PROPOSED CHARGING LETTER

CERTIFIED MAIL -- RETURN RECEIPT REQUESTED

EPMedSystems, Inc.
Cooper Run Executive Park
575 Route 73 North, Building D
West Berlin, New Jersey 08091

*Attn: David Bruce*
*Chief Executive Officer*

Dear Mr. Bruce:

The Bureau of Industry and Security, U.S. Department of Commerce ("BIS"), has reason to believe that EPMedSystems, Inc. of West Berlin, New Jersey ("EPMed") committed 23 violations of the Export Administration Regulations (the "Regulations"),[1] which are issued under the authority of the Export Administration Act of 1979, as amended (the "Act").[2] Specifically, BIS charges that EPMed committed the following violations:

**Charges 1-4** **15 C.F.R. § 764.2(a) -- Export to Iran without the Required U.S. Government Authorization**

As described in greater detail in the attached Schedule of Violations, which is incorporated herein by reference, on four occasions, between on or about March 13, 2001 and on or about January 7, 2004, EPMed engaged in conduct prohibited by the Regulations by exporting cardiac equipment, which is subject to the Regulations[3] and to the Iranian Transactions Regulations of

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[1] The Regulations are currently codified in the Code of Federal Regulations at 15 C.F.R. Parts 730-774 (2006). The charged violations occurred during 2000, 2001, 2002, 2003, and 2004. The Regulations governing the violations at issue are found in the 2000, 2001, 2002, 2003, and 2004 versions of the Code of Federal Regulations (15 C.F.R. Parts 730-774). The 2006 Regulations establish the procedures that apply to this matter.

[2] 50 U.S.C. app. §§ 2401-2420 (2000). From August 21, 1994 through November 12, 2000, the Act was in lapse. During that period, the President, through Executive Order 12924, which was extended by successive Presidential Notices, the last of which was August 3, 2000 (3 C.F.R., 2000 Comp. 397 (2001)), continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. §§ 1701 - 1706 (2000)) ("IEEPA"). On November 13, 2000, the Act was reauthorized by Pub. L. No. 106-508 (114 Stat. 2360 (2000)) and it remained in effect through August 20, 2001. Since August 21, 2001, Executive Order 13222 of August 17, 2001 (3 C.F.R., 2001 Comp. 783 (2002)), which has been extended by successive Presidential Notices, the most recent being that of August 3, 2006 (71 Fed. Reg. 44,551 (Aug. 7, 2006)), has continued the Regulations in effect under IEEPA. The Act and the Regulations are available on the Government Printing Office website at: *http://www.access.gpo.gov/bis/.*

[3] These items were classified as EAR99.

the Treasury Department's Office of Foreign Assets Control ("OFAC"),[4] to an end-user in Iran without the required U.S. Government authorization. Specifically, EPMed exported Workmate heart monitor systems through Germany, the Netherlands, and the United Kingdom to Iran. Pursuant to Section 560.204 of the Iranian Transactions Regulations, an export to a third country intended for transshipment to Iran is a transaction subject to the Iranian Transactions Regulations that requires OFAC authorization. Pursuant to Section 746.7 of the Regulations, no person may export items subject to both the Regulations and the Iranian Transactions Regulations without authorization from OFAC. EPMed knew or had reason to know that the items were destined for Iran, and no OFAC authorization was obtained for the exports. In engaging in this activity, EPMed committed four violations of Section 764.2(a) of the Regulations.

**Charges 5-8 15 C.F.R. § 764.2(e) -- Acting with Knowledge of a Violation**

On four occasions, between on or about March 9, 2001 and on or about January 7, 2004, in connection with Charges 1-4, above, EPMed violated the Regulations by selling and/or transferring items to be exported from the United States with knowledge that a violation of the Regulations was occurring in connection with the items. Specifically, EPMed sold and/or transferred the items described above, which were subject to the Regulations and the Iranian Transactions Regulations, with knowledge or reason to know that licenses were required for such exports and that no licenses had been obtained. EPMed knew or had reason to know that it was violating the Regulations because EPMed's officers and/or agents knew or had reason to know, prior to these actions, of the U.S. Government's embargo on exports to Iran. In addition, on or about September 27, 2000, before the exports occurred, EPMed submitted a license application to OFAC in an attempt to gain authorization for export of certain items to Iran. This license application was subsequently withdrawn by EPMed. In engaging in this activity, EPMed committed four violations of Section 764.2(e) of the Regulations.

**Charges 9-12 15 C.F.R. § 764.2(h) – Acting to Evade the Requirements of the Regulations**

On four occasions between on or about March 9, 2001 and on or about January 7, 2004, in connection with Charges 1-4, above, EPMed violated the Regulations by engaging in a transaction or taking other action with intent to evade the provisions of the Regulations. Specifically, EPMed engaged in selling the items described above to Iran through transshipment networks consisting of its European facilities and European distributors. EPMed's selling of these items through its transshipment networks was accomplished for the purpose of concealing the fact that EPMed was selling items to Iran. In engaging in this activity, EPMed committed four violations of Section 764.2(h) of the Regulations.

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[4] *See* 31 C.F.R. § 560.204.

**Charges 13-14** **15 C.F.R. § 764.2(a) – Reexport to Iran without the Required U.S. Government Authorization**

As described in greater detail in the attached Schedule of Violations, which is incorporated herein by reference, on two occasions, between on or about October 11, 2000 and on or about April 27, 2004, EPMed engaged in conduct prohibited by the Regulations by reexporting cardiac equipment components and replacement parts, which were subject to the Regulations and to the Iranian Transactions Regulations of OFAC, to Iran without the required U.S. Government authorization. Specifically, EPMed's European facilities reexported these components and parts from the Netherlands to Iran. Pursuant to Section 560.204 of the Iranian Transactions Regulations, a reexport by a U.S. person from a third country to Iran is a transaction subject to the Iranian Transactions Regulations that requires OFAC authorization. Pursuant to Section 746.7 of the Regulations, no person may reexport items subject to both the Regulations and the Iranian Transactions Regulations without authorization from OFAC. EPMed, a U.S. person, knew or had reason to know that the items were destined for Iran, and no OFAC authorization was obtained for the exports. In engaging in this activity, EPMed committed two violations of Section 764.2(a) of the Regulations.

