products currently utilizing contract gamma sterilization services to E-beam sterilization. The rest of Paragraph 45 contains legal conclusions to which no response is required. To the extent that Paragraph 45 contains factual allegations, Synergy denies all other allegations contained in Paragraph 45.

#### IV.

#### RELEVANT GEOGRAPHIC MARKETS

46. Paragraph 46 contains legal conclusions to which no response is required. To the extent that Paragraph 46 contains factual allegations, Synergy denies the allegations contained in Paragraph 46.

47. Synergy admits the allegations contained in Paragraph 47 that most contract radiation sterilization customers seek to minimize transportation costs and turnaround times in seeking contract sterilization. Synergy also admits that customers may use sterilization providers more than 500 miles away from a customer's plants if the sterilization provider has a facility near the customer's regular shipping route. Synergy lacks sufficient information to admit or deny the allegation concerning where contract sterilization companies may decide to locate their plants. Synergy denies all other allegations contained in Paragraph 47.

48. Synergy lacks information sufficient to admit or deny the allegations contained in Paragraph 48 concerning how other contract sterilization providers set pricing. With regard to its own practices, Synergy denies the allegations of Paragraph 48.

49.

[REDACTED] Synergy denies all other allegations contained in Paragraph 49.

50. Synergy admits that it identified users of sterilization services located near Decatur, Indiana. Synergy denies all other allegations contained in Paragraph 50.

51. Synergy denies the allegations contained in Paragraph 51.

52. Synergy denies the allegations contained in Paragraph 52.

53. Synergy lacks information sufficient to admit or deny the allegations contained in Paragraph 53 concerning the supply chain of the vast majority of U.S. sterilization customers. Synergy denies the other allegations contained in Paragraph 53.

V.

**MARKET STRUCTURE**

54. On information and belief, Synergy admits the allegations contained in Paragraph 54 that STERIS and Sterigenics are currently the only providers of contract gamma sterilization services in the United States. Synergy denies all other allegations contained in Paragraph 54.

A.

**Market Participants**

**Contract Gamma Sterilization Services**

55. Synergy lacks information sufficient to admit or deny the allegations contained in Paragraph 55 regarding STERIS' revenues. On information and belief, Synergy admits all other allegations contained in Paragraph 55.

56. Synergy lacks information sufficient to admit or deny the allegations contained in Paragraph 56 regarding Sterigenics' revenues. On information and belief, Synergy admits all other allegations contained in Paragraph 56.

**Contract X-ray Sterilization Services**

57. Synergy denies the allegations contained in Paragraph 57 that it had a well-developed strategy to enter the United States with contract X-ray sterilization services, and that those services would have competed with contract gamma sterilization services. Synergy admits all other allegations contained in Paragraph 57.

58. Synergy denies the allegations contained in Paragraph 58.

59. Synergy admits the allegations contained in Paragraph 59 that third party sterilization service providers, like Nutek, may attempt to provide X-ray sterilization services. On information and belief, Synergy avers that such activity is already underway. Synergy denies all other allegations in Paragraph 59.

**Contract E-beam Sterilization Services**

60. Synergy admits the allegations contained in Paragraph 60, except that it denies that [REDACTED]

61. On information and belief, Synergy admits the allegations contained in Paragraph 61 that Sterigenics operates a contract E-beam sterilization facility in San Diego, California. Synergy lacks information sufficient to admit or deny all other allegations contained in Paragraph 61.

62. On information and belief, Synergy admits the allegations contained in Paragraph 62 that STERIS does not currently provide E-beam sterilization services in the United States. Synergy lacks information sufficient to admit or deny all other allegations contained in Paragraph 62.

63. On information and belief, Synergy admits the allegations contained in Paragraph 63 that E-beam contract sterilization services are offered by 1) E-BEAM Services Inc. in Cranbury, New Jersey and Lebanon, Ohio, 2) Nutek in Hayward, California, and 3) Iotron in Columbia City, Indiana. Synergy denies the allegations contained in Paragraph 63 that Nutek lacks experience and efficiency and denies the implication that Iotron lacks the technical expertise to serve medical device manufacturers. Synergy lacks information sufficient to admit or deny all other allegations contained in Paragraph 63. Synergy avers that the Commission's selective quotation and summation of unidentified written material or communications, offered without context, is misleading as framed, and Synergy respectfully refers the Court to the quoted and summarized documents, once identified, for a complete and accurate description of their contents.

