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UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

UNITED STATES OF AMERICA, Plaintiff, v. ATRIUM MEDICAL CORP., MAQUET HOLDING B.V. & CO. KG, MAQUET CARDIOVASCULAR, LLC, and MAQUET CARDIOPULMONARY AG, corporations, and HEINZ JACQUI, and GAIL CHRISTIE, individuals, Defendants.	)	NO. 15-CV-00041-SM

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction ("Complaint") against Atrium Medical Corp. ("Atrium"), Maquet Holding B.V. & Co. KG ("Maquet"), Maquet Cardiovascular, LLC ("Maquet CV"), and Maquet Cardiopulmonary AG ("Maquet CP"), corporations ("Corporate Defendants"), and Heinz Jacqui, who assumed his position as Chief Executive Officer and Managing Director of Maquet on April 1, 2012, and Gail Christie, who assumed her position as Corporate Chief Quality Assurance/Regulatory Affairs and Compliance Officer of Maquet on October 1, 2013, individuals (collectively "Defendants"), alleging the following:

(1) Defendants violate the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce articles of device, as defined by 21 U.S.C. § 321(h), that are (a) adulterated within the meaning of 21 U.S.C. § 351(h), in that the methods used in, and the facilities and controls used for, their manufacture, packing, storage, and installation are not in conformity with the current good manufacturing practice ("CGMP") requirements for devices, *see* 21 U.S.C. § 360j(f) and 21 C.F.R. Part 820 (the Quality System ("QS") regulation); and (b) misbranded within the meaning of 21 U.S.C. § 352(t)(2), in that Defendants fail to furnish information or material respecting their devices, as set forth in 21 U.S.C. § 360i and the medical device reporting ("MDR") and correction and removals ("CR") regulations, 21 C.F.R. Parts 803 and 806;

(2) Defendants violate the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(k), by doing acts that result in the adulteration, within the meaning of 21 U.S.C. § 351(h), of articles of device, as defined by 21 U.S.C. § 321(h), while such devices are held for sale after the shipment of one or more of their components in interstate commerce; and

(3) Defendants violate the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(e), by failing to maintain and/or submit reports respecting their devices, as required by 21 U.S.C. § 360i; and

Defendants, without admitting or denying the allegations of the Complaint and disclaiming any liability in connection herewith, having appeared and having consented to entry of this Consent Decree of Permanent Injunction ("Decree") without contest and before any testimony has been taken, and the United States of America having consented to this Decree:

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IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action under 21 U.S.C. § 332(a) and 28 U.S.C. § 1345.

2. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c).

3. The Complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*

DEFINITIONS

4. For purposes of this Decree, the following definitions shall apply:

A. "Specified Facilities" are the following facilities:

i. Atrium, 5 Wentworth Dr., Hudson, NH 03051; and

ii. Atrium, 29 Flagstone Dr., Hudson, NH 03051.

B. "Additional Facilities" are the following facilities:

i. Maquet CV, 45 Barbour Pond Dr., Wayne, NJ 07470;

ii. Maquet Medical Systems USA, 45 Barbour Pond Dr., Wayne, NJ 07470;

iii. Maquet CP, Kehler Str. 31, Rastatt, Germany 76437;

iv. Maquet CP, Neue Rottenburger Str. 37, Hechingen, Germany 72379; and

v. Any facility added to this Decree pursuant to paragraphs 8 and 14.

C. "Days" shall refer to calendar days unless otherwise stated.

D. A device is "medically necessary" if:

i. It is used to treat or prevent a disease or medical condition;

ii. . There are not other readily available sources of that product or alternative products judged by FDA to be adequate substitutes; and

iii. An authorized representative of Defendants' U.S. customers or international customers, after reviewing the Notification Guide described in paragraph 4.F, signs an FDA-approved Certificate of Medical Necessity ("CMN") certifying that s/he is aware of FDA's findings and deems the device necessary.

E. A device listed below is deemed to satisfy the requirements of paragraphs 4.D.i and ii and becomes "medically necessary" for a particular U.S. customer or international customer when an authorized representative of that customer has signed a CMN, as described in paragraph 4.D.iii, for such device:

i. ClearWay Rx;

ii. ClearWay OTW;

iii. Express Dry Suction Dry Seal Drains, including accessories;

iv. Ocean Wet Suction Water Seal Drains, including accessories;

v. Oasis Dry Suction Water Seal Drains, including accessories; and

vi. Any other device, component and/or accessory that both FDA and Defendants agree in writing are "medically necessary."

