U.S. Department of Justice

United States Attorney
District of New Jersey
970 Broad Street, Suite 700 *(973) 645-2700*
Newark, New Jersey 07102

November 28, 2018

Geoffrey E. Hobart, Esq.
Matthew J. O'Connor, Esq.
Covington & Burling LLP
One City Center
850 Tenth Street, NW
Washington, DC 20001-4956

18727

Re: Plea Agreement with Olympus Medical Systems Corporation

Dear Messrs. Hobart and O'Connor:

This letter sets forth the plea agreement between the United States Attorney for the District of New Jersey and the United States Department of Justice, by and through the Consumer Protection Branch (collectively, the "United States") and your client, Olympus Medical Systems Corporation ("Olympus"). The offer of the United States to enter into this plea agreement will expire on December 3, 2018, if it is not accepted in writing by that date.

Charge

Conditioned on the understandings specified below, the United States will accept a guilty plea from Olympus to a three-count Information, which charges Olympus with the introduction into interstate commerce of medical devices that were misbranded (pursuant to 21 U.S.C. § 352(t)(2)) in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 331(a) and 333(a)(1). If Olympus enters a guilty plea and a judgment of conviction is entered that is consistent with the terms of the agreed disposition included in this plea agreement under Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure, and if Olympus otherwise fully complies with all of the terms of this agreement, the United States will not initiate any further criminal charges against Olympus, Olympus Corporation, or their subsidiaries pursuant to the terms set forth in the section, "Agreement Not to Prosecute." However, in the event that a guilty plea in this matter is not entered for any reason or the judgment of conviction entered as a result of this guilty plea does not remain in full force and effect, Olympus agrees that any dismissed charges and any other charges that are not time-barred by the applicable statute of limitations on the date this agreement is signed by Olympus may be commenced against

Olympus, notwithstanding the expiration of the limitations period after Olympus signs the agreement.

Should the Court at any time reject this plea under Federal Rule of Criminal Procedure 11(c)(1)(C) or act contrary to its terms, either party may elect to be relieved of the terms of this plea and the parties will be returned to the status prior to the entry of the plea. In the event that the Court defers a decision to accept the plea until the Court has reviewed the presentence report neither party will move to withdraw from this agreement unless or until the Court ultimately determines to reject the proposed plea. This Office will advise the Court and the United States Probation Department of information related to sentencing, and such information may be used by the Court in determining Olympus's sentence.

The United States expressly reserves the right to prosecute any individual, including but not limited to present and former officers, directors, employees, and agents of Olympus, in connection with the conduct encompassed by this plea agreement or known to the United States.

Sentencing

The violations of 21 U.S.C. §§ 331(a) and 333(a)(1) to which Olympus agrees to plead guilty each carry a statutory maximum term of probation of 5 years, and a statutory maximum fine equal to the greatest of: (1) $200,000; (2) twice the gross amount of any pecuniary gain that any persons derived from the offense; or (3) twice the gross amount of any pecuniary loss sustained by any victims of the offense. See 18 U.S.C. §§ 3561(c)(2), 3571(c)(5), 3571(d). Fines imposed by the sentencing judge may be subject to the payment of interest.

Further, in addition to imposing any other penalty on Olympus, the sentencing judge: (1) pursuant to 18 U.S.C. § 3013, will order Olympus to pay an assessment of $375, which assessment must be paid by the date of sentencing; and (2) pursuant to 18 U.S.C. § 3663 et seq., may order Olympus to pay restitution.