## **B. Market Concentration**

64. Paragraph 64 contains legal conclusions to which no response is required. To the extent that Paragraph 64 contains factual allegations, Synergy denies the allegations contained in Paragraph 64.

65. Synergy admits that the HHI is used by the Commission as a measure of purported concentration and avers that the Horizontal Merger Guidelines issued by the Antitrust Division of the United States Department of Justice and the Federal Trade Commission on August 19, 2010, speak for themselves. Synergy further avers that the Horizontal Merger Guidelines do not necessarily mirror, and do not substitute for, controlling case law. The rest of Paragraph 65 contains legal conclusions to which no response is required. To the extent that Paragraph 65 contains factual allegations, Synergy denies all other allegations contained in Paragraph 65.

66. Paragraph 66 contains legal conclusions to which no response is required. To the extent that Paragraph 66 contains factual allegations, Synergy denies all other allegations contained in Paragraph 66. Synergy specifically denies that contract radiation sterilization services and the geographic markets identified constitute relevant markets.

67. Paragraph 67 contains legal conclusions to which no response is required. To the extent that Paragraph 67 contains factual allegations, Synergy denies all other allegations contained in Paragraph 67. Synergy specifically denies that "contract gamma and x-ray sterilization services sold to targeted customers" constitute a relevant market.

## VI.

### ANTICOMPETITIVE EFFECTS

68. Synergy admits the allegations contained in Paragraph 68 that it is a worldwide sterilization company without a gamma offering in the United States and, on information and belief, that STERIS and Sterigenics are the only two contract gamma sterilization providers in the United States. The rest of Paragraph 68 contains legal conclusions to which no response is required. To the extent that Paragraph 68 contains factual allegations, Synergy denies all other allegations contained in Paragraph 68. Synergy specifically denies that there is any likely future competition arising from Synergy's deployment of X-ray sterilization in the United States.

69. Synergy avers that its documents speak for themselves and respectfully refers the Court to the quoted and summarized documents, once identified, for a complete and accurate description of their contents. Synergy admits that, at one time, certain Synergy personnel explored the possibility of building X-ray sterilization facilities in the United States. [REDACTED]

[REDACTED] Synergy denies all other allegations contained in Paragraph 69.

70. Synergy avers that its documents speak for themselves and respectfully refers the Court to the quoted and summarized documents, once identified, for a complete and accurate description of their contents. Synergy denies all other allegations contained in Paragraph 70.

#### A.

#### **Synergy Was Entering the Relevant Markets Prior to the Merger**

##### The Early Stages of Synergy's U.S. X-ray Plan

71. Synergy admits that it acquired an X-ray facility in Däniken, Switzerland. Synergy avers that its documents speak for themselves and respectfully refers the Court to the quoted and summarized documents, once identified, for a complete and accurate description of their contents. Synergy denies all other allegations contained in Paragraph 71.

72. Synergy admits that Andrew McLean joined Synergy in June 2013 as Vice President of Global AST Business Development and that Mr. McLean was responsible for Synergy's initiative to explore potential X-ray sterilization entry in the United States. Synergy avers that its documents speak for themselves and respectfully refers the Court to the quoted and summarized documents, once identified, for a complete and accurate description of their contents. Synergy denies all other allegations in Paragraph 72.

##### The X-ray Plan Ramp-Up

73. Synergy denies the allegations contained in Paragraph 73.

74. Synergy denies the allegations contained in Paragraph 74.

75. Synergy admits the allegations contained in Paragraph 75 that it [REDACTED]

[REDACTED]  
[REDACTED] Synergy denies all other allegations in Paragraph 75.

76. [REDACTED]

[REDACTED] and that Synergy's SEB includes the members identified. Synergy avers that its documents speak for themselves and respectfully refers the Court to the quoted and summarized documents, once identified, for a complete and accurate description of their contents. Synergy denies all other allegations contained in Paragraph 76.