F. "Notification Guide" shall refer to the document developed by Defendants, and reviewed and approved by FDA, that notifies Defendants' U.S. customers and international customers of FDA's findings at each Specified Facility, so that they may make an informed decision concerning whether to use Defendants' devices or to transition to alternative products. The Notification Guide (attached hereto as Exhibit 1 and incorporated by reference herein) must contain, among other information, the CMN referenced in paragraph 4.D.iii.

G. "International Distributor" means an international first-level distributor or other customer that purchases a medically necessary device directly from Defendants.

H. "International End-User" means an international facility, hospital, and any group of clinicians or doctors that purchases a medically necessary device directly or indirectly from an International Distributor.

SPECIFIED FACILITIES

5. Except as provided in paragraphs 6 and 11, Defendants and each and all of their directors, officers, agents, representatives, employees, successors, assigns, and attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise (collectively "Associated Person(s)"), are permanently enjoined under 21 U.S.C. § 332(a) from manufacturing, processing, packing, labeling, and distributing any device, including components parts, accessories, and in-process and finished devices, (hereinafter collectively referred to as "devices") at or from the Specified Facilities unless and until, for each Specified Facility:

A. Defendants' facilities, methods, processes, and controls used to manufacture, process, pack, label, hold, and distribute devices at or from the Specified Facility are established, operated, and administered in conformity with 21 U.S.C. §§ 351(h) and 352(t)(2) (hereinafter collectively referred to as "the Act"), and the QS, CR, and MDR regulations. Specifically, Defendants shall take the following actions, among others:

i. Establish and maintain procedures to control Defendants' devices' designs in order to ensure that specified design requirements are met;

ii. Ensure that all devices meet the requirements for design development and planning, design input, design output, design review, design verification, design validation, design change, design transfer, and design history file;

iii. Conduct design evaluations of all marketed devices to ensure that current designs have been properly validated and transferred into appropriate product specifications;

iv. Validate processes whose results cannot be fully verified by subsequent inspection and testing;

v. Develop, conduct, control, and monitor production processes to ensure that devices conform to their specifications;

vi. Establish and implement adequate written procedures to control devices that do not conform to specified requirements;

vii. Establish and maintain adequate written procedures for corrective and preventive actions ("CAPAs") and for documenting those activities;

viii. Maintain accurate and complete complaint files and establish and implement adequate written procedures for receiving, reviewing, and evaluating complaints; and

ix. Develop and implement adequate written MDR procedures in compliance with 21 C.F.R. Part 803, including, but not limited to, adequate procedures for management review, and ensure that employees are trained on, understand, and properly implement the MDR requirements and procedures;

B. Defendants retain, at Corporate Defendants' expense, an independent person(s) (the "expert") to inspect the Specified Facilities and review their manufacturing procedures and records to determine whether the methods, facilities, and controls are operated

and currently administered in conformity with this Decree, the Act, and the QS, CR, and MDR regulations. The expert shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than the retention agreement) to Defendants or their families. Defendants shall notify FDA in writing of the identity of the expert and the expert's qualifications within fifteen (15) days after retaining such expert. The expert shall:

i. Perform a comprehensive inspection of the methods, processes, and controls used to manufacture devices at each Specified Facility and determine whether each is in compliance with this Decree, the Act, and the QS, CR, and MDR regulations; in conducting this inspection, the expert shall review all deviations at each Specified Facility brought to Defendants' attention in writing by FDA since October 2009 (including, but not limited to, all Forms FDA-483 issued to Defendants since October 2009), by the expert, or by any other source. The expert is permitted to conduct separate inspections for designated categories of the Specified Facilities' devices so long as each inspection includes an evaluation of all of the methods and controls necessary for compliance with the QS regulation for that designated category of devices. If the expert decides to conduct separate inspections for designated categories of the Specified Facilities' devices, Defendants shall submit to FDA a written statement delineating the designated categories of devices. For purposes of complying with this paragraph, Defendants may not include more than a total of five (5) designated categories of devices;

ii. Within thirty (30) days after completing any inspection under paragraph 5.B.i, the expert shall submit simultaneously to FDA and Defendants a complete written report of the inspection, which shall include, but not necessarily be limited to:

a. Identifying in detail which methods, processes, controls, and FDA observations the expert reviewed and the expert's evaluation as to whether each such method, process, and control is now operated in compliance with this Decree, the Act, and the QS, CR, and MDR regulations, and, if applicable, listing any observed deviations from compliance with this Decree, the Act, and the QS, CR, and MDR regulations;

b. Identifying whether each observation listed on a Form FDA-483 issued at the Specified Facility since October 2009 has been corrected.