The parties agree that while the fine provisions of the United States Sentencing Guidelines ("U.S.S.G.") do not apply to organizational defendants for misdemeanor violations of the FDCA, see U.S.S.G. § 8C2.1, the fine agreed upon by the parties is consistent with the U.S.S.G. and takes into account Olympus's conduct under 18 U.S.C. §§ 3553 and 3572, as follows:

(1) The parties agree that the base fine is $33,000,000, in that such amount was the reasonably estimated pecuniary gain to Olympus from the offense, see U.S.S.G. §§ 8C2.3, 8C2.4(a);

(2) Pursuant to U.S.S.G. § 8C2.5, the culpability score is seven (7), which is determined as follows:

i. Base culpability score of five (5) pursuant to U.S.S.G. § 8C2.5(a);

ii. Add four (4) points pursuant to U.S.S.G. § 8C2.5(b)(2)(A) because the organization had 1,000 or more employees and an individual within high-level personnel of the organization participated in, condoned, or was willfully ignorant of the offense;

iii. Deduct two (2) points pursuant to U.S.S.G. § 8C2.5(g)(2) based on Olympus's full cooperation in the investigation and clearly demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct.

(3) Pursuant to U.S.S.G. § 8C2.6, the appropriate multiplier range associated with a culpability score of seven (7) is 1.4 to 2.8; and

(4) Therefore, the advisory Guidelines Fine Range is $46,200,000 to $92,400,000.

Agreed Disposition

The United States and Olympus agree that, pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C), the appropriate disposition of the case is as follows, and will result in the imposition of a reasonable sentence that is sufficient, but not greater than necessary, taking into consideration all of the factors set forth in 18 U.S.C. §§ 3553(a) and 3572:

(1) Olympus shall pay a criminal fine in the amount of $80,000,000 within seven (7) days after sentencing;

(2) Olympus shall pay criminal forfeiture in the amount of $5,000,000 within seven (7) days after sentencing;

(3) Olympus shall pay a special assessment of $375;

(4) The United States agrees that it will not seek a separate restitution order as to Olympus as part of the resolution of the charges in the

Information. While violations of the FDCA create risk of patient harm, direct and proximate harm to specific persons from Olympus's offense conduct has not been established so as to provide a basis for restitution; and

(5) The United States further agrees that it will not seek a term of probation in light of: (i) the remedial measures undertaken by Olympus to date; and (ii) the enhanced corporate compliance measures and certifications agreed to by Olympus as attached hereto as Exhibit 1.

Pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C), the United States and Olympus agree that no other sentence or fine is appropriate, beside those set forth above. If the Court accepts this plea agreement, Olympus must be sentenced accordingly. If the Court rejects any aspect of this plea agreement or fails to impose a sentence consistent herewith, this agreement shall be null and void at the option of either the United States or Olympus, except that Olympus expressly waives, and agrees that it will not interpose, any defense to any charges brought against Olympus which Olympus might otherwise have under the Constitution for pre-indictment delay, any statute of limitations defenses that arose following the date of this agreement, or the Speedy Trial Act. If Olympus fails to pay any amounts within the time frames specified in this plea agreement, this agreement shall be null and void at the sole option of the United States. See 18 U.S.C. § 3614.

Rights of the Parties Regarding Sentencing

Except as otherwise provided in this agreement, all parties to this agreement reserve their rights to correct any misstatements relating to the sentencing proceedings, and to provide the sentencing judge and the United States Probation Office all law and information relevant to sentencing, favorable or otherwise. In addition, this Office may inform the sentencing judge and the United States Probation Office of: (1) this agreement; and (2) the full nature and extent of Olympus's activities and relevant conduct with respect to this case.

Agreement Not to Prosecute

Except as provided herein, the United States agrees that, other than the charges in the Information in this case, it will not bring any other criminal charges or forfeiture actions against Olympus, Olympus Corporation, or their present and former parent companies and each of their direct or indirect affiliates, divisions, and subsidiaries, and each of their predecessors, successors, and assigns, for conduct that (1) falls within the scope of the

investigation in the District of New Jersey relating to the TJF-Q180V, or (2) was known to the United States Attorney's Office for the District of New Jersey or the Consumer Protection Branch of the Department of Justice as of the date of the execution of this plea agreement, and which concerned the TJF-Q180V.