77. Synergy avers that its documents speak for themselves and respectfully refers the Court to the quoted and summarized document, once identified, for a complete and accurate description of its contents. Synergy denies all other allegations contained in Paragraph 77.

78. [REDACTED] that the plc board includes the individuals identified, and that [REDACTED] Synergy avers that its documents speak for themselves and respectfully refers the Court to the summarized documents, once identified, for a complete and accurate description of their contents. [REDACTED] Synergy denies all other allegations contained in Paragraph 78.

79. [REDACTED]

[REDACTED] Synergy avers that its documents speak for themselves and respectfully refers the Court to the summarized documents, once identified, for a complete and accurate description of their contents. Synergy denies all other allegations in Paragraph 79.

80. Synergy admits the allegations contained in Paragraph 80.

#### **Synergy's Actions Post-Merger Announcement**

81. Synergy admits that, after consummation of the proposed merger of Synergy and STERIS, the merged entity could make a decision whether to continue exploring the introduction of X-ray technology in the U.S. Synergy avers that its documents speak for themselves and respectfully refers the Court to the quoted and summarized documents, once identified, for a complete and accurate description of their contents. Synergy denies all other allegations contained in Paragraph 81.

82. Synergy avers that its documents speak for themselves and respectfully refers the Court to the quoted and summarized documents, once identified, for a complete and accurate description of their contents. Synergy denies all other allegations contained in Paragraph 82.

83. Synergy avers that its documents speak for themselves and respectfully refers the Court to the quoted and summarized documents, once identified, for a complete and accurate description of their contents. Synergy denies all other allegations contained in Paragraph 83.

84. [REDACTED]  
[REDACTED] Synergy avers that its documents speak for themselves and respectfully refers the Court to the referenced and summarized documents, once fully identified, for a complete and accurate description of their contents. Synergy denies all other allegations contained in Paragraph 84.

85. Synergy avers that its documents speak for themselves and respectfully refers the Court to the quoted and summarized documents, once identified, for a complete and accurate description of their contents. Synergy denies all other allegations contained in Paragraph 85.

**Synergy's Actions After the FTC Issued Second Requests**

86. Synergy admits the allegations contained in Paragraph 86.

87. [REDACTED]  
[REDACTED] Synergy denies all other allegations contained in Paragraph 87.

88. Synergy admits that Mr. McLean executed a declaration on February 24, 2015 and that, [REDACTED]  
[REDACTED] Synergy avers that its documents speak for themselves and respectfully refers the Court to the quoted and summarized documents, once fully identified, for a complete and accurate description of their contents. Synergy further avers that the Commission's selective quotation of unidentified written material offered without context is misleading as framed. Synergy denies all other allegations contained in Paragraph 88.

**B.**

**Synergy's U.S. X-ray Entry Would Result in Substantial Procompetitive Effects**

**Synergy's Entry Would Have a Significant De-concentrating Effect on the Relevant Markets**

89. Synergy avers that its documents speak for themselves and respectfully refers the Court to the summarized documents, once identified, for a complete and accurate description of their contents. Synergy denies all other allegations contained in Paragraph 89.

90. Synergy denies the allegations contained in Paragraph 90.

91. Paragraph 91 contains legal conclusions and argument to which no response is required. To the extent that Paragraph 91 contains factual allegations, Synergy denies the allegations contained in Paragraph 91. Synergy specifically denies that contract radiation sterilization and/or contract gamma sterilization constitute a relevant product markets.

92. Paragraph 92 contains legal conclusions and argument to which no response is required. To the extent that Paragraph 92 contains factual allegations, Synergy denies the allegations contained in Paragraph 92. Synergy specifically denies that contract radiation services and/or contract gamma/x-ray market constitute a relevant product markets.

93. Synergy lacks information sufficient to admit or deny the unspecified statements by an unidentified Sterigenics employee. Synergy avers that the Commission's selective quotation of unidentified written material or communications, offered without context, is misleading as framed, and Synergy respectfully refers the Court to the quoted documents, once identified, for a complete and accurate description of their contents. Synergy denies all other allegations contained in Paragraph 93.