**Charges 15-16** **15 C.F.R. § 764.2(e) -- Acting with Knowledge of a Violation**

On two occasions, between on or about October 11, 2000 and on or about April 27, 2004, in connection with Charges 13-14, above, EPMed violated the Regulations by selling and/or transferring items exported from the United States with knowledge that a violation of the Regulations was occurring in connection with the items. Specifically, EPMed sold and/or transferred the items described above, which were subject to the Regulations and the Iranian Transactions Regulations, with knowledge or reason to know that licenses were required for such reexports and that no licenses had been obtained. EPMed knew or had reason to know that it was violating the Regulations because EPMed's officers and/or agents knew or had reason to know, prior to these actions, of the U.S. Government's embargo on exports to Iran. In addition, on or about September 27, 2000, before the reexports occurred, EPMed submitted a license application to OFAC in an attempt to gain authorization for export of certain items to Iran. This license application was subsequently withdrawn by EPMed. In engaging in this activity, EPMed committed two violations of Section 764.2(e) of the Regulations.

**Charge 17** **15 C.F.R. § 764.2(d) -- Conspiracy to Export Items from the United States to Iran without the Required Licenses**

Between on or about March 2001 through on or about January 2004, EPMed conspired and acted in concert with others, known and unknown, to bring about an act that constitutes a violation of the Regulations by agreeing to export cardiac equipment from the United States to Iran without the required U.S. Government authorization. Pursuant to Section 746.7 of the Regulations, authorization was required from OFAC before the cardiac equipment, items subject to both the

Regulations[5] and the Iranian Transactions Regulations, could be exported from the United States to Iran. No OFAC authorization was obtained for the shipment of these items to Iran. In furtherance of the conspiracy, EPMed and its co-conspirators devised and arranged a transshipment network scheme under which EPMed would sell the items through a distributor in Germany, which would then forward the items to Iran. On one occasion, EPMed and its co-conspirators also included EPMed's United Kingdom facility in the transshipment network. The purpose of devising and arranging this scheme was to export cardiac equipment to Iran in violation of the Regulations. In engaging in this activity, EPMed committed one violation of Section 764.2(d) of the Regulations.

**Charge 18** **15 C.F.R. § 764.2(d) -- Conspiracy to Export Items from the United States to Iran without the Required Licenses**

On or about September 2003, EPMed conspired and acted in concert with others, known and unknown, to bring about an act that constitutes a violation of the Regulations by agreeing to export cardiac equipment from the United States to Iran without the required U.S. Government authorization. Pursuant to Section 746.7 of the Regulations, authorization was required from OFAC before the cardiac equipment, items subject to both the Regulations[6] and the Iranian Transactions Regulations, could be exported from the United States to Iran. No OFAC authorization was obtained for the shipment of these items to Iran. In furtherance of the conspiracy, EPMed and its co-conspirators devised and arranged a transshipment network scheme under which EPMed would sell the items through a distributor in the United Kingdom, which would then forward the items to Iran. The purpose of devising and arranging this scheme was to export cardiac equipment to Iran in violation of the Regulations. In engaging in this activity, EPMed committed one violation of Section 764.2(d) of the Regulations.

**Charges 19-20** **15 C.F.R. § 764.2(g) - False Statements to U.S. Government Officials**

On two occasions, on or about October 13, 2003, EPMed made a false or misleading representation, statement, or certification to BIS in the course of an action subject to the Regulations. These false or misleading representations, statements, or certifications were made to BIS's Office of Export Enforcement ("OEE") in a preliminary voluntary self-disclosure filed pursuant to Section 764.5 of the Regulations by EPMed. The accuracy of the representations, statements, or certifications contained therein was certified to by EPMed's then-President and Chief Executive Officer, Reinhard Schmidt.

In its disclosure, EPMed stated that, prior to on or about October 2, 2003, the company "had no record of ever having sold any of its products to any customer in Iran, either directly or indirectly." This statement, representation, or certification is false or misleading because before

[5] These items were classified as EAR99.

[6] These items were classified as EAR99.

October 2, 2003, numerous EPMed officials including EPMed's Chief Executive Officer, Chief Financial Officer, Vice President of Engineering and Operations, and Director of Operations were aware that an EPMed system was located in Iran. Moreover, EPMed's Chief Executive Officer was aware that EPMed had made sales to Iran. In addition, at the time of its representation, statement, or certification, EPMed had in its possession a number of documents indicating that the company had sold its products to Iran. These documents include an e-mail between EPMed officials dated on or about May 22, 2003, which listed five Iranian hospitals that were operating EPMed equipment.

EPMed also stated in its disclosure that "[i]n the investigation that was immediately initiated, the Company determined that a total of five of its products (three Workmate® 24-channel heart monitors and two Workmate® 56-channel heart monitors), including the one that triggered this inquiry, apparently were sold to end-users in Iran . . . ." This statement, representation, or certification is false or misleading because EPMed did not initiate an investigation immediately after learning of sales to Iran, as the company knew before October 2, 2003 that sales to Iran had occurred. In addition, EPMed was aware at the time of its representation, statement, or certification that six Workmate systems had been exported to Iran and that other exports to Iran of components had also occurred.

Pursuant to Section 764.5(c)(5) of the Regulations, false statements provided to OEE in connection with voluntary self-disclosures are violations of Section 764.2(g) of the Regulations. In engaging in this activity, EPMed committed two violations of Section 764.2(g) of the Regulations.

**Charges 21-23 15 C.F.R. § 764.2(g) - False Statements to U.S. Government Officials**

On three occasions, on or about November 20, 2003, EPMed made a false or misleading representation, statement, or certification to BIS in the course of an action subject to the Regulations. These false or misleading representations, statements, or certifications were made to OEE in a voluntary self-disclosure filed pursuant to Section 764.5 of the Regulations by EPMed. The accuracy of the representations, statements, or certifications contained therein was certified to by EPMed's then-President and Chief Executive Officer, Reinhard Schmidt.

In its disclosure, EPMed stated that it "has no record of ever having sold any of its products to any customer in Iran." This statement, representation, or certification is false or misleading because, at the time it was made, EPMed had in its possession a number of documents indicating that the company had sold its products to Iran. These documents include an e-mail between EPMed officials dated on or about May 22, 2003, which listed five Iranian hospitals that were operating EPMed equipment.

