

**UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION**

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)	
In the Matter of)	
)	File No. 991-0095
SNIA S.p.A.,)	
a corporation.)	
)	
)	

AGREEMENT CONTAINING CONSENT ORDER

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by SNIA S.p.A. (“SNIA”), through Sorin Biomedica S.p.A. (“Sorin”), of one hundred percent (100%) of the outstanding voting securities of COBE Cardiovascular, Inc., as well as certain cardiopulmonary and other cardiovascular assets and liabilities from COBE Laboratories, Inc. and other subsidiaries of Gambro AB (“Gambro”), and it now appearing that SNIA, hereinafter sometimes referred to as “Proposed Respondent,” is willing to enter into an Agreement Containing Consent Order (“Agreement”) to divest certain assets, contract manufacture certain products and provide for certain other relief:

IT IS HEREBY AGREED by and between Proposed Respondent, by its duly authorized officers and its attorneys, and counsel for the Commission that:

1. Proposed Respondent SNIA is a corporation organized, existing, and doing business under and by virtue of the laws of Italy, with its headquarters located at Borgonuovo 14, 20121 Milano, Italy. Sorin Biomedical, Inc., a wholly owned subsidiary of SNIA, is located at 17600 Gillette Ave., Irvine, CA 92614-5751.
2. Proposed Respondent admits all the jurisdictional facts set forth in the draft of complaint here attached.
3. Proposed Respondent waives:
 - a. any further procedural steps;
 - b. the requirement that the Commission’s decision contain a statement of findings of fact and conclusions of law;

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c. all rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this Agreement; and

d. any claims under the Equal Access to Justice Act.

4. Proposed Respondent shall submit within forty-five (45) days of the date this Agreement is signed by Proposed Respondent, an initial report, pursuant to Section 2.33 of the Commission's Rules signed by the Proposed Respondent setting forth in detail the manner in which the Proposed Respondent is complying and will comply with this order. Such report will not become part of the public record unless and until the accompanying agreement and order are accepted by the Commission for public comment.

5. This Agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this Agreement is accepted by the Commission it, together with the draft of complaint contemplated thereby, will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this Agreement and so notify the Proposed Respondent, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision, in disposition of the proceeding.

6. This Agreement is for settlement purposes only and does not constitute an admission by the Proposed Respondent that the law has been violated as alleged in the draft of complaint here attached, or that the facts as alleged in the draft complaint, other than jurisdictional facts, are true.

7. This Agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Section 2.34 of the Commission's Rules, the Commission may, without further notice to Proposed Respondent: (1) issue its complaint corresponding in form and substance with the draft of complaint here attached and its decision containing the following order to divest and contract manufacture in disposition of the proceeding, and (2) make information public with respect thereto. When so entered, the order shall have the same force and effect and may be altered, modified, or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service. Delivery by the United States Postal Service of the complaint and decision containing the agreed-to order to Proposed Respondent's United States counsel named in this agreement shall constitute service. Proposed

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Respondent waives any right it may have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the order or the Agreement may be used to vary or contradict the terms of the order.

8. By signing this Agreement Containing Consent Order, Proposed Respondent represents that it can accomplish the full relief contemplated by the order.

9. Proposed Respondent has read the proposed complaint and order contemplated hereby. Proposed Respondent understands that once the order has been issued, it will be required to file one or more compliance reports showing it has fully complied with the order. Proposed Respondent agrees to comply with the requirements of Paragraph II. and Paragraph III. of the proposed order from the date this Agreement Containing Consent Order is signed. Proposed Respondent further understands that it may be liable for civil penalties in the amount provided by law for each violation of the order after it becomes final.

ORDER

I.

IT IS ORDERED that, as used in this order, the following definitions shall apply:

A. “SNIA” or “Respondent” means SNIA S.p.A., formerly SNIA BPD S.p.A., its directors, officers, employees, agents, representatives, successors, and assigns; its subsidiaries, divisions, groups and affiliates controlled by SNIA S.p.A., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

B. “Sorin” means Sorin Biomedica S.p.A., a subsidiary of SNIA, and any other SNIA subsidiary involved in the Acquisition.

C. “COBE” means COBE Cardiovascular, Inc., a corporation organized, existing and doing business under the laws of Colorado with its headquarters located at 14401 West 65th Way, Arvada, Colorado 80004. COBE also includes other assets or businesses of Gambro AB that are acquired in the Acquisition.