**Synergy's X-ray Entry Would Have Created Substantial Price and Non-Price Benefits for Customers**

94. Synergy denies the allegations contained in Paragraph 94.

95. Synergy avers that its documents speak for themselves and respectfully refers the Court to the quoted and summarized documents, once fully identified, for a complete and accurate description of their contents. Synergy further avers that the Commission's selective quotation of unidentified written material offered without context is misleading as framed. Synergy denies all other allegations contained in Paragraph 95.

96. Synergy avers that its documents speak for themselves and respectfully refers the Court to the quoted and summarized documents, once fully identified, for a complete and accurate description of their contents. Synergy further avers that the Commission's selective quotation of unidentified written material offered without context is misleading as framed. Synergy denies all other allegations contained in Paragraph 96.

97. Synergy avers that its executives' testimony speaks for itself and respectfully refers the Court to the complete transcripts of the identified executives' testimony for a complete and accurate transcription of the same. Synergy further avers that the Commission's selective quotation of testimony offered without context is misleading as framed. Synergy denies all other allegations contained in Paragraph 97.

98. Synergy avers that Mr. Steeves' testimony speaks for itself and respectfully refers the Court to the complete transcript of Mr. Steeves' testimony for a complete and accurate transcription of the same. Synergy further avers that the Commission's selective quotation of testimony offered without context is misleading as framed. Synergy denies all other allegations contained in Paragraph 98.

99. Synergy lacks information sufficient to admit or deny the allegations in Paragraph 99 regarding the purported statements of unidentified customers. Synergy admits that many customers would have to validate their products for X-ray sterilization before they could switch those products over from gamma radiation sterilization. Synergy denies all other allegations contained in Paragraph 99.

100. Synergy lacks information sufficient to admit or deny the allegations in Paragraph 100 regarding the purported concerns of unidentified customers.

101. Synergy lacks information sufficient to admit or deny the allegations in Paragraph 101 regarding the statements and activities of unidentified customers. Synergy admits the allegations contained in Paragraph 101 regarding Synergy's understanding that it would take significant time, cost, and effort for customers to switch from gamma to X-ray sterilization. Synergy further admits that Johnson & Johnson has obtained FDA approval for Surgicel. Synergy avers that, [REDACTED]

[REDACTED] Synergy denies all other allegations contained in Paragraph 101.

102. Synergy lacks information sufficient to admit or deny the allegations in Paragraph 102 concerning other entities' intentions. [REDACTED]

[REDACTED] Synergy denies all other allegations contained in Paragraph 102.

103. Synergy lacks information sufficient to admit or deny the allegations in Paragraph 103 regarding the purported concerns and statements of unidentified customers.

104. Synergy lacks information sufficient to admit or deny the allegations in Paragraph 104 regarding the purported concerns and statements of unidentified customers.

## VII.

### **ENTRY WILL NOT PREVENT THE MERGER'S COMPETITIVE HARM**

105. Paragraph 105 contains legal conclusions and argument to which no response is required. To the extent that Paragraph 105 contains factual allegations, Synergy denies the allegations contained in Paragraph 105.

#### A.

#### **Barriers to Entry for X-ray Sterilization Services**

#### **Synergy Has X-ray Entry Advantages Unmatched by Any Other Firm**

106. Synergy admits that it is a small player in the U.S. contract radiation sterilization services business and that it provides E-beam and EO in the United States is E-beam. Synergy denies all other allegations contained in Paragraph 106.

107. Synergy admits that, at the time Synergy executed the merger agreement with STERIS, Synergy had been operating its Däniken, Switzerland X-ray sterilization facility for approximately two years and had considered the possibility of entering the U.S. with X-ray. [REDACTED]



[REDACTED]  
Synergy denies all other allegations contained in Paragraph 107.

108. Synergy admits that, at the time of the merger agreement, Synergy had reached an agreement with IBA. Synergy avers that the IBA agreement speaks for itself and respectfully refers the Court to the IBA agreement for a complete and accurate description of its contents. Similarly, Synergy avers that the testimony of the Däniken facility manager speaks for itself and respectfully refer the Court to the complete transcript of the testimony in question for a complete and accurate transcription of the same. Synergy denies all other allegations contained in Paragraph 108.