EPMed also stated in its disclosure that "[i]n the investigation that was immediately initiated, the Company determined that a total of five of its products (three Workmate® 24-channel heart

monitors and two Workmate® 56-channel heart monitors), including the one that triggered this inquiry, apparently were re-exported to European distributors to another distributor in Iran who in turn sold them to hospitals in Iran . . . ." This statement, representation, or certification is false or misleading because EPMed did not initiate an investigation immediately after learning of sales to Iran, as the company knew before October 2, 2003 that sales to Iran had occurred. In addition, EPMed was aware at the time of its representation, statement, or certification that six Workmate systems had been exported to Iran and that other exports to Iran of components had also occurred.

EPMed further stated in its disclosure that its European Sales Manager was "totally unfamiliar with U.S. Government restrictions on exports to Iran" and that "he had no cause to consider whether his facilitation of sales of the Company's products to [a German distributor] for re-export to Iran was permissible." This statement, representation, or certification is false or misleading because EPMed's European Sales Manager had been informed of the U.S. embargo of Iran and knew that certain equipment required a license for export to Iran.

Pursuant to Section 764.5(c)(5) of the Regulations, false statements provided to the Office of Export Enforcement in connection with voluntary self-disclosures are violations of Section 764.2(g) of the Regulations. In engaging in this activity, EPMed committed three violations of Section 764.2(g) of the Regulations.

* * * * *

Accordingly, EPMed is hereby notified that an administrative proceeding is instituted against it pursuant to Section 13(c) of the Act and Part 766 of the Regulations for the purpose of obtaining an order imposing administrative sanctions, including any or all of the following:

- The maximum civil penalty allowed by law of $11,000 per violation;[7]
- Denial of export privileges; and/or
- Exclusion from practice before BIS.

If EPMed fails to answer the charges contained in this letter within 30 days after being served with notice of issuance of this letter, that failure will be treated as a default. *See* 15 C.F.R. §§ 766.6 and 766.7. If EPMed defaults, the Administrative Law Judge may find the charges alleged in this letter are true without a hearing or further notice to EPMed. The Under Secretary of Commerce for Industry and Security may then impose up to the maximum penalty on each of the charges in this letter.

[7] *See* 15 C.F.R. § 6.4(a)(4) (2000-2004).

EPMed is further notified that it is entitled to an agency hearing on the record if it files a written demand for one with its answer. *See* 15 C.F.R. § 766.6. EPMed is also entitled to be represented by counsel or other authorized representative who has power of attorney to represent it. *See* 15 C.F.R. §§ 766.3(a) and 766.4.

The Regulations provide for settlement without a hearing. *See* 15 C.F.R. § 766.18. Should EPMed have a proposal to settle this case, EPMed or its representative should transmit it to the attorney representing BIS named below.

The U.S. Coast Guard is providing administrative law judge services in connection with the matters set forth in this letter. Accordingly, EPMed's answer must be filed in accordance with the instructions in Section 766.5(a) of the Regulations with:

U.S. Coast Guard ALJ Docketing Center
40 S. Gay Street
Baltimore, Maryland 21202-4022

In addition, a copy of EPMed's answer must be served on BIS at the following address:

Office of Chief Counsel for Industry and Security
Attention: Thea D. R. Kendler, Esq.
Room H-3839
United States Department of Commerce
14th Street and Constitution Avenue, N.W.
Washington, D.C. 20230

Thea D. R. Kendler is the attorney representing BIS in this case; any communications that EPMed may wish to have concerning this matter should occur through her. Ms. Kendler may be contacted by telephone at 202-482-5301.

Sincerely,

Michael D. Turner
Director
Office of Export Enforcement

| Charges | Invoice Date(s) | U.S. Export Date | Date of Shipment to Iran | Items Shipped | Intermediate Destination | Ultimate Destination | Approx. Value |
|---|---|---|---|---|---|---|---|
| 1, 5, 9 | 13-Mar-01 | 9-Mar-01 | 14-Mar-01 | (1) Workmate 24<br>(2) Workmate 56 | Germany | Iran | $300,000 |
| 2, 6 , 10 | 28-Feb-02 | 28-Mar-02 | 4-Apr-02 | (1) Workmate 24 | Germany | Iran | $48,000 |
| 3, 7, 11 | 28-Sep-03 | 30-Sep-03 | | (1) Workmate 56 | United Kingdom | Iran | $47,000 |
| 4, 8, 12 | 17-Nov-03<br>24-Jun-03 | 17-Nov-03 | 7-Jan-04 | (1) Workmate 56 | Germany | Iran | $115,000 |
| 13, 15 | 11-Oct-00<br>19-Oct-00 | 11-Oct-00 | | (2) Assy, Catheter Interface, EPT Basket | The Netherlands | Iran | $545 |
| 14, 16 | 21-Apr-04 | 27-Apr-04 | | (1) Cine Capture Card | The Netherlands | Iran | $50 |

UNITED STATES DEPARTMENT OF COMMERCE
BUREAU OF INDUSTRY AND SECURITY
WASHINGTON, D.C. 20230

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| In the Matter of: | ) |
| | ) |
| EPMedSystems, Inc. | ) |
| Cooper Run Executive Park | ) |
| 575 Route 73 North, Building D | ) |
| West Berlin, New Jersey 08091 | ) |
| | ) |
| Respondent | ) |

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is made by and between EPMedSystems, Inc. ("EPMed"), and the Bureau of Industry and Security, U.S. Department of Commerce ("BIS") (collectively, the "Parties"), pursuant to Section 766.18(a) of the Export Administration Regulations (currently codified at 15 C.F.R. Parts 730-774 (2006)) (the "Regulations"),[1] issued pursuant to the Export Administration Act of 1979, as amended (50 U.S.C. app. §§ 2401-2420 (2000)) (the "Act"),[2]

[1] The violations alleged to have been committed occurred during 1999, 2000, 2001, 2002, 2003, and 2004. The Regulations governing the violations at issue are found in the 1999, 2000, 2001, 2002, 2003, and 2004 versions of the Code of Federal Regulations (15 C.F.R. Parts 730-774). The 2006 Regulations establish the procedures that apply to this matter.