D. “Acquirer” means either Baxter Healthcare Corporation, a corporation organized, existing and doing business under the laws of Delaware with its headquarters located at One Baxter Parkway, Deerfield, Illinois 60015, or any other entity to whom Respondent shall divest the COBE Heart-Lung Machine Assets pursuant to Paragraph II. of this order.

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E. “Acquisition” means the acquisition by SNIA, through Sorin, of one hundred percent (100%) of the outstanding voting securities of COBE Cardiovascular, Inc., as well as certain cardiopulmonary and other cardiovascular assets and liabilities from COBE Laboratories, Inc. and other subsidiaries of Gambro AB pursuant to the Asset & Stock Purchase Agreement dated November 23, 1998.

F. “CE Mark” means Conformance European Mark or any other designation indicating that all pertinent European Community legal requirements for a medical device have been met enabling the manufacture and sale of the device in any member country.

G. “COBE Heart-Lung Machine” means any Heart-Lung Machine researched, developed, manufactured or sold by COBE.

H. “COBE Heart-Lung Machine Assets” means all of COBE’s assets (excluding receivables, cash, securities or other liquid assets), business, goodwill and rights, as of the date this Agreement Containing Consent Order is signed by the Respondent, that will be transferred to Respondent through the Acquisition relating to the research, development, manufacture, marketing or sale of any COBE Heart-Lung Machine, including, but not limited to: all machinery, fixtures, equipment and other tangible property, trade names, trademarks, brand names, formulations, inventory, contractual rights, Patents, trade secrets, technology, know-how, specifications, designs, drawings, processes, production information, manufacturing information, testing and quality control data, research materials, technical information, marketing and distribution information, customer lists, software, information stored on management information systems (and specifications sufficient for the Acquirer or New Acquirer to use such information) and all data, contractual rights, materials and information relating to FDA and other government or regulatory approvals relating to COBE Heart-Lung Machines. COBE Heart-Lung Machine Assets do not include purchase orders requiring delivery of all COBE Heart-Lung Machines within ninety (90) days of the date this Agreement Containing Consent Order is accepted for public comment and inventory required to fulfill such purchase orders; lease, rental and cost per treatment contracts for COBE Heart-Lung Machines and the underlying Heart-Lung Machines and related assets; or insurance and tax rights.

I. “Commercial Capability to Manufacture” means the practical ability to manufacture (including by subcontracting other than to Respondent or COBE) COBE Heart-Lung Machines whether or not any are actually sold.

J. “Commission” means the Federal Trade Commission.

K. “Contract Manufacture” or “Contract Manufacturing” means the manufacture and supply of COBE Heart-Lung Machines pursuant to a Divestiture Agreement with the Acquirer or New Acquirer.

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L. “Cost” means the cost of manufacturing an item, as determined by Generally Accepted Accounting Principles, including the actual cost of raw materials, direct labor, reasonably allocated factory overhead and reasonable, actual contracted services. The cost of raw materials and direct labor is the actual cost of materials and labor consumed to manufacture the item.

M. “Designee” means any entity that will manufacture COBE Heart-Lung Machines for the Acquirer or New Acquirer.

N. “Divestiture Agreement” means the Asset Purchase Agreement dated April 23, 1999 between Baxter Healthcare Corporation and Sorin Biomedica, S.p.A., the Supplemental Agreement dated April 23, 1999 between Baxter Healthcare Corporation and Sorin Biomedica, S.p.A., and Amendment No. 1 to Supplemental Agreement dated April 27, 1999 between Baxter Healthcare Corporation and Sorin Biomedica, S.p.A., or any other agreement(s) between Respondent and the Acquirer or New Acquirer, as applicable.

O. “Divestiture Trustee” means the trustee appointed pursuant to Paragraph IV. of this order.

P. “FDA” means the United States Food and Drug Administration.

Q. “Heart-Lung Machine” means any durable machine used to shunt blood away from the heart, oxygenate the blood and return the blood to the body, but does not include any other components of the perfusion system, such as tubing, connectors, oxygenators, reservoirs and filters.

R. “Interim Trustee” means the trustee appointed pursuant to Paragraph III. of this order.

S. “Material Confidential Information” means competitively sensitive or proprietary information not independently known to an entity from sources other than the entity to which the information pertains, and includes, but is not limited to, customer lists, price lists, marketing methods, Patents, technologies, processes or other trade secrets.