iii. Notwithstanding the foregoing, if, at any time before the completion of the expert's inspection(s), Defendants notify FDA in writing that all manufacturing operations have ceased at a Specified Facility or that all manufacturing operations with respect to one or more designated categories of the Specified Facilities' devices have ceased at a Specified Facility, any requirement that the expert inspect the methods, facilities, processes, equipment, and controls used to manufacture all or any such designated categories of devices at such Specified Facility shall cease. If, at any time before the completion of the expert's inspection(s), Defendants notify FDA in writing that manufacturing operations for any designated category of devices have been transferred from one Specified Facility to another Specified Facility, the expert must thereafter inspect the methods, facilities, processes, equipment, and controls used to manufacture any such designated category of devices at the transferee Specified Facility; and

C. Within thirty (30) days after receiving the expert's inspection report(s) under paragraph 5.B.ii , Defendants shall submit a written report ("work plan") to FDA detailing the specific actions Defendants have taken and/or will take at the Specified Facility to address the expert's observations and bring the Specified Facility's methods, facilities, processes, and

controls used to manufacture, process, pack, hold, and distribute devices into compliance with the requirements of this Decree, the Act, and the QS, CR, and MDR regulations. The specific actions in the work plan shall be set forth in numbered steps and, where appropriate, the numbered steps may include subordinate lettered steps. The work plan shall include a timetable to be approved by FDA, and FDA will approve or disapprove in writing the proposed work plan within thirty (30) days after receiving the proposed work plan. If the expert conducts separate inspections for designated categories of the Specified Facilities' devices, the Defendants are permitted to submit one addendum per designated category of devices, so long as the work plan and each addendum together detail the specific actions Defendants have taken and/or will take at a Specified Facility to address the expert's observations and bring the methods, facilities, processes, and controls used to manufacture, process, pack, hold, and distribute a designated category of devices into compliance with this Decree, the Act, and the QS, CR, and MDR regulations. In the event that Defendants notify FDA in writing that all manufacturing operations for a designated category of devices have ceased at a Specified Facility, any requirement in the work plan related to such Specified Facility shall cease with regard to such devices. In the event that Defendants notify FDA in writing that manufacturing operations for any designated category of devices have been transferred from one Specified Facility to another Specified Facility, any requirement in the work plan related to the transferor Specified Facility will be deemed to apply to the transferee Specified Facility; and

D. As the actions detailed in the work plan are completed at each Specified Facility, Defendants shall notify the expert in writing, who shall promptly inspect and verify whether those actions have been completed in a manner that complies with the requirements of this Decree, the Act, and the QS, CR, and MDR regulations to the expert's satisfaction and in

accordance with the work plan timetable approved by FDA. The expert is permitted to conduct separate inspections for designated categories of the Specified Facilities' devices so long as each inspection includes an evaluation of all of the methods and controls necessary for compliance with the QS regulation for the designated category of devices. If the expert determines that an action has not been completed to his or her satisfaction, the expert shall promptly notify Defendants and FDA in writing. Beginning thirty (30) days after approval of the work plan by FDA, and quarterly thereafter until submission of a certification set forth in paragraph 5.E, the expert shall submit to FDA a table that summarizes the expert's findings regarding whether the actions have been completed to the expert's satisfaction and in accordance with the numbered steps in the work plan timetable. FDA may, in its discretion and without prior notice, periodically inspect any and all Specified Facilities and undertake such additional examinations, reviews, and analyses as FDA deems appropriate to verify whether the actions reported to have been completed have, in fact, been completed adequately and on time. In the event that FDA determines that an action that has been reported to be completed is inadequate, FDA will notify Defendants in writing, and Defendants shall take appropriate action in accordance with a timetable that is subject to approval by FDA;

E. When the expert determines that all of the actions identified in the work plan approved by FDA have been completed to his or her satisfaction, the expert shall provide Defendants and FDA with a written certification that all of the actions have been completed and that, based on the inspection(s) conducted under paragraph 5 and on the satisfactory completion of the actions in the work plan identified under paragraph 5.C, Defendants' methods, facilities, processes, and controls used to manufacture, process, pack, hold, and distribute devices are in conformity with the requirements of this Decree, the Act, and the QS, CR, and MDR regulations.