109. Synergy admits that it has the experience needed to meet the needs of large medical device manufacturers effectively and economically. On information and belief, Synergy also admits that no company has an agreement with IBA to use its X-ray equipment in the United States. Synergy lacks information sufficient to admit or deny the allegations in Paragraph 109 regarding STERIS and Sterigenics, and IBA's purported beliefs. Synergy denies all other allegations contained in Paragraph 109.

110. On information and belief, Synergy admits that other E-beam sterilization service providers in the United States have contemplated converting their E-beam sterilization machines into X-ray sterilization machines. Synergy lacks information sufficient to admit or deny the allegations in Paragraph 110 regarding the conclusions purportedly reached by [REDACTED]. Synergy denies all other allegations contained in Paragraph 110.

#### **B.**

#### **Barriers to Entry for Gamma Sterilization Services**

111. On information and belief, Synergy admits that no contract gamma sterilization provider has built a new gamma sterilization facility in the United States in over fifteen years. On information and belief, Synergy avers that in-house gamma sterilization facilities have been constructed and that contract gamma sterilization providers have added capacity at their existing facilities in the United States in the last fifteen years. Synergy also admits that regulations govern gamma sterilization facilities. Synergy lacks information sufficient to admit or deny the allegations in Paragraph 111 regarding the purported threat of future legislative restrictions. Synergy denies all other allegations contained in Paragraph 111.

112. Synergy denies the allegations contained in Paragraph 112. [REDACTED]

113. Paragraph 113 contains opinions and legal conclusions to which no response is required. To the extent that Paragraph 113 contains factual allegations, Synergy admits the allegations contained in Paragraph 113.

114. Synergy admits that the prices of Cobalt 60 are likely to increase because of Sterigenics' ownership of Nordion. Synergy avers that its documents and its executives' testimony speak for themselves and respectfully refers the Court to the quoted and summarized documents and/or testimony, once identified, for a complete and accurate description of their

contents and/or transcription. Synergy further avers that the Commission's selective quotation of unidentified written material and/or testimony offered without context is misleading as framed. The rest of Paragraph 114 contains opinions and legal conclusions to which no response is required. To the extent that Paragraph 114 contains factual allegations, Synergy denies the allegations contained in Paragraph 114.

### C.

#### **Barriers to Entry for E-beam Sterilization Services**

115. Synergy admits that a potential E-beam entrant would need to secure customers willing to use its facility and that customers would need to test and validate their products with a potential E-beam sterilization provider before committing to use its services. Synergy lacks information sufficient to admit or deny the allegations in Paragraph 115 regarding the length of time an unnamed firm seeking to open an E-beam sterilization facility has been planning to enter or when it expects to begin operations. Synergy denies all other allegations contained in Paragraph 115. [REDACTED]

116. Synergy lacks information sufficient to admit or deny the unspecified statements by an unidentified STERIS employee. Synergy avers that the Commission's selective quotation of unidentified written material or communications, offered without context, is misleading as framed, and Synergy respectfully refers the Court to the quoted documents, once identified, for a complete and accurate description of their contents. Synergy denies all other allegations contained in Paragraph 116.

117. Synergy lacks information sufficient to admit or deny the unspecified statements by an unidentified STERIS employee. Synergy avers that the Commission's selective quotation of unidentified written material or communications, offered without context, is misleading as framed, and Synergy respectfully refers the Court to the quoted documents, once identified, for a complete and accurate description of their contents. Synergy denies all other allegations contained in Paragraph 117.

### VIII.

#### **EFFICIENCIES WILL NOT COUNTERACT THE MERGER'S COMPETITIVE HARM**

118. Paragraph 118 contains legal conclusions and argument to which no response is required. To the extent that Paragraph 118 contains factual allegations, Synergy denies the allegations contained in Paragraph 118.