[2] From August 21, 1994 through November 12, 2000, the Act was in lapse. During that period, the President, through Executive Order 12924, which was extended by successive Presidential Notices, the last of which was August 3, 2000 (3 C.F.R., 2000 Comp. 397 (2001)), continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. §§ 1701 - 1706 (2000)) ("IEEPA"). On November 13, 2000, the Act was reauthorized by Pub. L. No. 106-508 (114 Stat. 2360 (2000)) and it remained in effect through August 20, 2001. Since August 21, 2001, Executive Order 13222 of August 17, 2001 (3 C.F.R., 2001 Comp. 783 (2002)), which has been extended by successive Presidential Notices, the most recent being that of August 3, 2006 (71 Fed. Reg. 44,551 (Aug. 7, 2006)), has continued the Regulations in effect under IEEPA.

WHEREAS, BIS has notified EPMed of its intention to initiate an administrative proceeding against EPMed, pursuant to the Act and the Regulations;

WHEREAS, BIS has issued a proposed charging letter to EPMed that alleged that EPMed committed 23 violations of the Regulations, specifically:

**Charges 1-4 15 C.F.R. § 764.2(a) -- Export to Iran without the Required U.S. Government Authorization**

On four occasions, between on or about March 13, 2001 and on or about January 7, 2004, EPMed engaged in conduct prohibited by the Regulations by exporting cardiac equipment, which is subject to the Regulations[3] and to the Iranian Transactions Regulations of the Treasury Department's Office of Foreign Assets Control ("OFAC"),[4] to an end-user in Iran without the required U.S. Government authorization. Specifically, EPMed exported Workmate heart monitor systems through Germany, the Netherlands, and the United Kingdom to Iran. Pursuant to Section 560.204 of the Iranian Transactions Regulations, an export to a third country intended for transshipment to Iran is a transaction subject to the Iranian Transactions Regulations that requires OFAC authorization. Pursuant to Section 746.7 of the Regulations, no person may export items subject to both the Regulations and the Iranian Transactions Regulations without authorization from OFAC. EPMed knew or had reason to know that the items were destined for Iran, and no OFAC authorization was obtained for the exports. In engaging in this activity, EPMed committed four violations of Section 764.2(a) of the Regulations.

**Charges 5-8 15 C.F.R. § 764.2(e) -- Acting with Knowledge of a Violation**

On four occasions, between on or about March 9, 2001 and on or about January 7, 2004, in connection with Charges 1-4, above, EPMed violated the Regulations by selling and/or transferring items to be exported from the United States with knowledge that a violation of the Regulations was occurring in connection with the items. Specifically, EPMed sold and/or transferred the items described above, which were subject to the Regulations and the Iranian Transactions Regulations, with knowledge or reason to know that licenses were required for such exports and that no licenses had been obtained. EPMed knew or had reason to know that it was violating the Regulations because EPMed's officers and/or agents knew or had reason to know, prior to these actions, of the U.S. Government's embargo on exports to Iran. In addition, on or about September 27, 2000, before the exports occurred, EPMed submitted a license application to OFAC in an attempt to gain authorization for export of certain items to Iran. This license application was subsequently withdrawn by EPMed. In engaging in this activity, EPMed committed four violations of Section 764.2(e) of the Regulations.

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[3] These items were classified as EAR99.

[4] *See* 31 C.F.R. § 560.204.

**Charges 9-12** **15 C.F.R. § 764.2(h) – Acting to Evade the Requirements of the Regulations**

On four occasions between on or about March 9, 2001 and on or about January 7, 2004, in connection with Charges 1-4, above, EPMed violated the Regulations by engaging in a transaction or taking other action with intent to evade the provisions of the Regulations. Specifically, EPMed engaged in selling the items described above to Iran through transshipment networks consisting of its European facilities and European distributors. EPMed's selling of these items through its transshipment networks was accomplished for the purpose of concealing the fact that EPMed was selling items to Iran. In engaging in this activity, EPMed committed four violations of Section 764.2(h) of the Regulations.

**Charges 13-14** **15 C.F.R. § 764.2(a) – Reexport to Iran without the Required U.S. Government Authorization**

On two occasions, between on or about October 11, 2000 and on or about April 27, 2004, EPMed engaged in conduct prohibited by the Regulations by reexporting cardiac equipment components and replacement parts, which were subject to the Regulations and to the Iranian Transactions Regulations of OFAC, to Iran without the required U.S. Government authorization. Specifically, EPMed's European facilities reexported these components and parts from the Netherlands to Iran. Pursuant to Section 560.204 of the Iranian Transactions Regulations, a reexport by a U.S. person from a third country to Iran is a transaction subject to the Iranian Transactions Regulations that requires OFAC authorization. Pursuant to Section 746.7 of the Regulations, no person may reexport items subject to both the Regulations and the Iranian Transactions Regulations without authorization from OFAC. EPMed, a U.S. person, knew or had reason to know that the items were destined for Iran, and no OFAC authorization was obtained for the exports. In engaging in this activity, EPMed committed two violations of Section 764.2(a) of the Regulations.

**Charges 15-16** **15 C.F.R. § 764.2(e) -- Acting with Knowledge of a Violation**

On two occasions, between on or about October 11, 2000 and on or about April 27, 2004, in connection with Charges 13-14, above, EPMed violated the Regulations by selling and/or transferring items exported from the United States with knowledge that a violation of the Regulations was occurring in connection with the items. Specifically, EPMed sold and/or transferred the items described above, which were subject to the Regulations and the Iranian Transactions Regulations, with knowledge or reason to know that licenses were required for such reexports and that no licenses had been obtained. EPMed knew or had reason to know that it was violating the Regulations because EPMed's officers and/or agents knew or had reason to know, prior to these actions, of the U.S. Government's embargo on exports to Iran. In addition, on or about September 27, 2000, before the reexports occurred, EPMed submitted a license application to OFAC in an attempt to gain authorization for export of certain items to Iran. This license application was

subsequently withdrawn by EPMed. In engaging in this activity, EPMed committed two violations of Section 764.2(e) of the Regulations.