The expert's certification shall include a detailed report of the results of the expert's inspection(s). The expert may provide FDA with a separate certification under this paragraph for each Specified Facility. If the expert conducts separate inspections for designated categories of the Specified Facilities' devices, the expert is permitted to submit a separate certification and certification report for each designated category of devices so long as each certification and accompanying report contains all of the information required by this provision for the designated category of devices. In the event the Defendants have notified FDA in writing that all manufacturing operations with regard to a designated category of devices have ceased at a Specified Facility, the expert need not certify as to the completion of work plan actions or as to compliance with this Decree, the Act, and the QS, CR, and MDR regulations that relate to such devices at the Specified Facility. In the event the Defendants have notified FDA in writing that manufacturing operations for any designated category of devices have been transferred from one Specified Facility to another Specified Facility, the expert must certify as to the completion of work plan actions or as to the compliance with this Decree, the Act, and the QS, CR, and MDR regulations that relate to such devices at the transferee Specified Facility;

F. In addition to paragraph 17 and FDA's authority to conduct inspections under 21 U.S.C. § 374, within sixty (60) days after FDA receives a certification described in paragraph 5.E, FDA, as it deems necessary, may inspect any or all of the applicable Specified Facilities to evaluate Defendants' compliance with this Decree, the Act, and its implementing regulations;

G. Corporate Defendants pay all costs of inspections, supervision, and review for FDA oversight with respect to paragraph 5; and

H. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraphs 5.A-G. If FDA conducts an inspection or reinspection pursuant to paragraph 5.F, and finds that the manufacturing, processing, packing, holding, and distribution of devices at and/or from a Specified Facility appear to be in conformity with this Decree, the Act, and the QS, CR, and MDR regulations, this notice will be issued within sixty (60) days after completion of the inspection. If FDA does not conduct an inspection or re-inspection pursuant to paragraph 5.F, this notice will be issued within sixty (60) days after receipt of the expert's certification under paragraph 5.E. If the expert has provided a certification and certification report limited to designated categories of the Specified Facilities' devices or a particular Specified Facility pursuant to paragraph 5.E, then FDA may issue the notification under this paragraph to authorize resumption of manufacturing processing, packing, holding, labeling and/or distribution limited to designated categories of devices or to one or more of the Specified Facilities.

6. A. Notwithstanding paragraph 5, Defendants and all Associated Persons may continue manufacturing, processing, holding, packing, labeling and distributing at or from the Specified Facilities:

i. Medically necessary devices, as defined in paragraph 4.D to customers who have received the Notification Guide described in paragraph 4.F and have submitted a signed CMN to Corporate Defendants, provided that Defendants maintain a record of all sales and distribution of medically necessary devices, including shipping documents and the following information regarding the devices distributed: the name, model number, and lot numbers for the medically necessary devices, the names of the consignees to whom they are shipped, and the

number of devices shipped. Defendants shall make the records described in this paragraph available to FDA immediately upon request. Within ninety (90) days after entry of this Decree, and quarterly thereafter, Defendants shall submit to FDA a summary of the medically necessary devices distributed, which shall include: the names of the medically necessary devices shipped, the names of the consignees to whom they were shipped, and the total number of devices shipped.

ii. Devices for use in product demonstrations, workshops, and laboratories, provided that the subject devices are labeled "For In-Office/In-Facility Demonstration Use Only - Not for Sale";

iii. Devices solely for the purpose of conducting clinical trials in accordance with 21 C.F.R. Part 812, provided that Defendants comply with all applicable laws and regulations relating to the manufacture and distribution of investigational devices;

iv. Devices, including warranty replacements, that both FDA and Defendants agree in writing are necessary to distribute and sell to fulfill contracts and agreements with foreign governments;

v. Devices to testing laboratories solely for the purpose of developing, testing, verifying, or validating design changes or modifications in accordance with 21 C.F.R. Part 820 or comparable international standards; and

vi. Devices that are necessary for the sole purpose of preparing or supporting a premarket approval application (PMA), premarket notification (510k), or supplement thereto, but such products may not be distributed without prior written authorization from FDA.

B. Corporate Defendants shall pay the United States Treasury the amount of six million dollars ($6,000,000.00) in equitable disgorgement, to be paid within twenty-eight (28)

days after entry of this Decree (hereinafter "initial payment"). Six (6) months after the date of the initial payment, Corporate Defendants shall pay the United States Treasury an additional amount of six million dollars ($6,000,000.00) in equitable disgorgement, unless by that date Defendants have received FDA authorization to resume, with regard to all medically necessary devices, all operations at the Specified Facilities as set forth in paragraph 5.H and/or Defendants have transferred all manufacturing, processing, packing, holding, and distribution of all medically necessary devices at and/or from the Specified Facilities to another manufacturing site owned or controlled by Corporate Defendants (hereinafter "new site(s)").

7. Within thirty (30) days after receiving the written notification in paragraph 5.H for a Specified Facility, Defendants shall select and retain at Corporate Defendants' expense an independent person(s) (the "specified facility auditor") to conduct audit inspections of the Specified Facility not less than once every six (6) months for a period of one (1) year, after which the specified facility auditor shall conduct audit inspections annually for an additional period of four (4) years. The specified facility auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than the retention agreement) to Defendants or their families, except that the specified facility auditor may be the same person(s) as the expert described in paragraph 5.B and/or the additional facility auditor described in paragraph 9.