T. “New Acquirer” means the entity to whom the Divestiture Trustee shall divest the COBE Heart-Lung Machine Assets pursuant to Paragraph IV. of this order.

U. “Patent” means the patent and patent rights, patent applications, patents of addition, re-examinations, reissues, extensions, granted supplementary protection certificates, substitutions, confirmations, registrations, revalidations, revisions, additions and the like, of or to said patent and patent rights and any and all continuations and continuations-in-part and divisionals.

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V. “Relevant Area” means any country, including but not limited to the United States, where COBE sells COBE Heart-Lung Machines as of the date of the Acquisition.

W. “Regulatory Approvals” means approval by the FDA, approval to receive a CE Mark, and any other governmental or regulatory approvals held by COBE for any COBE Heart-Lung Machine as of the date of the Acquisition.

X. “Reimbursable Costs” means the reasonable, direct, out-of-pocket expenses incurred by Respondent in providing referenced assistance.

II.

IT IS FURTHER ORDERED that:

A. Respondent shall divest absolutely and in good faith the COBE Heart-Lung Machine Assets as a competitively viable, on-going product line: (1) to Baxter Healthcare Corporation in accordance with the Divestiture Agreement, within ten (10) business days after the date the Commission accepts the Agreement Containing Consent Order for public comment, or (2) at no minimum price to an Acquirer that receives the prior approval of the Commission and only in a manner that receives the prior approval of the Commission, within one hundred eighty (180) days of the date on which this Agreement Containing Consent Order is accepted for public comment; **provided, however**, that Respondent may negotiate with the Acquirer for a non-exclusive license to, and an agreement not to assert against Respondent, any divested intellectual property rights related to the COBE Heart-Lung Machines currently being researched and developed but not manufactured or sold by COBE.

B. The purpose of this order is to ensure the continued use of the COBE Heart-Lung Machine Assets in the same business in which they are engaged at the time of the Acquisition, and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission’s complaint.

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C. Respondent shall comply with all terms of the Divestiture Agreement with Baxter Healthcare Corporation and such agreement is incorporated by reference into this order and made a part hereof as Confidential Appendix I. If the COBE Heart-Lung Machine Assets are divested pursuant to Paragraph II.A.(2) of this order, Respondent shall comply with all terms of the resulting Divestiture Agreement with the Acquirer and such agreement shall be deemed incorporated by reference into this order. Any failure by Respondent to comply with the requirements of such agreement(s) shall constitute a failure to comply with this order.

D. Respondent's Divestiture Agreement with the Acquirer or the New Acquirer, as applicable, shall include the following provisions, and Respondent shall commit to satisfy the following:

1. Respondent shall Contract Manufacture and deliver to the Acquirer or the New Acquirer in a timely manner and under reasonable terms and conditions a supply of COBE Heart-Lung Machines, specified in the Divestiture Agreement at Cost or such other price specified in the Divestiture Agreement with the approval of the Commission for a period not to exceed two (2) years from the date of the Divestiture Agreement, or three (3) months after the date the Acquirer or New Acquirer obtains all necessary Regulatory Approvals to manufacture and sell COBE Heart-Lung Machines and obtains the Commercial Capability to Manufacture, whichever is earlier; **provided, however**, that the two (2) year period may be extended by the Commission in three (3) month increments for a period not to exceed two (2) years. **Provided further, however**, three (3) months after the Acquirer obtains all necessary Regulatory Approvals and obtains the Commercial Capability to Manufacture COBE Heart-Lung Machines for any Relevant Area, Respondent shall have no further obligation to Contract Manufacture COBE Heart-Lung Machines for sale in that Relevant Area.

2. After Respondent commences delivery of COBE Heart-Lung Machines to the Acquirer or the New Acquirer pursuant to the Divestiture Agreement and for the term of the Contract Manufacturing arrangement referred to in Paragraph II.D.1. of this order, Respondent shall produce COBE Heart-Lung Machines only for fulfillment of the purchase orders described in Definition I.H. or for sale to the Acquirer or the New Acquirer.