**Charge 17** **15 C.F.R. § 764.2(d) -- Conspiracy to Export Items from the United States to Iran without the Required Licenses**

Between on or about March 2001 through on or about January 2004, EPMed conspired and acted in concert with others, known and unknown, to bring about an act that constitutes a violation of the Regulations by agreeing to export cardiac equipment from the United States to Iran without the required U.S. Government authorization. Pursuant to Section 746.7 of the Regulations, authorization was required from OFAC before the cardiac equipment, items subject to both the Regulations[5] and the Iranian Transactions Regulations, could be exported from the United States to Iran. No OFAC authorization was obtained for the shipment of these items to Iran. In furtherance of the conspiracy, EPMed and its co-conspirators devised and arranged a transshipment network scheme under which EPMed would sell the items through a distributor in Germany, which would then forward the items to Iran. On one occasion, EPMed and its co-conspirators also included EPMed's United Kingdom facility in the transshipment network. The purpose of devising and arranging this scheme was to export cardiac equipment to Iran in violation of the Regulations. In engaging in this activity, EPMed committed one violation of Section 764.2(d) of the Regulations.

**Charge 18** **15 C.F.R. § 764.2(d) -- Conspiracy to Export Items from the United States to Iran without the Required Licenses**

On or about September 2003, EPMed conspired and acted in concert with others, known and unknown, to bring about an act that constitutes a violation of the Regulations by agreeing to export cardiac equipment from the United States to Iran without the required U.S. Government authorization. Pursuant to Section 746.7 of the Regulations, authorization was required from OFAC before the cardiac equipment, items subject to both the Regulations[6] and the Iranian Transactions Regulations, could be exported from the United States to Iran. No OFAC authorization was obtained for the shipment of these items to Iran. In furtherance of the conspiracy, EPMed and its co-conspirators devised and arranged a transshipment network scheme under which EPMed would sell the items through a distributor in the United Kingdom, which would then forward the items to Iran. The purpose of devising and arranging this scheme was to export cardiac equipment to Iran in violation of the Regulations. In engaging in this activity, EPMed committed one violation of Section 764.2(d) of the Regulations.

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[6] These items were classified as EAR99.

**Charges 19-20** **15 C.F.R. § 764.2(g) - False Statements to U.S. Government Officials**

On two occasions, on or about October 13, 2003, EPMed made a false or misleading representation, statement, or certification to BIS in the course of an action subject to the Regulations. These false or misleading representations, statements, or certifications were made to BIS's Office of Export Enforcement ("OEE") in a preliminary voluntary self-disclosure filed pursuant to Section 764.5 of the Regulations by EPMed. The accuracy of the representations, statements, or certifications contained therein was certified to by EPMed's then-President and Chief Executive Officer, Reinhard Schmidt.

In its disclosure, EPMed stated that, prior to on or about October 2, 2003, the company "had no record of ever having sold any of its products to any customer in Iran, either directly or indirectly." This statement, representation, or certification is false or misleading because before October 2, 2003, numerous EPMed officials including EPMed's Chief Executive Officer, Chief Financial Officer, Vice President of Engineering and Operations, and Director of Operations were aware that an EPMed system was located in Iran. Moreover, EPMed's Chief Executive Officer was aware that EPMed had made sales to Iran. In addition, at the time of its representation, statement, or certification, EPMed had in its possession a number of documents indicating that the company had sold its products to Iran. These documents include an e-mail between EPMed officials dated on or about May 22, 2003, which listed five Iranian hospitals that were operating EPMed equipment.

EPMed also stated in its disclosure that "[i]n the investigation that was immediately initiated, the Company determined that a total of five of its products (three Workmate® 24-channel heart monitors and two Workmate® 56-channel heart monitors), including the one that triggered this inquiry, apparently were sold to end-users in Iran . . . ." This statement, representation, or certification is false or misleading because EPMed did not initiate an investigation immediately after learning of sales to Iran, as the company knew before October 2, 2003 that sales to Iran had occurred. In addition, EPMed was aware at the time of its representation, statement, or certification that six Workmate systems had been exported to Iran and that other exports to Iran of components had also occurred.

Pursuant to Section 764.5(c)(5) of the Regulations, false statements provided to OEE in connection with voluntary self-disclosures are violations of Section 764.2(g) of the Regulations. In engaging in this activity, EPMed committed two violations of Section 764.2(g) of the Regulations.

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Regulations by EPMed. The accuracy of the representations, statements, or certifications contained therein was certified to by EPMed's then-President and Chief Executive Officer, Reinhard Schmidt.

In its disclosure, EPMed stated that it "has no record of ever having sold any of its products to any customer in Iran." This statement, representation, or certification is false or misleading because, at the time it was made, EPMed had in its possession a number of documents indicating that the company had sold its products to Iran. These documents include an e-mail between EPMed officials dated on or about May 22, 2003, which listed five Iranian hospitals that were operating EPMed equipment.

EPMed also stated in its disclosure that "[i]n the investigation that was immediately initiated, the Company determined that a total of five of its products (three Workmate® 24-channel heart monitors and two Workmate® 56-channel heart monitors), including the one that triggered this inquiry, apparently were re-exported to European distributors to another distributor in Iran who in turn sold them to hospitals in Iran . . . ." This statement, representation, or certification is false or misleading because EPMed did not initiate an investigation immediately after learning of sales to Iran, as the company knew before October 2, 2003 that sales to Iran had occurred. In addition, EPMed was aware at the time of its representation, statement, or certification that six Workmate systems had been exported to Iran and that other exports to Iran of components had also occurred.

EPMed further stated in its disclosure that its European Sales Manager was "totally unfamiliar with U.S. Government restrictions on exports to Iran" and that "he had no cause to consider whether his facilitation of sales of the Company's products to [a German distributor] for re-export to Iran was permissible." This statement, representation, or certification is false or misleading because EPMed's European Sales Manager had been informed of the U.S. embargo of Iran and knew that certain equipment required a license for export to Iran.

Pursuant to Section 764.5(c)(5) of the Regulations, false statements provided to the Office of Export Enforcement in connection with voluntary self-disclosures are violations of Section 764.2(g) of the Regulations. In engaging in this activity, EPMed committed three violations of Section 764.2(g) of the Regulations.

WHEREAS, EPMed has reviewed the proposed charging letter and is aware of the allegations made against it and the administrative sanctions which could be imposed against it if the allegations are found to be true;

WHEREAS, EPMed fully understands the terms of this Agreement and the Order ("Order") that the Assistant Secretary of Commerce for Export Enforcement will issue if he approves this Agreement as the final resolution of this matter;

WHEREAS, EPMed enters into this Agreement voluntarily and with full knowledge of its rights;

WHEREAS, EPMed states that no promises or representations have been made to it other than the agreements and considerations herein expressed;

WHEREAS, EPMed neither admits nor denies the allegations contained in the proposed charging letter;

WHEREAS, EPMed wishes to settle and dispose of all matters alleged in the proposed charging letter by entering into this Agreement; and

WHEREAS, EPMed agrees to be bound by the Order, if entered;

NOW THEREFORE, the Parties hereby agree as follows:

1. BIS has jurisdiction over EPMed, under the Regulations, in connection with the matters alleged in the proposed charging letter.