A. At the conclusion of each audit inspection at each such facility, the specified facility auditor shall prepare a written audit report ("audit report") analyzing whether Defendants are in compliance with this Decree, the Act, and the QS, CR, and MDR regulations, and identifying all deviations from this Decree, the Act, and the QS, CR, and MDR regulations ("audit report observations"). As part of every audit report, except the first audit report, the

specified facility auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous audit report observations. The audit report shall be delivered contemporaneously to Defendants and FDA no later than thirty (30) days after the date an audit inspection is completed.

B. If an audit report contains any audit report observations, Defendants shall, within thirty (30) days after receipt of the audit report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving an audit report, Defendants believe that correction of any audit report observations will take longer than thirty (30) days, Defendants shall, within ten (10) business days after receipt of the audit report, propose a schedule for completing corrections ("correction schedule"). The correction schedule shall be reviewed and approved by FDA in writing prior to implementation. Defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) days after being notified that Defendants have taken actions to correct audit report observations, the auditor shall review the actions taken by Defendants to correct the audit report observations. Within fifteen (15) business days after completion of such a review, the specified facility auditor shall report in writing to FDA and to the Defendants whether each of the audit report observations has been corrected.

8. Not less than three months before Defendants transfer any manufacturing operations from any of the Specified Facilities to any new site that Defendants own or control, Defendants shall submit to FDA a written transfer plan. However, in the event Defendants notified FDA before the date of entry of this Decree of a planned transfer of manufacturing operations from any Specified Facility(ies) to any new site(s), Defendants shall submit to FDA a written transfer plan within thirty (30) business days from the date of entry of this Decree. Any

such new site, if not already an Additional Facility, as described in paragraph 4.B, shall thereafter be fully subject to the provisions of this Decree without further action by the parties or this Court, as though it were listed as an Additional Facility in paragraph 4.B, but only to the extent that manufacturing operations have been transferred from a Specified Facility to that new site.

ADDITIONAL FACILITIES

9. Within ninety (90) days after entry of this Decree, Defendants shall select and retain at Corporate Defendants' expense an independent person(s) (the "additional facilities auditor") to conduct audit inspections of each of the Additional Facilities not less than once every twelve (12) months for a period of four (4) years from the date of entry of this Decree, for a total of not less than four audit inspections. The auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than the retention agreement) to Defendants or their families, except that the auditor may be the same person(s) as the expert described in paragraph 5.B and/or the specified facilities auditor described in paragraph 7. The requirements in paragraphs 7.A and B shall apply to all audit inspections conducted under this paragraph.

ADDITIONAL INJUNCTION PROVISION

10. Upon entry of this Decree and except as provided for in paragraphs 6 and 11, Defendants and each and all Associated Persons shall, with regard to any device manufactured at any of the Specified or Additional Facilities, be permanently enjoined from directly or indirectly doing or causing to be done any act that:

A. Violates 21 U.S.C. § 331(a) by doing or causing the introduction, and delivery for introduction, into interstate commerce of any device, as defined by 21 U.S.C.

§ 321(h), that is adulterated within the meaning of 21 U.S.C. § 351(h), or misbranded within the meaning of 21 U.S.C. § 352(t)(2);

B. Violates 21 U.S.C. § 331(k) by doing or causing any act that results in the adulteration, within the meaning of 21 U.S.C. § 351(h), or misbranding, within the meaning of 21 U.S.C. § 352(t)(2), of any device, as defined by 21 U.S.C. § 321(h), while such device is held for sale after the shipment of one or more of its components in interstate commerce; and/or

C. Violates 21 U.S.C. § 331(e) by doing or causing the failure to maintain and/or submit reports respecting devices, as defined by 21 U.S.C. § 321(h), as required by 21 U.S.C. § 360i.

EXCLUSIONS

11. The prohibitions set forth in paragraphs 5 and 10 or in any order issued under paragraphs 13 or 14 shall not apply to any device manufactured, processed, packaged, labeled, held for sale, or introduced into interstate commerce solely for export from the United States, provided that the applicable requirements of 21 U.S.C. §§ 381(e) and/or 382 have been satisfied with respect to such device. Independent of their right to export other devices, Defendants may export any medically necessary device to support their International Distributors, provided that:

(A) Defendants ask their International Distributors to ask their International End-Users to execute a signed CMN;

(B) Defendants exercise their best efforts to ask their International Distributors to confirm that the person signing the CMN form has read the form and is who s/he purports to be;

(C) Defendants document these efforts and provide to FDA, on a quarterly basis for two years, a summary of these efforts; and

(D) Defendants maintain records evidencing compliance with this subparagraph for two years.