The non-prosecution provisions of this paragraph are binding on the Office of the United States Attorney for the District of New Jersey, the Consumer Protection Branch, Civil Division, of the Department of Justice, and the United States Attorney's Offices for each of the other 93 judicial districts of the United States. The non-prosecution provisions in this paragraph are also binding on the Criminal Division of the United States Department of Justice. A copy of the letter to Rachael Honig, Attorney for the United States Acting Under Authority Conferred by 28 U.S.C. § 515, from Joseph H. Hunt, Assistant Attorney General, Civil Division, Department of Justice, authorizing this agreement is attached hereto as Exhibit 2.

Olympus understands that this guilty plea does not bind any other government agency, or any component of the Department of Justice, except as specified in this agreement. Further, Olympus understands that the United States takes no position as to the proper tax treatment of any of the payments made by Olympus pursuant to this plea agreement.

Waiver of Appeal and Post-Sentencing Rights

Olympus knowingly and voluntarily waives the right to file any appeal, any collateral attack, or any other writ or motion, including but not limited to an appeal under 18 U.S.C. § 3742 or a motion under 28 U.S.C. § 2255, which challenges the conviction or sentence imposed by the Court if the plea is accepted and the sentence is imposed in accordance with the terms of this agreement.

The United States will not file any appeal, motion or writ which challenges the conviction or sentence imposed by the Court if that sentence is imposed in accordance with the terms of this agreement. Furthermore, if the Court accepts the terms of this plea agreement, both parties waive the right to file an appeal, collateral attack, writ, or motion claiming that the Court erred in doing so.

Both parties reserve the right to oppose or move to dismiss any appeal, collateral attack, writ, or motion barred by the preceding paragraphs.

Forfeiture

Olympus agrees that as part of its acceptance of responsibility, Olympus will forfeit to the United States assets subject to forfeiture pursuant to 21

U.S.C. § 334 and 28 U.S.C. § 2461(c). Olympus admits that the value of certain quantities of the TJF-Q180V duodenoscope that were distributed in violation of 21 U.S.C. § 331 totaled approximately $5,000,000 in United States currency.

Olympus acknowledges and agrees that the quantities of the TJF-Q180V duodenoscope that were distributed in violation of 21 U.S.C. § 331 cannot be located upon the exercise of due diligence, or have been transferred or sold to, or deposited with, a third party, placed beyond the jurisdiction of the Court, substantially diminished in value, or commingled with other property that cannot be divided without difficulty. Accordingly, Olympus agrees that the United States is entitled to forfeit as "substitute assets" any other assets of Olympus up to the $5,000,000 value of the now-missing directly forfeitable assets.

Olympus agrees that, within seven (7) days after sentencing, it shall remit the amount of $5,000,000 in United States currency to the United States Marshals Service. Olympus and the United States agree that this payment shall satisfy any and all forfeiture obligations that Olympus may have as a result of its guilty plea.

Forfeiture of substitute assets shall not be deemed an alteration of Olympus's sentence. The forfeitures set forth herein shall not satisfy or offset any fine, restitution, cost of imprisonment, or other penalty imposed upon Olympus, nor shall the forfeiture be used to offset Olympus's tax liability or any other debt owed to the United States.

Olympus agrees to consent to the entry of an order of forfeiture for $5,000,000 in United States currency, and waives the requirements of Federal Rules of Criminal Procedure 32.2 and 43(a) regarding notice of the forfeiture in the charging instrument, entry of a preliminary order of forfeiture, announcement of the forfeiture at sentencing, and incorporation of the forfeiture in the judgment. Olympus acknowledges that it understands that the forfeiture of assets is part of the sentence that may be imposed in this case and waives any failure by the Court to advise it of this, pursuant to Federal Rule of Criminal Procedure 11(b)(1)(J), at the time the guilty plea is accepted.