2. The following sanction shall be imposed against EPMed in complete settlement of the alleged violations of the Regulations relating to the transactions specifically detailed in the proposed charging letter:

a. With respect to Charges 1-18, specified above, EPMed shall be assessed a civil penalty in the amount of $189,000, and with respect to Charges 19-23, specified above, EPMed shall be assessed a civil penalty in the amount of $55,000, for a total civil penalty of $244,000, all of which shall be paid to the U.S. Department of Commerce within 30 days from the date of entry of the Order.

b. The timely payment of the civil penalty agreed to in paragraph 2.a is hereby made a condition to the granting, restoration, or continuing validity of any export license, permission, or privilege granted, or to be granted, to EPMed.

Failure to make timely payment of the civil penalty set forth above may result in the denial of all of EPMed's export privileges for a period of one year from the date of imposition of the penalty.

3. Subject to the approval of this Agreement pursuant to paragraph 8 hereof, EPMed hereby waives all rights to further procedural steps in this matter (except with respect to any alleged violations of this Agreement or the Order, if entered), including, without limitation, any right to: (a) an administrative hearing regarding the allegations in any charging letter; (b) request a refund of any civil penalty paid pursuant to this Agreement and the Order, if entered; (c) request any relief from the Order, if entered, including without limitation relief from the terms of a denial order under 15 C.F.R. § 764.3(a)(2); and (d) seek judicial review or otherwise contest the validity of this Agreement or the Order, if entered.

4. Upon entry of the Order and timely payment of the $244,000 civil penalty, BIS will not initiate any further administrative proceeding against EPMed in connection with any violation of the Act or the Regulations arising out of the transactions identified in the proposed charging letter and voluntary self-disclosure.

5. BIS will make the proposed charging letter, this Agreement, and the Order, if entered, available to the public.

6. This Agreement is for settlement purposes only. Therefore, if this Agreement is not accepted and the Order is not issued by the Assistant Secretary of Commerce for Export Enforcement pursuant to Section 766.18(a) of the Regulations, no Party may use this Agreement in any administrative or judicial proceeding and the Parties

shall not be bound by the terms contained in this Agreement in any subsequent administrative or judicial proceeding.

7. No agreement, understanding, representation or interpretation not contained in this Agreement may be used to vary or otherwise affect the terms of this Agreement or the Order, if entered, nor shall this Agreement serve to bind, constrain, or otherwise limit any action by any other agency or department of the U.S. Government with respect to the facts and circumstances addressed herein.

8. This Agreement shall become binding on the Parties only if the Assistant Secretary of Commerce for Export Enforcement approves it by entering the Order, which will have the same force and effect as a decision and order issued after a full administrative hearing on the record.

9. Each signatory affirms that he has authority to enter into this Settlement Agreement and to bind his respective party to the terms and conditions set forth herein.

BUREAU OF INDUSTRY AND SECURITY
U.S. DEPARTMENT OF COMMERCE

Michael D. Turner
Director
Office of Export Enforcement

Date: 11/1/06

EPMEDSYSTEMS, INC.

David Bruce
Chief Executive Officer

Date: 10/26/06

UNITED STATES DEPARTMENT OF COMMERCE
BUREAU OF INDUSTRY AND SECURITY
WASHINGTON, D.C. 20230

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| In the Matter of: | ) |
| | ) |
| EPMedSystems, Inc. | ) |
| Cooper Run Executive Park | ) |
| 575 Route 73 North, Building D | ) |
| West Berlin, New Jersey 08091 | ) |
| | ) |
| Respondent | ) |

ORDER RELATING TO EPMEDSYSTEMS, INC.

The Bureau of Industry and Security, U.S. Department of Commerce ("BIS") has notified EPMedSystems, Inc. ("EPMed"), of its intention to initiate an administrative proceeding against EPMed pursuant to Section 766.3 of the Export Administration Regulations (currently codified at 15 C.F.R. Parts 730-774 (2006)) (the "Regulations"),[1] and Section 13(c) of the Export Administration Act of 1979, as amended (50 U.S.C. app. §§ 2401-2420 (2000)) (the "Act"),[2] through issuance of a proposed charging letter to EPMed that alleged that EPMed committed 23 violations of the Regulations. Specifically, these charges are:

[1] The violations alleged to have been committed occurred during 1999, 2000, 2001, 2002, 2003, and 2004. The Regulations governing the violations at issue are found in the 1999, 2000, 2001, 2002, 2003, and 2004 versions of the Code of Federal Regulations (15 C.F.R. Parts 730-774). The 2006 Regulations establish the procedures that apply to this matter.

[2] From August 21, 1994 through November 12, 2000, the Act was in lapse. During that period, the President, through Executive Order 12924, which was extended by successive Presidential Notices, the last of which was August 3, 2000 (3 C.F.R., 2000 Comp. 397 (2001)), continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. §§ 1701 - 1706 (2000)) ("IEEPA"). On November 13, 2000, the Act was reauthorized by Pub. L. No. 106-508 (114 Stat. 2360 (2000)) and it remained in effect through August 20, 2001. Since August 21, 2001, Executive Order 13222 of August 17, 2001 (3 C.F.R., 2001 Comp. 783 (2002)), which has been extended by successive Presidential Notices, the most recent being that of August 3, 2006 (71 Fed. Reg. 44,551 (Aug. 7, 2006)), has continued the Regulations in effect under IEEPA.