ADDITIONAL PROVISIONS

12. Defendants shall establish and document management control over quality policy, as defined in 21 C.F.R. § 820.3(u), at the Specified and Additional Facilities for all devices intended for introduction into interstate commerce, to ensure continuous compliance with this Decree, the Act, and the QS, CR, and MDR regulations. Corporate Defendants shall vest responsibility for all quality system functions, as defined in 21 C.F.R. § 820.3(v), in the Specified and Additional Facilities, in an individual who shall be authorized and responsible for all quality system functions at the Specified and Additional Facilities, including establishing, implementing, and maintaining a comprehensive written quality program, to ensure Defendants' continuous compliance with this Decree, the Act, and the QS, CR, and MDR regulations. Within ninety (90) days after entry of this Decree, Defendants shall provide to FDA an affidavit of compliance stating the fact and manner of compliance with this paragraph.

13. If, at any time after this Decree has been entered, FDA determines, on the basis of the results of an inspection, the analyses of samples, a report or data prepared or submitted by Defendants or an expert or auditor under this Decree, or any other information, that Defendants have failed to comply with any provision of this Decree, or have violated the Act, the QS, CR, or MDR regulations at any of the Specified or Additional Facilities, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, and the QS, CR, and MDR regulations at any of the Specified or Additional Facilities, FDA may, as and when it deems necessary, order Defendants in writing, specifying the noncompliance(s) giving rise to the order, to take appropriate action, including, but not limited to, the following:

A. Cease manufacturing, processing, packing, labeling, holding, or distributing any or all devices at any Specified or Additional Facility that was involved in the failure to comply;

B. Recall at Corporate Defendants' expense, adulterated or misbranded devices manufactured, distributed, and/or sold by Defendants from any Specified or Additional Facility, and/or that are under the custody and control of Defendants' U.S. agents, distributors, or customers;

C. Revise, modify, expand, or continue to submit any reports or plans described in this Decree;

D. Submit additional reports or information relating to any Specified or Additional Facility, to FDA as requested;

E. Issue a safety alert, public health advisory, and/or press release;

F. Take any other corrective actions relating to any Specified or Additional Facility as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Decree, the Act, or the QS, CR, or MDR regulations.

These remedies shall be separate and apart from, and in addition to, any other remedy available to the United States under this Decree or the law. The cost of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement these remedies shall be borne by Corporate Defendants at the rates specified in paragraph 18. However, nothing in this paragraph authorizes FDA to take any action with regard to products that are not manufactured, processed, packed, labeled or distributed in the United States.

14. If FDA inspects any facilities owned and/or operated by Corporate Defendants and/or their subsidiaries and/or affiliates, other than the Specified and Additional Facilities, and

finds violations of the Act or the QS, CR, or MDR regulations, FDA may, without further action by the parties or this Court, order that such facility or facilities shall thereafter be fully subject to the provisions of this Decree as though it or they were listed as an Additional Facility or Additional Facilities in paragraph 4.B when the Decree was entered, and FDA, with respect to such facility or facilities, may thereafter, based on subsequent violations, order Defendants to take any or all of the actions described in paragraph 13.

15. Upon receipt of any order issued by FDA pursuant to this Decree, the following procedures shall apply:

A. Unless a different time frame is specified by FDA in its order, Defendants shall, within ten (10) business days after receiving such order, notify FDA in writing that:

i. Defendants are undertaking or have undertaken corrective action, in which event Defendants shall describe the specific action(s) taken or proposed to be taken and the proposed schedule for completing the action(s); or

ii. Defendants do not agree with FDA's order, including a written explanation of the basis for their disagreement; in doing so, Defendants may propose specific alternative actions and specific time frames for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it will explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's notice of affirmation or modification, immediately implement the order (as modified, if

applicable), and, if they so choose, bring the matter before this Court on an expedited basis. Defendants shall continue to diligently implement FDA's order, as modified if applicable, unless the Court sets aside, stays, reverses, vacates, or modifies FDA's order. Any review of FDA's order under this paragraph shall be made in accordance with the terms set forth in paragraph 27.