In addition to all other waivers or releases set forth in this agreement, Olympus hereby waives any and all claims arising from or relating to the forfeiture set forth in this section, including, without limitation, any claims arising under the Double Jeopardy Clause of the Fifth Amendment, or the Excessive Fines Clause of the Eighth Amendment to the United States Constitution, or any other provision of state or federal law. The United States

District Court for the District of New Jersey shall retain jurisdiction to enforce the provisions of this section.

Notification to Healthcare Providers

Within ninety (90) days after Olympus is sentenced pursuant to this agreement, Olympus will provide notice of the Information and this agreement to all customers in the United States to whom Olympus distributed the TJF-Q180V duodenoscope between August 2012 and October 2014. Specifically, Olympus shall send, by first class mail, postage prepaid, a notice containing the language set forth below to all Health Care Providers in the United States to whom Olympus distributed the TJF-Q180V duodenoscope between August 2012 and October 2014:

> "In November 2018, Olympus Medical Systems Corporation agreed to enter into a criminal plea agreement with the United States in connection with Olympus's failure to make necessary disclosures to the Food and Drug Administration ("FDA") between August 2012 and October 2014. Specifically, Olympus has admitted that it failed to submit required Medical Device Reports ("MDRs") or supplemental MDRs regarding three European adverse events involving the TJF-Q180V duodenoscope between August 2012 and October 2014. This letter provides you with additional information about the criminal plea agreement.
>
> In general terms, Olympus has admitted that Olympus failed to disclose to the FDA certain information relating to adverse events involving the TJF-Q180V duodenoscope.
>
> Federal law requires a medical device manufacturer such as Olympus to submit MDRs to the FDA, generally within 30 days, when it learns that one of its marketed devices may have caused or contributed to a death or serious injury, or malfunctioned and such a malfunction would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. Medical device manufacturers are also required to submit supplemental MDRs when they obtain certain additional information relating to previous adverse event filings.
>
> Between August 2012 and October 2014, Olympus failed to file two required supplemental MDRs and failed to file one required initial MDR. As a result, Olympus did not inform the FDA of certain information relating to three separate European adverse events.

> Because Olympus had not made the required MDR filings regarding these three European events to the FDA between August 2012 and October 2014, all TJF-Q180V duodenoscopes distributed by Olympus during that time are considered to have been "misbranded" medical devices under the Federal Food, Drug, and Cosmetic Act ("FDCA"), and their distribution was thus in violation of the FDCA.
>
> Olympus pleaded guilty to three misdemeanor violations of the FDCA in the United States District Court for the District of New Jersey. Olympus has agreed to pay a fine and forfeiture of $85 million, to enact enhanced corporate rehabilitative compliance measures, and to regularly make certain certifications. These measures were designed to promote compliance with the Federal health care program and FDCA requirements. Olympus also agreed to provide this notice to Health Care Providers. More information about this agreement, including Olympus's plea agreement and the Information, may be found at [Olympus shall include a link to the USAO website in the letter].
>
> You may report any improper conduct associated with device marketing to the FDA's Center for Devices and Radiological Health (CDRH) Allegations of Regulatory Misconduct Branch at OCMedicalDeviceCO@fda.hhs.gov."

Cooperation

Olympus shall cooperate completely and truthfully in any trial or other proceeding arising out of any civil, criminal, or administrative investigation by the United States of its current and former officers, agents, employees, and customers in connection with matters described in the Information. Olympus shall make reasonable efforts to facilitate access to, and to encourage the cooperation of, its current and former officers, agents, and employees for interviews sought by law enforcement agents, upon request and reasonable notice in connection with matters described in the Information. Olympus shall also take reasonable measures to encourage its current and former officers, agents, and employees to testify truthfully and completely before any grand jury, and at any trial or other hearing, at which they are requested to do so by any government entity in connection with matters described in the Information.

In addition, Olympus shall promptly furnish to any federal agency, upon its request, all non-privileged documents and records in its possession, custody, or control relating to the conduct that are within the scope of any investigation, proceeding, or trial, in connection with the matters described in the Information.