**Charges 1-4** **15 C.F.R. § 764.2(a) -- Export to Iran without the Required U.S. Government Authorization**

On four occasions, between on or about March 13, 2001 and on or about January 7, 2004, EPMed engaged in conduct prohibited by the Regulations by exporting cardiac equipment, which is subject to the Regulations[3] and to the Iranian Transactions Regulations of the Treasury Department's Office of Foreign Assets Control ("OFAC"),[4] to an end-user in Iran without the required U.S. Government authorization. Specifically, EPMed exported Workmate heart monitor systems through Germany, the Netherlands, and the United Kingdom to Iran. Pursuant to Section 560.204 of the Iranian Transactions Regulations, an export to a third country intended for transshipment to Iran is a transaction subject to the Iranian Transactions Regulations that requires OFAC authorization. Pursuant to Section 746.7 of the Regulations, no person may export items subject to both the Regulations and the Iranian Transactions Regulations without authorization from OFAC. EPMed knew or had reason to know that the items were destined for Iran, and no OFAC authorization was obtained for the exports. In engaging in this activity, EPMed committed four violations of Section 764.2(a) of the Regulations.

**Charges 5-8** **15 C.F.R. § 764.2(e) -- Acting with Knowledge of a Violation**

On four occasions, between on or about March 9, 2001 and on or about January 7, 2004, in connection with Charges 1-4, above, EPMed violated the Regulations by selling and/or transferring items to be exported from the United States with knowledge that a violation of the Regulations was occurring in connection with the items. Specifically, EPMed sold and/or transferred the items described above, which were subject to the Regulations and the Iranian Transactions Regulations, with knowledge or reason to know that licenses were required for such exports and that no licenses had been obtained. EPMed knew or had reason to know that it was violating the Regulations because EPMed's officers and/or agents knew or had reason to know, prior to these actions, of the U.S. Government's embargo on exports to Iran. In addition, on or about September 27, 2000, before the exports occurred, EPMed submitted a license application to OFAC in an attempt to gain authorization for export of certain items to Iran. This license application was subsequently withdrawn by EPMed. In engaging in this activity, EPMed committed four violations of Section 764.2(e) of the Regulations.

**Charges 9-12** **15 C.F.R. § 764.2(h) – Acting to Evade the Requirements of the Regulations**

On four occasions between on or about March 9, 2001 and on or about January 7, 2004, in connection with Charges 1-4, above, EPMed violated the Regulations by engaging in a transaction or taking other action with intent to evade the provisions of the Regulations. Specifically, EPMed engaged in selling the items described above to Iran through

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[3] These items were classified as EAR99.

[4] *See* 31 C.F.R. § 560.204.

transshipment networks consisting of its European facilities and European distributors. EPMed's selling of these items through its transshipment networks was accomplished for the purpose of concealing the fact that EPMed was selling items to Iran. In engaging in this activity, EPMed committed four violations of Section 764.2(h) of the Regulations.

**Charges 13-14** **15 C.F.R. § 764.2(a) – Reexport to Iran without the Required U.S. Government Authorization**

On two occasions, between on or about October 11, 2000 and on or about April 27, 2004, EPMed engaged in conduct prohibited by the Regulations by reexporting cardiac equipment components and replacement parts, which were subject to the Regulations and to the Iranian Transactions Regulations of OFAC, to Iran without the required U.S. Government authorization. Specifically, EPMed's European facilities reexported these components and parts from the Netherlands to Iran. Pursuant to Section 560.204 of the Iranian Transactions Regulations, a reexport by a U.S. person from a third country to Iran is a transaction subject to the Iranian Transactions Regulations that requires OFAC authorization. Pursuant to Section 746.7 of the Regulations, no person may reexport items subject to both the Regulations and the Iranian Transactions Regulations without authorization from OFAC. EPMed, a U.S. person, knew or had reason to know that the items were destined for Iran, and no OFAC authorization was obtained for the exports. In engaging in this activity, EPMed committed two violations of Section 764.2(a) of the Regulations.

**Charges 15-16** **15 C.F.R. § 764.2(e) -- Acting with Knowledge of a Violation**

On two occasions, between on or about October 11, 2000 and on or about April 27, 2004, in connection with Charges 13-14, above, EPMed violated the Regulations by selling and/or transferring items exported from the United States with knowledge that a violation of the Regulations was occurring in connection with the items. Specifically, EPMed sold and/or transferred the items described above, which were subject to the Regulations and the Iranian Transactions Regulations, with knowledge or reason to know that licenses were required for such reexports and that no licenses had been obtained. EPMed knew or had reason to know that it was violating the Regulations because EPMed's officers and/or agents knew or had reason to know, prior to these actions, of the U.S. Government's embargo on exports to Iran. In addition, on or about September 27, 2000, before the reexports occurred, EPMed submitted a license application to OFAC in an attempt to gain authorization for export of certain items to Iran. This license application was subsequently withdrawn by EPMed. In engaging in this activity, EPMed committed two violations of Section 764.2(e) of the Regulations.

**Charge 17** **15 C.F.R. § 764.2(d) -- Conspiracy to Export Items from the United States to Iran without the Required Licenses**

Between on or about March 2001 through on or about January 2004, EPMed conspired and acted in concert with others, known and unknown, to bring about an act that constitutes a violation of the Regulations by agreeing to export cardiac equipment from

the United States to Iran without the required U.S. Government authorization. Pursuant to Section 746.7 of the Regulations, authorization was required from OFAC before the cardiac equipment, items subject to both the Regulations[5] and the Iranian Transactions Regulations, could be exported from the United States to Iran. No OFAC authorization was obtained for the shipment of these items to Iran. In furtherance of the conspiracy, EPMed and its co-conspirators devised and arranged a transshipment network scheme under which EPMed would sell the items through a distributor in Germany, which would then forward the items to Iran. On one occasion, EPMed and its co-conspirators also included EPMed's United Kingdom facility in the transshipment network. The purpose of devising and arranging this scheme was to export cardiac equipment to Iran in violation of the Regulations. In engaging in this activity, EPMed committed one violation of Section 764.2(d) of the Regulations.

**Charge 18** **15 C.F.R. § 764.2(d) -- Conspiracy to Export Items from the United States to Iran without the Required Licenses**

On or about September 2003, EPMed conspired and acted in concert with others, known and unknown, to bring about an act that constitutes a violation of the Regulations by agreeing to export cardiac equipment from the United States to Iran without the required U.S. Government authorization. Pursuant to Section 746.7 of the Regulations, authorization was required from OFAC before the cardiac equipment, items subject to both the Regulations[6] and the Iranian Transactions Regulations, could be exported from the United States to Iran. No OFAC authorization was obtained for the shipment of these items to Iran. In furtherance of the conspiracy, EPMed and its co-conspirators devised and arranged a transshipment network scheme under which EPMed would sell the items through a distributor in the United Kingdom, which would then forward the items to Iran. The purpose of devising and arranging this scheme was to export cardiac equipment to Iran in violation of the Regulations. In engaging in this activity, EPMed committed one violation of Section 764.2(d) of the Regulations.