3. Respondent shall make representations and warranties that the COBE Heart-Lung Machines supplied pursuant to the Divestiture Agreement meet all Regulatory Approval specifications. Respondent shall agree to indemnify, defend and hold the Acquirer or the New Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses resulting from the failure of a COBE Heart-Lung Machine supplied by Respondent to the Acquirer or New Acquirer pursuant to the Divestiture Agreement to meet regulatory specifications. This obligation shall be contingent upon the Acquirer or the New Acquirer giving Respondent prompt, adequate notice of such claim, cooperating fully in the defense

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of such claim, and permitting Respondent to assume the sole control of all phases of the defense and/or settlement of such claim, including the selection of counsel; **provided, however,** any such defense and/or settlement shall be consistent with the obligations assumed by Respondent under this order. This obligation shall not require Respondent to be liable for any negligent act or omission of the Acquirer or the New Acquirer or for any representations and warranties, express or implied, made by the Acquirer or the New Acquirer that exceed the representations and warranties made by Respondent to the Acquirer or the New Acquirer.

4. Respondent shall make representations and warranties that Respondent will hold harmless and indemnify the Acquirer or New Acquirer for any liabilities or loss of profits resulting from the failure by Respondent to deliver the COBE Heart-Lung Machines in a timely manner as required by the Divestiture Agreement unless Respondent can demonstrate that its failure was entirely beyond the control of Respondent and in no part the result of negligence or willful misconduct on Respondent's part.

5. During the time that Respondent is Contract Manufacturing COBE Heart-Lung Machines for the Acquirer or the New Acquirer, upon request by the Acquirer, New Acquirer or the Interim Trustee, Respondent shall make available to the Interim Trustee all records that relate to the manufacture of the COBE Heart-Lung Machines.

6. Upon reasonable notice and request from the Acquirer or the New Acquirer to Respondent, Respondent shall use all commercially reasonable efforts to provide in a timely manner: (a) assistance and advice to enable the Acquirer or the New Acquirer (or the Designees of the Acquirer or New Acquirer) to obtain all necessary Regulatory Approvals to manufacture and sell COBE Heart-Lung Machines; (b) assistance to the Acquirer or New Acquirer (or the Designees thereof) as is necessary to enable the Acquirer or New Acquirer (or the Designees thereof) to manufacture COBE Heart-Lung Machines in substantially the same manner and quality employed or achieved by COBE at the time of the Acquisition; and (c) consultation with knowledgeable employees of Respondent and training, at the request of and at the facility of the Acquirer's or the New Acquirer's choosing, until the Acquirer or New Acquirer (or the Designees thereof) receive all necessary Regulatory Approvals or abandon their efforts to obtain all necessary Regulatory Approvals and until the Acquirer or the New Acquirer obtains the Commercial Capability to Manufacture or abandons its efforts to obtain the Commercial Capability to Manufacture, reasonably sufficient to satisfy the management of the Acquirer or New Acquirer that its personnel (or the Designees' personnel) are adequately trained in the manufacture of the COBE Heart-Lung Machines. Such assistance shall include on-site inspections, at the Acquirer's or New Acquirer's request, of the plant that is the specified source of supply of the Contract Manufacturing. Respondent may require reimbursement from the Acquirer or New

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Acquirer for all its Reimbursable Costs incurred in providing the services required by this Paragraph II.D.6.

7. The Divestiture Agreement shall require the Acquirer or the New Acquirer to submit to the Commission within ten (10) days of signing the Divestiture Agreement a certification attesting to the good faith intention of the Acquirer or the New Acquirer, including a plan by the Acquirer or the New Acquirer, to obtain in an expeditious manner all necessary Regulatory Approvals to manufacture and sell the COBE Heart-Lung Machine and to obtain the Commercial Capability to Manufacture.