Notwithstanding any provision of this agreement, (1) Olympus is not required to request of its current or former officers, agents, or employees that they forgo seeking the advice of an attorney or that they act contrary to that advice; (2) Olympus is not required to take any action against its officers, agents, or employees for following their attorney's advice; and (3) Olympus is not required to waive any privilege or claim of work product protection.

Other Provisions

Olympus agrees that it is authorized to enter into this agreement, that it has authorized the undersigned corporate representative, Akihiro Okubo, to take this action, and that all corporate formalities for such authorization have been observed. By entering this guilty plea, Olympus hereby waives all objections to the form of the charging document and admits that it is in fact guilty of the offense charged in the Information.

Corporate Authorization

Olympus has provided to the United States a certified copy of a resolution of the governing body of Olympus, affirming that it has authority to enter into this agreement and has (1) reviewed this plea agreement and the Information in this case; (2) consulted with legal counsel in this matter; (3) authorized execution of this agreement; (4) authorized Olympus to plead guilty to the Information; and (5) authorized Akihiro Okubo to execute this agreement and all other documents necessary to carry out the provisions of this agreement. A copy of this resolution is attached hereto as Exhibit 3.

No Other Promises

This agreement and the Exhibits hereto constitute the plea agreement between Olympus and the United States and supersedes any previous agreements between them. No additional promises, agreements, or conditions have been made or will be made unless set forth in writing and signed by the parties.

Very truly yours,

RACHAEL HONIG
Attorney for the United States
Acting Under Authority Conferred by
28 U.S.C. § 515

By: JACOB T. ELBERG
R. DAVID WALK, JR.
Assistant U.S. Attorneys

PATRICK JASPERSE
Senior Litigation Counsel
Consumer Protection Branch
U.S. Department of Justice

APPROVED:

John Gay
Chief, Criminal Division
U.S. Attorney's Office
District of New Jersey

Gustav W. Eyler
Acting Director
U.S. Department of Justice
Consumer Protection Branch

I am the authorized corporate representative for Olympus Medical Systems Corporation ("Olympus"). I have received this letter from Geoffrey E. Hobart, Esq. and Matthew J. O'Connor, Esq., who are the attorneys for Olympus. It has been translated for me into Japanese. I have read the letter, and Mr. Hobart, Mr. O'Connor, and I have discussed it and all of its provisions, including those addressing the charges, sentencing, stipulations, forfeiture and waiver, as well as the impact Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure has upon this agreement. I understand this letter fully. On behalf of and with the express authorization of Olympus, I hereby accept its terms and conditions and acknowledge that it constitutes the plea agreement between the parties. Olympus understands that no additional promises, agreements, or conditions have been made or will be made unless set forth in writing and signed by the parties. Olympus wants to plead guilty pursuant to this plea agreement.

AGREED AND ACCEPTED:

A. Okubo Date: 12/10/18

Akihiro Okubo
President and Representative Director, Olympus Medical Systems Corporation
As Authorized Corporate Representative
for Olympus Medical Systems Corporation

I am counsel for Olympus Medical Systems Corporation ("Olympus"). I have discussed with my client this plea agreement and all of its provisions, including those addressing the charge, sentencing, stipulations, forfeiture and waiver, as well as the impact Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure has upon this agreement. Further, I have fully advised the authorized corporate representative, Akihiro Okubo, of Olympus's rights regarding this plea agreement and all of its provisions, including those addressing the charge, sentencing, stipulations, forfeiture and waiver, as well as the impact Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure has upon this agreement. My client, Olympus, understands this plea agreement fully and wants to plead guilty pursuant to it.

Date: 12/10/18

Geoffrey E. Hobart, Esq.
Matthew J. O'Connor, Esq.