**Charges 19-20** **15 C.F.R. § 764.2(g) - False Statements to U.S. Government Officials**

On two occasions, on or about October 13, 2003, EPMed made a false or misleading representation, statement, or certification to BIS in the course of an action subject to the Regulations. These false or misleading representations, statements, or certifications were made to BIS's Office of Export Enforcement ("OEE") in a preliminary voluntary self-disclosure filed pursuant to Section 764.5 of the Regulations by EPMed. The accuracy of the representations, statements, or certifications contained therein was certified to by EPMed's then-President and Chief Executive Officer, Reinhard Schmidt.

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[5] These items were classified as EAR99.

[6] These items were classified as EAR99.

In its disclosure, EPMed stated that, prior to on or about October 2, 2003, the company "had no record of ever having sold any of its products to any customer in Iran, either directly or indirectly." This statement, representation, or certification is false or misleading because before October 2, 2003, numerous EPMed officials including EPMed's Chief Executive Officer, Chief Financial Officer, Vice President of Engineering and Operations, and Director of Operations were aware that an EPMed system was located in Iran. Moreover, EPMed's Chief Executive Officer was aware that EPMed had made sales to Iran. In addition, at the time of its representation, statement, or certification, EPMed had in its possession a number of documents indicating that the company had sold its products to Iran. These documents include an e-mail between EPMed officials dated on or about May 22, 2003, which listed five Iranian hospitals that were operating EPMed equipment.

EPMed also stated in its disclosure that "[i]n the investigation that was immediately initiated, the Company determined that a total of five of its products (three Workmate® 24-channel heart monitors and two Workmate® 56-channel heart monitors), including the one that triggered this inquiry, apparently were sold to end-users in Iran . . . ." This statement, representation, or certification is false or misleading because EPMed did not initiate an investigation immediately after learning of sales to Iran, as the company knew before October 2, 2003 that sales to Iran had occurred. In addition, EPMed was aware at the time of its representation, statement, or certification that six Workmate systems had been exported to Iran and that other exports to Iran of components had also occurred.

Pursuant to Section 764.5(c)(5) of the Regulations, false statements provided to OEE in connection with voluntary self-disclosures are violations of Section 764.2(g) of the Regulations. In engaging in this activity, EPMed committed two violations of Section 764.2(g) of the Regulations.

**Charges 21-23** **15 C.F.R. § 764.2(g) - False Statements to U.S. Government Officials**

On three occasions, on or about November 20, 2003, EPMed made a false or misleading representation, statement, or certification to BIS in the course of an action subject to the Regulations. These false or misleading representations, statements, or certifications were made to OEE in a voluntary self-disclosure filed pursuant to Section 764.5 of the Regulations by EPMed. The accuracy of the representations, statements, or certifications contained therein was certified to by EPMed's then-President and Chief Executive Officer, Reinhard Schmidt.

In its disclosure, EPMed stated that it "has no record of ever having sold any of its products to any customer in Iran." This statement, representation, or certification is false or misleading because, at the time it was made, EPMed had in its possession a number of documents indicating that the company had sold its products to Iran. These documents include an e-mail between EPMed officials dated on or about May 22, 2003, which listed five Iranian hospitals that were operating EPMed equipment.

EPMed also stated in its disclosure that "[i]n the investigation that was immediately initiated, the Company determined that a total of five of its products (three Workmate® 24-channel heart monitors and two Workmate® 56-channel heart monitors), including the one that triggered this inquiry, apparently were re-exported to European distributors to another distributor in Iran who in turn sold them to hospitals in Iran . . . ." This statement, representation, or certification is false or misleading because EPMed did not initiate an investigation immediately after learning of sales to Iran, as the company knew before October 2, 2003 that sales to Iran had occurred. In addition, EPMed was aware at the time of its representation, statement, or certification that six Workmate systems had been exported to Iran and that other exports to Iran of components had also occurred.

EPMed further stated in its disclosure that its European Sales Manager was "totally unfamiliar with U.S. Government restrictions on exports to Iran" and that "he had no cause to consider whether his facilitation of sales of the Company's products to [a German distributor] for re-export to Iran was permissible." This statement, representation, or certification is false or misleading because EPMed's European Sales Manager had been informed of the U.S. embargo of Iran and knew that certain equipment required a license for export to Iran.

Pursuant to Section 764.5(c)(5) of the Regulations, false statements provided to the Office of Export Enforcement in connection with voluntary self-disclosures are violations of Section 764.2(g) of the Regulations. In engaging in this activity, EPMed committed three violations of Section 764.2(g) of the Regulations.

WHEREAS, BIS and EPMed have entered into a Settlement Agreement pursuant to Section 766.18(a) of the Regulations whereby they agreed to settle this matter in accordance with the terms and conditions set forth therein, and

WHEREAS, I have approved of the terms of such Settlement Agreement;

IT IS THEREFORE ORDERED:

FIRST, that a civil penalty of $244,000 is assessed against EPMed, which shall be paid to the U.S. Department of Commerce within 30 days from the date of entry of this Order. Payment shall be made in the manner specified in the attached instructions.

SECOND, that, pursuant to the Debt Collection Act of 1982, as amended (31 U.S.C. §§ 3701-3720E (2000)), the civil penalty owed under this Order accrues interest as more fully described in the attached Notice, and, if payment is not made by the due date specified herein, EPMed will be assessed, in addition to the full amount of the civil

penalty and interest, a penalty charge and an administrative charge, as more fully described in the attached Notice.

THIRD, that the timely payment of the civil penalty set forth above is hereby made a condition to the granting, restoration, or continuing validity of any export license, license exception, permission, or privilege granted, or to be granted, to EPMed. Accordingly, if EPMed should fail to pay the civil penalty in a timely manner, the undersigned may enter an Order denying all of EPMed's export privileges for a period of one year from the date of entry of this Order.

FOURTH, that the proposed charging letter, the Settlement Agreement, and this Order shall be made available to the public.

This Order, which constitutes the final agency action in this matter, is effective immediately.

Darryl W. Jackson
Assistant Secretary of Commerce
for Export Enforcement

Entered this 3rd day of November, 2006.