8. The Divestiture Agreement shall require the Acquirer or the New Acquirer to submit to the Commission and Interim Trustee periodic verified written reports, setting forth in detail the efforts of the Acquirer or the New Acquirer to sell COBE Heart-Lung Machines obtained pursuant to the Divestiture Agreement and to obtain all Regulatory Approvals necessary to manufacture and sell COBE Heart-Lung Machines and the efforts of the Acquirer or the New Acquirer to obtain the Commercial Capability to Manufacture. The Divestiture Agreement shall require the first such report to be submitted sixty (60) days from the date the Divestiture Agreement is approved by the Commission and every sixty (60) days thereafter until all necessary Regulatory Approvals are obtained by the Acquirer or the New Acquirer to manufacture and sell COBE Heart-Lung Machines and until the Acquirer or the New Acquirer obtains the Commercial Capability to Manufacture. The Divestiture Agreement shall also require the Acquirer or the New Acquirer to report to the Commission and the Interim Trustee within ten (10) days of its ceasing the sale of COBE Heart-Lung Machines obtained pursuant to the Divestiture Agreement for any time period exceeding sixty (60) days; abandoning its efforts to obtain all necessary Regulatory Approvals to manufacture and sell COBE Heart-Lung Machines; or abandoning efforts to obtain the Commercial Capability to Manufacture. The Divestiture Agreement shall require the Acquirer or New Acquirer to provide the Interim Trustee access to all records and all facilities that relate to its efforts, pursuant to the Divestiture Agreement, to sell or manufacture COBE Heart-Lung Machines or obtain all necessary Regulatory Approvals.

9. The Divestiture Agreement shall provide that the Commission may terminate the Divestiture Agreement if the Acquirer or the New Acquirer: (a) voluntarily ceases for sixty (60) days or more the sale of, or otherwise fails to pursue good faith efforts to sell, COBE Heart-Lung Machines prior to obtaining all necessary Regulatory Approvals to manufacture and sell COBE Heart-Lung Machines or prior to obtaining the Commercial Capability to Manufacture; (b) fails to pursue good faith efforts to obtain all necessary Regulatory Approvals to manufacture and sell COBE Heart-Lung Machines; or (c) fails to obtain all necessary Regulatory Approvals of its own to manufacture and sell COBE Heart-Lung Machines or to obtain the Commercial Capability to Manufacture within two (2) years from the date of the Divestiture Agreement; **provided, however**, that the two (2) year period

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may be extended by the Commission in three (3) month increments for a period not to exceed two (2) years if it appears that such Regulatory Approvals are likely to be obtained or the Acquirer or the New Acquirer is likely to obtain the Commercial Capability to Manufacture such products within such extended time period.

10. The Divestiture Agreement shall provide that if it is terminated, the COBE Heart-Lung Machine Assets shall revert back to Respondent and shall be held separate, and the COBE Heart-Lung Machine Assets shall be divested by the Divestiture Trustee to a New Acquirer pursuant to the provisions of Paragraph IV. of this order.

E. During the pendency of any Patent dispute that: (1) challenges or seeks to render invalid any of the Patents divested pursuant to this order; and (2) could affect the manufacture or sale of COBE Heart-Lung Machines, Respondent shall cooperate, at its own expense, in the defense of rights it has transferred to the Acquirer or New Acquirer.

F. Within five (5) business days after the Acquisition or after Respondent signs the Divestiture Agreement, whichever is later, Respondent shall provide the Acquirer or New Acquirer with a complete list of all employees who are engaged in research, development, manufacture, marketing, or sales of any COBE Heart-Lung Machine on the date of the Acquisition. The list shall state each such individual's name, position, address, business telephone number, or if no business telephone number exists, a home telephone number, if available and with the consent of the employee, and a description of the duties and work performed by the individual in connection with the COBE Heart-Lung Machine Assets. Respondent shall provide the Acquirer or New Acquirer the opportunity to enter into employment contracts with such individuals provided that such contracts are contingent upon the Commission's approval of the Divestiture Agreement.

G. Within five (5) business days after the Acquisition or after Respondent signs the Divestiture Agreement, whichever is later, and subject to the consent of the employees, Respondent shall provide the Acquirer or New Acquirer with an opportunity to inspect the personnel files and other documentation relating to the individuals identified in Paragraph II.F. of this order to the extent possible under applicable laws. For the term of the Contract Manufacturing arrangement and two (2) months thereafter, Respondent shall provide the Acquirer or New Acquirer with a further opportunity to interview such individuals and negotiate employment contracts with them.

H. Respondent shall provide all employees identified in Paragraph II.F. of this order with reasonable financial incentives to continue in their employment positions in order that such employees may be in a position to accept employment with the Acquirer or New Acquirer. Such incentives shall include, but not be limited to, continuation of all employee benefits offered by Respondent, and vesting of all pension benefits (as permitted by law) for each such employee who accepts an offer of employment from the Acquirer or New Acquirer within one hundred eighty

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(180) days after the Agreement Containing Consent Order is accepted for public comment by the Commission.