119. Synergy lacks information sufficient to admit or deny the unspecified statements by an unidentified STERIS employee. Synergy avers that the Commission's selective quotation of unidentified written material or communications, offered without context, is misleading as framed, and Synergy respectfully refers the Court to the quoted documents, once identified, for a complete and accurate description of their contents. Synergy denies all other allegations contained in Paragraph 119.

**IX.**

**VIOLATION**

**COUNT I-ILLEGAL AGREEMENT**

120. Except where specifically admitted above, the allegations contained in Paragraphs 1 through 119 of the Complaint are denied.

121. Synergy denies the allegations contained in Paragraph 121.

**COUNT II-ILLEGAL ACQUISITION**

122. Except where specifically admitted above, the allegations contained in Paragraphs 1 through 119 of the Complaint are denied.

123. Synergy denies the allegations contained in Paragraph 123.

**AFFIRMATIVE AND OTHER DEFENSES**

Synergy asserts the following defenses, without assuming the burden of proof on such defenses that would otherwise rest with the Commission:

1. The Complaint fails to state a claim on which relief can be granted.
2. Granting the relief sought is contrary to the public interest.
3. The alleged relevant geographic market definitions fail as a matter of law.
4. The Complaint fails adequately to allege a relevant product market.
5. The Complaint fails to allege harm to competition.
6. The Complaint fails to allege harm to any consumers.
7. The Complaint fails to allege harm to consumer welfare.
8. The alleged harm to potential competition is not actionable.
9. The Commission cannot show that, even if it succeeds in blocking the proposed merger, Synergy will ever provide contact X-ray sterilization services in the United States
10. The combination of the Respondents' businesses will be procompetitive. The merger will result in substantial merger-specific efficiencies, cost synergies, and other procompetitive effects that will directly benefit consumers. The benefits greatly outweigh any and all proffered anticompetitive effects.

11. Synergy reserves the right to assert any other defenses as they become known to Synergy.

WHEREFORE, having fully answered the Complaint, Synergy respectfully requests that the Commission: (1) deny Plaintiff the relief requested in the Complaint; (2) dismiss the Complaint in its entirety with prejudice; (3) award Synergy its costs of suit, including expert fees and reasonable attorneys' fees, as may be allowed by law; and (4) award such other and further relief as the Commission may deem just and proper.

Dated: June 22, 2015

Respectfully submitted,

**DLA PIPER LLP (US)**

By: /s/ Laura M. Kam

PAOLO MORANTE  
STEVEN E. LEVITSKY  
1251 Avenue of the Americas, 27th Floor  
New York, NY 10020  
Tel: 212.335.4500  
Fax: 212.606.5101

DAVID H. BAMBERGER  
JULIE GRyce  
500 Eighth Street, NW  
Washington, DC 20004  
TEL: 202.799.4000  
FAX: 202.799.5000

LAURA M. KAM  
2525 East Camelback Road, Suite 1000  
Phoenix, AZ 85016  
TEL: 480.606.5100  
FAX: 480.606.5101

Attorneys for Defendant Synergy Health PLC

CERTIFICATE OF SERVICE

I hereby certify that on June 22, 2015 with the Court's permission, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

**Donald S. Clark**  
SECRETARY  
FEDERAL TRADE COMMISSION  
600 Pennsylvania Ave., NW, Rm. H-113  
Washington, DC 20580

I also certify that I delivered via electronic mail and U.S. Mail a copy of the foregoing document to:

**The Honorable Judge D. Michael Chappell**  
ADMINISTRATIVE LAW JUDGE  
FEDERAL TRADE COMMISSION  
600 Pennsylvania Ave., NW  
Washington, DC 20580

I further certify that I delivered via electronic mail a copy of the foregoing document to:

**Michael Moiseyev**  
**Tara Reinhart**  
**Daniel K. Zach**  
**Peter Colwell**  
**Jonathan L. Kessler**  
FEDERAL TRADE COMMISSION  
400 7th St., SW  
Washington, DC 20024  
[mmoiseyev@ftc.gov](mailto:mmoiseyev@ftc.gov)  
[treinhart@ftc.gov](mailto:treinhart@ftc.gov)  
[dazch@ftc.gov](mailto:dazch@ftc.gov)  
[pcolwell@ftc.gov](mailto:pcolwell@ftc.gov)  
[jkessler@ftc.gov](mailto:jkessler@ftc.gov)