D. The procedures set forth in paragraphs 15A-C shall not apply to any order issued under paragraph 13 if such order states that it is based on FDA's judgment that the matter raises significant public health concerns, and FDA's judgment and basis for such decision are stated in the order. In such case, Defendants shall immediately and fully comply with the terms of that order. If they so choose, Defendants may bring the matter before this Court on an expedited basis. Defendants shall continue to diligently implement FDA's order, unless the Court sets aside, stays, reverses, vacates, or modifies FDA's order. Any review of FDA's order under this paragraph shall be made in accordance with the terms set forth in paragraph 27.

16. Any cessation of operations or other actions described in paragraph 13 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and the QS, CR, and MDR regulations, and that Defendants may, therefore, resume operations. After receiving Defendants' written request to resume operations, FDA will determine whether it needs to inspect any of Defendants' facilities to determine Defendants' compliance with this Decree, the Act, and the QS, CR, and MDR regulations. If FDA determines that an inspection is necessary, it shall conduct the inspection and determine whether Defendants appear to be in compliance with this Decree, the Act, and the QS, CR, and MDR regulations and, if so, FDA will issue to Defendants a written notification permitting resumption of operations. With regard to U.S. facilities, FDA will decide within forty-five (45) days after receipt of the request whether Defendants appear to be in compliance

and, if so, issue to Defendants a written notification permitting resumption of actions described in paragraph 13. With regard to facilities located outside of the United States, FDA will, as soon as reasonably practicable, act on the request whether Defendants appear to be in compliance and, if so, issue to Defendants a written notification permitting resumption of actions described in paragraph 13.

17. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of any of the Specified or Additional Facilities, collect samples, and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and the QS, CR, and MDR regulations. During such inspections, FDA representatives shall be permitted ready access to the Specified and Additional Facilities including, but not limited to, all buildings, equipment, finished and unfinished materials and products, containers and packaging materials, and labeling; to take photographs and make video recordings; to take samples (without charge to FDA) of Defendants' finished and unfinished materials and products, containers and packaging materials, and labeling; and to examine and copy all records relating to the manufacture, processing, packing, labeling, receiving, holding, installing, and distribution of any and all devices in order to ensure continuing compliance with this Decree, the Act, and the QS, CR, and MDR regulations. FDA will provide Defendants with a receipt for any samples taken pursuant to 21 U.S.C. § 374 and with copies of any photographs and video recordings made, upon a written request by Defendants and at Corporate Defendants' expense. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374.

18. Corporate Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree at the standard rates prevailing at the time the costs are incurred. As of the date of entry of this Decree, these rates are: $88.45 per hour or fraction thereof per representative for inspection and investigative work; $106.03 per hour or fraction thereof per representative for analytical or review work; $0.56 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate for subsistence expenses where necessary. FDA shall submit a reasonably detailed bill of costs to Corporate Defendants. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

19. Within ten (10) business days after entry of this Decree, Defendants shall post a copy of this Decree in a common area at each of the Specified and Additional Facilities and shall ensure that the Decree remains posted for as long as the Decree remains in effect.

20. Within ten (10) business days after the entry of this Decree, Defendants shall provide a copy of this Decree, by electronic means, personal service, or registered mail, to each and all Associated Persons. Within thirty (30) days after entry of this Decree, Defendants shall provide to FDA an affidavit of compliance stating the fact and manner of compliance with this paragraph and identifying the names, addresses, and positions of all Associated Persons located in the U.S. who have received a copy of this Decree.

21. In addition to the requirements in paragraph 8, Defendants shall notify FDA at least ten (10) business days before any change in ownership or character of their business, such as dissolution, assignment, bankruptcy, or sale resulting in emergence of a successor corporation,

the creation or dissolution of subsidiaries, or any other change in the corporate structure of any Corporate Defendant, or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that, in each case, may affect compliance with this Decree. Defendants shall provide a copy of this Decree to any proposed successor or assignee at least thirty (30) business days prior to making any assignment or transferring any interest in the company as described in this paragraph. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) business days prior to such assignment or change in ownership.

22. In the event that any of the Defendants becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants shall within ten (10) business days of the commencement of such association provide a copy of this Decree, by electronic mail, personal service, or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Every six (6) months, if during that time Defendants become associated with any such additional Associated Person(s), Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all Associated Person(s) who received a copy of this Decree pursuant to this paragraph. Within ten (10) business days after receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

23. In the event Defendants replace any third-party expert or auditor required under this Decree, Defendants shall notify FDA in writing of the successor to such third-party expert or auditor and Defendants' reasons for replacing the expert or auditor within ten (10) business days

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after such replacement. In satisfying the requirements of this Decree, any third-party expert or auditor may review the previous expert's or auditor's work, and refer to such work to satisfy the requirements of the Decree; however, when such work is referenced by the new expert or auditor, s/he shall identify the specific prior work referenced.