I. Respondent shall not enforce any confidentiality or non-compete restrictions relating to the COBE Heart-Lung Machine Assets that apply to any employee identified in Paragraph II.F. who accepts employment with the Acquirer or New Acquirer, but Respondent may enforce all other rights thereunder relating to any other products or services.

J. For a period of one (1) year commencing on the date of the individual's employment by the Acquirer or New Acquirer, Respondent shall not solicit for employment any of the individuals identified in Paragraph II.F. of this order who accept employment with the Acquirer or New Acquirer, unless such individual has been separated from employment by the Acquirer or New Acquirer against that individual's wishes.

K. Prior to divestiture and during the term of the Contract Manufacturing arrangement, Respondent shall not transfer, without the consent of the Acquirer or New Acquirer, any of the individuals identified in Paragraph II.F. of this order to any other position.

L. While the obligations imposed by this order are in effect, Respondent:

1. shall take such actions as are necessary to: (a) maintain all necessary Regulatory Approvals to manufacture and sell COBE Heart-Lung Machines; (b) maintain the viability and marketability of the COBE Heart-Lung Machine Assets consistent with general practices in the medical devices industry, as well as all tangible assets, including Respondent's facilities, used to manufacture and sell COBE Heart-Lung Machines; and (c) prevent the destruction, removal, wasting, deterioration or impairment of the COBE Heart-Lung Machine Assets and the plant that is the specified source of supply of the Contract Manufacturing, except for ordinary wear and tear; and

2. shall not receive or have access to any Material Confidential Information about the COBE Heart-Lung Machines, except as required by law, and except to the extent that necessary information is exchanged in the course of evaluating the Acquisition, defending investigations or litigation, obtaining legal advice, negotiating agreements to divest assets, or complying with this order.

III.

IT IS FURTHER ORDERED that:

A. At any time after Respondent signs the Agreement Containing Consent Order in this matter, the Commission may appoint an Interim Trustee to ensure that Respondent and the

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Acquirer or New Acquirer expeditiously perform their respective responsibilities as required by this order and the Divestiture Agreement approved by the Commission.

B. If an Interim Trustee is appointed pursuant to Paragraph III.A. of this order, Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Trustee:

1. The Commission shall select the Interim Trustee, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed trustee within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed trustee, Respondent shall be deemed to have consented to the selection of the proposed trustee.

2. The Interim Trustee shall have the power and authority to monitor Respondent's compliance with the terms of this order and with the terms of the Divestiture Agreement, and shall exercise such power and authority in a manner consistent with the purposes of this order and in consultation with the Commission.

3. Within ten (10) days after appointment of the Interim Trustee, Respondent shall execute a trust agreement that, subject to the prior approval of the Commission, confers on the Interim Trustee all the rights and powers necessary to permit the Interim Trustee to monitor Respondent's compliance with the terms of this order and with the Divestiture Agreement, and to monitor the compliance of the Acquirer or New Acquirer under the Divestiture Agreement.

4. The Interim Trustee shall serve until such time as the Acquirer or the New Acquirer has received all necessary Regulatory Approvals to manufacture and sell COBE Heart-Lung Machines and has obtained the Commercial Capability to Manufacture.

5. The Interim Trustee shall have full and complete access to Respondent's personnel, books, records, documents, facilities and technical information relating to the research, development, manufacture, importation, distribution and sale of COBE Heart-Lung Machines, or to any other relevant information, as the Interim Trustee may reasonably request, including, but not limited to, all documents and records kept in the normal course of business that relate to the manufacture of COBE Heart-Lung Machines and all materials and information relating to Regulatory Approvals. Respondent shall cooperate with any reasonable request of the Interim Trustee. Respondent shall take no action to interfere with or impede the Interim Trustee's ability to monitor Respondent's compliance with this order and the Divestiture Agreement.

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6. The Interim Trustee shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions as the Commission may set. The Commission may, among other things, require the Interim Trustee to sign an appropriate confidentiality agreement relating to Commission materials and information received in connection with the performance of the Interim Trustee's duties. The Interim Trustee shall have authority to employ, at the expense of Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Trustee's duties and responsibilities. The Interim Trustee shall account for all expenses incurred, including fees for his or her services, subject to the approval of the Commission.