*Counsel for Plaintiff Federal Trade Commission*

**John M. Majoras**

JONES DAY

Street Address:

325 John H. McConnell Blvd., Suite 600  
Columbus, OH 43215

Mailing Address:

P.O. Box 165017  
Columbus, OH 43216

[jmmajoras@jonesday.com](mailto:jmmajoras@jonesday.com)

**Louis K. Fisher**

**Michael S. Fried**

**Geoffrey S. Irwin**

**Tara Lynn R. Zurawski**

**Kerri Ruttenberg**

JONES DAY

51 Louisiana Ave., N.W.

Washington, DC 20001

[lkfisher@jonesday.com](mailto:lkfisher@jonesday.com)

[msfried@jonesday.com](mailto:msfried@jonesday.com)

[gsirwin@jonesday.com](mailto:gsirwin@jonesday.com)

[tzurawski@jonesday.com](mailto:tzurawski@jonesday.com)

[kruttenberg@jonesday.com](mailto:kruttenberg@jonesday.com)

*Counsel for Defendant STERIS Corporation*

*/s/ April Natzke* \_\_\_\_\_

CERTIFICATE FOR ELECTRONIC FILING

I certify that the electronic copy sent to the Secretary of the Commission is a true and correct copy of the paper original and that I possess a paper original of the signed document that is available for review by the parties and the adjudicator.

June 22, 2015

By: /s/ April Natzke

Notice of Electronic Service

**I hereby certify that on June 22, 2015, I filed an electronic copy of the foregoing Redacted Answer of Respondent Synergy Health plc, with:**

D. Michael Chappell  
Chief Administrative Law Judge  
600 Pennsylvania Ave., NW  
Suite 110  
Washington, DC, 20580

Donald Clark  
600 Pennsylvania Ave., NW  
Suite 172  
Washington, DC, 20580

**I hereby certify that on June 22, 2015, I served via E-Service an electronic copy of the foregoing Redacted Answer of Respondent Synergy Health plc, upon:**

Louis Fisher  
Jones Day  
lkfisher@jonesday.com  
Respondent

Michael Fried  
Jones Day  
msfried@jonesday.com  
Respondent

Tara Zurawski  
Jones Day  
tzurawski@jonesday.com  
Respondent

Geoffrey Irwin  
Jones Day  
gsirwin@jonesday.com  
Respondent

John Majoras  
Jones Day  
jmmajoras@jonesday.com  
Respondent

Kerri Ruttenberg  
Jones Day  
kruttenberg@jonesday.com  
Respondent

Paolo Morante  
Mr.  
DLA Piper LLP (US)  
paolo.morante@dlapiper.com  
Respondent

David Bamberger  
Mr.  
DLA Piper LLP (US)  
david.bamberger@dlapiper.com



Respondent

Steven Levitsky

Mr.

DLA Piper LLP (US)

steven.levitsky@dlapiper.com

Respondent

Laura Kam

DLA Piper LLP (US)

laura.kam@dlapiper.com

Respondent

Julie Gryce

DLA Piper LLP (US)

julie.gryce@dlapiper.com

Respondent

Tara Reinhart

Federal Trade Commission

treinhart@ftc.gov

Complaint

Thomas H. Brock

Federal Trade Commission

TBrock@ftc.gov

Complaint

**I hereby certify that on June 22, 2015, I served via other means, as provided in 4.4(b) of the foregoing Redacted Answer of Respondent Synergy Health plc, upon:**

Daniel K. Zach

Attorney

FTC

dzach@ftc.gov

Complaint

Michael Moiseyev

Attorney

FTC

mmoiseyev@ftc.gov

Complaint

Tara Reinhart

Attorney

FTC

treinhart@ftc.gov

Complaint

Peter Colwell

Attorney

FTC

pcolwell@ftc.gov

Complaint

Jonathan L. Kessler

Attorney

FTC

jkessler@ftc.gov

Complaint

Laura Kam  
Attorney