24. Unless otherwise specified, all notifications, certifications, reports, correspondence, and other communications to FDA required by the terms of this Decree shall be addressed to the Director, FDA New England District Office, One Montvale Avenue, Stoneham, MA 02180. All notifications, correspondence, and communications required to be sent to Defendants or Corporate Defendants by the terms of the Decree shall be addressed to the General Counsel's Office, Maquet/Atrium Shared Legal Group, 1300 MacArthur Boulevard, Mahwah, NJ 07430.

25. Should Defendants fail to comply with any provision of this Decree, including any time frame imposed by this Decree, at any Specified or Additional Facility, then Corporate Defendants shall pay to the United States of America: fifteen thousand dollars ($15,000) in liquidated damages for each day such violation continues; an additional sum of fifteen thousand dollars ($15,000) in liquidated damages per day, per violation for each violation of the Act, its implementing regulations, and/or this Decree. In addition, should Defendants distribute from any Specified or Additional Facility after entry of this Decree any device that violates this Decree, the Act, or its implementing regulations, Corporate Defendants shall, in addition to the foregoing, also pay to the United States as liquidated damages a sum equal to two times the retail value of such devices. The amount of liquidated damages imposed under this paragraph shall not exceed ten million dollars ($10,000,000) in any one calendar year. The parties acknowledge that any payments to the government under any provision of this Decree are not a fine, penalty,

forfeiture, or payment in lieu thereof. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this Decree or the law.

26. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Corporate Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), investigational and analytical expenses, expert witness fees, and court costs relating to such contempt proceedings.

27. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, if contested, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

28. The parties may at any time petition each other in writing to modify any deadline provided herein; and, if the parties mutually agree in writing to modify a deadline, such modification may be granted without seeking leave of Court.

29. If any deadline in this Decree falls on a weekend or federal holiday, the deadline shall be continued to the next business day.

30. If, and for as long as, an individual Defendant ceases to be employed by or to act on behalf of Corporate Defendants or any of their subsidiaries, franchises, affiliates and/or "doing business as" entities (the "Corporate Defendant Entities"), then, without further order of the Court, that individual Defendant shall not be subject to the terms of this Decree but shall continue to be liable for such individual Defendant's act(s) or failure(s) to act under this Decree prior to the time such individual ceased to be employed by or to act on behalf of all of the

Corporate Defendant Entities. An individual Defendant shall notify FDA within thirty days after said Defendant ceases to be employed by or to act on behalf of all of the Corporate Defendant Entities. Once an individual Defendant ceases to be employed or otherwise act for all of the Corporate Defendant Entities, Corporate Defendants shall petition the Court to formally remove that individual Defendant's name from the caption of this Decree and the United States will not oppose such a motion, so long as FDA has sufficient evidence or information that the individual Defendant to be removed is no longer directly or indirectly working for or with, or in any way influencing, Corporate Defendant Entities. If Defendant Gail Christie's responsibilities are materially reduced, or the position of Corporate Chief Quality Assurance/Regulatory Affairs and Compliance Officer is eliminated, Corporate Defendants shall petition the Court to substitute for her as an individual Defendant either her successor as Corporate Chief Quality Assurance/Regulatory Affairs and Compliance Officer or the individual vested with responsibility for all quality system functions, as described in paragraph 12 ("Christie Substitute Defendant"). The United States will not oppose such a motion, so long as FDA has sufficient evidence or information that the Christie Substitute Defendant is vested with responsibility for all quality system functions, as described in paragraph 12. If removing an individual Defendant would result in no individual Defendant being subject to this Decree, Corporate Defendants shall designate an individual of similar position and responsibility to be substituted as an individual Defendant ("Substitute Individual Defendant"). Corporate Defendants shall petition the Court to add the Substitute Individual Defendant to the Decree and the United States will not oppose such a motion so long as FDA has sufficient evidence or information regarding the Substitute Individual Defendant's position and responsibilities. The obligations under this Decree of each individual named herein and any Substitute Defendant shall apply only to the extent of his or her

authority, responsibilities, and conduct within Maquet Holding B.V. & Co. KG and/or the Corporate Defendant Entities.

31. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

IT IS SO ORDERED.

DATED: February 3, 2015

UNITED STATES DISTRICT JUDGE

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We hereby consent to the entry of the foregoing Decree:

FOR THE DEFENDANTS:

HEINZ JACQUI
Individually, and on behalf of Corporate Defendants, as Chief Executive Officer and Managing Director of Maquet Holding B.V. & Co. KG

GAIL CHRISTIE
Individually, and as Corporate Chief Quality Assurance/Regulatory Affairs and Compliance Officer of Maquet Holding B.V. & Co. KG

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