7. Respondent shall indemnify the Interim Trustee and hold the Interim Trustee harmless against any losses, claims, damages, liabilities or expenses arising out of, or in connection with, the performance of the Interim Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparations for, or defense of, any claim whether or not resulting in any liability, except to the extent that such liabilities, losses, damages, claims, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Interim Trustee.

8. If the Commission determines that the Interim Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Trustee in the same manner as provided in Paragraph III.B.1. of this order.

9. The Commission may on its own initiative or at the request of the Interim Trustee issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this order and the Divestiture Agreement.

10. The Interim Trustee shall obtain and evaluate reports submitted to it by the Acquirer or the New Acquirer with respect to the performance of Respondent's obligations under the Divestiture Agreement and with respect to the efforts of the Acquirer or the New Acquirer to obtain all necessary Regulatory Approvals to manufacture and sell COBE Heart-Lung Machines and to obtain the Commercial Capability to Manufacture. The Interim Trustee shall report to the Commission in writing concerning compliance by Respondent and the Acquirer or New Acquirer with the provisions of this order and the Divestiture Agreement within ten (10) days from the date the Divestiture Agreement or trust agreement is approved, whichever is later, and every sixty (60) days thereafter until the Acquirer or New Acquirer obtains, or abandons efforts to obtain, all necessary Regulatory Approvals to manufacture and sell COBE Heart-Lung Machines in the United States and to obtain the Commercial Capability to Manufacture or until such time as the Interim Trustee's term ends pursuant to Paragraph III.B.4. of this order.

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C. If the Commission terminates the Divestiture Agreement pursuant to Paragraph II.D.9. of this order, the Commission may direct the Divestiture Trustee to seek a New Acquirer, as provided for in Paragraph IV. of this order.

IV.

IT IS FURTHER ORDERED that:

A. If Respondent fails to divest absolutely and in good faith, and with the Commission's prior approval, the COBE Heart-Lung Machine Assets and to comply with the requirements of Paragraph II. of this order, or if the Acquirer abandons its efforts or fails to obtain all necessary Regulatory Approvals or obtain the Commercial Capability to Manufacture in the manner set out in Paragraph II.D.9., and if the executed Divestiture Agreement between Respondent and the Acquirer has been terminated by the Commission pursuant to Paragraph II.D.9., then the Commission may appoint a Divestiture Trustee to divest the COBE Heart-Lung Machine Assets and execute a new Divestiture Agreement that satisfies the requirements of Paragraph II. of this order. If the COBE Heart-Lung Machine Assets are divested pursuant to this Paragraph IV.A., Respondent shall comply with all terms of the resulting Divestiture Agreement with the New Acquirer and such agreement shall be deemed incorporated by reference into this order. Any failure by Respondent to comply with the requirements of such agreement(s) shall constitute a failure to comply with this order. The Divestiture Trustee may be the same person as the Interim Trustee and will have the authority and responsibility to divest the COBE Heart-Lung Machine Assets absolutely and in good faith, and with the Commission's prior approval. Neither the decision of the Commission to appoint the Divestiture Trustee, nor the decision of the Commission not to appoint the Divestiture Trustee, to divest any of the assets under this Paragraph IV.A. shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by the Respondent to comply with this order.

B. If a Divestiture Trustee is appointed by the Commission or a court pursuant to Paragraph IV.A. of this order to divest the COBE Heart-Lung Machine Assets to a New Acquirer, Respondent shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:

1. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to

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Respondent of the identity of any proposed Divestiture Trustee, Respondent shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

2. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to divest the COBE Heart-Lung Machine Assets to a New Acquirer pursuant to the terms of this order and to negotiate the terms of the Divestiture Agreement with the New Acquirer pursuant to the terms of this order, which Divestiture Agreement shall be subject to the prior approval of the Commission.

3. Within ten (10) days after appointment of the Divestiture Trustee, Respondent shall execute a trust agreement (or amend the existing trust agreement) that, subject to the prior approval of the Commission and, in the case of a court-appointed trustee, of the court, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to divest the COBE Heart-Lung Machine Assets to a New Acquirer and to negotiate a Divestiture Agreement with the New Acquirer.

4. The Divestiture Trustee shall have twelve (12) months from the date the Commission approves the trust agreement described in Paragraph IV.B.3. of this order to divest the COBE Heart-Lung Machine Assets and to enter into a Divestiture Agreement with the New Acquirer that satisfies the requirements of Paragraph II. of this order. If, however, at the end of the applicable twelve (12) month period, the Divestiture Trustee has submitted to the Commission a plan of divestiture or believes that divestiture can be achieved within a reasonable time, such divestiture period may be extended by the Commission, or, in the case of a court-appointed trustee, by the court; **provided, however,** the Commission may extend such divestiture period only two (2) times.

5. The Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities of Respondent related to the manufacture, distribution, or sale of the COBE Heart-Lung Machine Assets or to any other relevant information, as the Divestiture Trustee may request. Respondent shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondent shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of his or her responsibilities.

6. The Divestiture Trustee shall use reasonable efforts to negotiate the most favorable price and terms available in each Divestiture Agreement or other contract that is submitted to the Commission, subject to Respondent's absolute and unconditional obligation to divest at no minimum price and the Divestiture Trustee's obligation to expeditiously accomplish the remedial purpose of the order; to assure that Respondent enters into a Divestiture Agreement that complies with the provisions of Paragraph II.D.; to assure that Respondent complies with the remaining provisions of Paragraph IV. of this order; and to assure that the New Acquirer obtains all necessary Regulatory Approvals to manufacture and sell COBE Heart-Lung Machines and obtains the Commercial Capability to Manufacture such products. The divestiture shall be made to, and the Divestiture Agreement executed with,

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the New Acquirer in the manner set forth in Paragraph II. of this order; **provided, however,** if the Divestiture Trustee receives bona fide offers from more than one (1) acquiring entity, and if the Commission determines to approve more than one (1) such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity selected by Respondent from among those approved by the Commission.

7. The Divestiture Trustee shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the expense of Respondent, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission and, in the case of a court-appointed trustee, by the court, of the account of the trustee, including fees for his or her services, all remaining monies shall be paid at the direction of Respondent. The Divestiture Trustee's compensation shall be based at least in significant part on a commission arrangement contingent on the Divestiture Trustee's locating a New Acquirer and assuring compliance with this order.

8. Respondent shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such liabilities, losses, damages, claims, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.

9. If the Commission determines that the Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute trustee in the same manner as provided in Paragraph IV.A. of this order.

10. The Commission or, in the case of a court-appointed trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to comply with the terms of this order.

11. The Divestiture Trustee shall have no obligation or authority to operate or maintain the COBE Heart-Lung Machine Assets.

12. The Divestiture Trustee shall report in writing to Respondent and the Commission every two (2) months from the date the Divestiture Trustee is appointed concerning his or her efforts to divest the relevant assets, Respondent's compliance with the terms of this

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order, and the New Acquirer's efforts to obtain all necessary Regulatory Approvals to manufacture and sell COBE Heart-Lung Machines and to obtain the Commercial Capability to Manufacture such products.

V.

IT IS FURTHER ORDERED that within thirty (30) days of the date this order becomes final and every ninety (90) days thereafter until Respondent has fully complied with the provisions of this order, Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this order. Respondent shall include in its compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with this order, including a description of all substantive contacts or negotiations for accomplishing the divestiture and entering into the Divestiture Agreement required by this order, including the identity of all parties contacted. Respondent shall include in its compliance reports copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning the Divestiture Agreement required by Paragraph II. of this order.

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VI.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this order, and subject to any legally recognized privilege, upon written request and on reasonable notice to Respondent, Respondent shall permit any duly authorized representatives of the Commission:

A. Access, during office hours and in the presence of counsel, to any facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and other records and documents in the possession or under the control of Respondent, relating to any matters contained in this order; and

B. Upon five (5) days' notice to Respondent, and without restraint or interference from Respondent, to interview officers or employees of Respondent, who may have counsel present, regarding such matters.

VII.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to any change in Respondent such as dissolution, assignment or sale resulting in the emergence of a successor, the creation or dissolution of subsidiaries or any other change that may affect compliance obligations arising out of the order.

Signed this _____ day of _____, 1999.

**FEDERAL TRADE COMMISSION
BUREAU OF COMPETITION**

SNIA S.p.A.

By: _____

Christina R. Perez, Esq.
Michael R. Barnett, Esq.
Attorneys

By: _____

SNIA S.p.A.

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[CONFIDENTIAL APPENDIX I REDACTED]