Schedule A

1. The United States and Olympus agree to stipulate to the following facts:

(a) On or about May 25, 2012, OMSC filed a Medical Device Report ("MDR") concerning 16 patients at Erasmus Medical Center in the Netherlands who were infected with *Pseudomonas aeruginosa* after the same Olympus TJF-Q180V duodenoscope was used on them. The hospital reported that the same bacteria was detected in a sample collected from the device.

(b) On or about August 6, 2012, OMSC received an English translation of "Investigation Report on Scope G-206" by Dr. Arjo Loeve of Delft University of Technology ("the Delft Report"), which reported on the results of inspecting and dismantling the Olympus TJF-Q180V duodenoscope used on the patients at Erasmus Medical Center. The Delft Report's conclusions included that the subject scope's tip had various cracks, corners, and crevices that could harbor bacteria and could be cleaned only with great difficulty; that undefined deposits were found at various places, including in an area that should have been sealed from liquids; and that an O-ring did "not seem to guarantee a reliable seal." The Delft Report recommended updating the cleaning instructions and improving the quality of the seals "by creating several barriers."

(c) OMSC was required to file Supplemental MDRs concerning the Delft Report but did not file Supplemental MDRs until on or about March 13, 2015. On or about March 13, 2015, OMSC filed Supplemental MDRs concerning the Erasmus incident for 22 patients who were infected with *Pseudomonas aeruginosa* after the same Olympus TJF-Q180V duodenoscope was used on them. The Supplemental MDRs stated that Delft University had disassembled the duodenoscope and found brownish deposits on both sides of the O-ring.

(d) On or about December 20, 2012, OMSC filed three MDRs concerning three patients at Clinique de Bercy in France who were infected with *Escherichia coli* after the same Olympus TJF-Q180V duodenoscope was used on them. The MDRs stated that the subject device "will be sent to an independent microbiology laboratory for microbiological testing" and that "[i]f significant additional information is received, a supplemental report will follow."

(e) On or about April 13, 2013, OMSC received a report prepared by Biotech Germande, an independent microbiological laboratory, of the results of testing the Olympus TJF-Q180V duodenoscope used on the three infected

patients at Clinique de Bercy. The Biotech Germande report stated that the Olympus TJF-Q180V duodenoscope was contaminated with various bacteria and that contamination remained after the duodenoscope was reprocessed according to OMSC's reprocessing instructions. Biotech Germande conducted additional testing on that duodenoscope to see if the duodenoscope could be cleaned effectively by following Olympus's reprocessing instructions. The Biotech Germande report concluded that "after completing a full cleaning/disinfection procedure according to the ministerial and endoscope manufacturer's guidelines, there is a risk of persistence of contamination . . . ."

(f) OMSC was required to file Supplemental MDRs concerning the results of the Biotech Germande testing. OMSC never filed Supplemental MDRs concerning the results of the Biotech Germande testing.

(g) On or about July 4, 2012, Olympus France received a report of five patients at Kremlin Bicetre in France who were infected with the identical strain of multi-drug resistant *Pseudomonas aeruginosa* after the same Olympus TJF-Q180V duodenoscope was used on them. On or about July 10, 2013, OMSC received an email from its subsidiary in Europe, which included a fax communication from ANSM referencing contamination of a scope at Kremlin Bicetre.

(h) OMSC was required to file MDRs concerning the Kremlin Bicetre infections. OMSC did not file MDRs concerning the Kremlin Bicetre infections until on or about July 7, 2016.

2. In accordance with the above, and pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure, the parties agree that the following sentence (hereinafter the "Stipulated Sentence") is reasonable, taking into account all of the factors under 18 U.S.C. §§ 3553(a) and 3572:

(a) Olympus shall pay a criminal fine in the amount of $80,000,000;

(b) Olympus shall pay forfeiture in the amount of $5,000,000;

(c) Olympus shall pay a special assessment of $375;

(d) Olympus shall not be ordered to pay restitution, direct and proximate harm to specific persons from Olympus's offense conduct having not been established; and

(e) Olympus shall not be subject to a term of probation.

3. The parties further agree that neither party will argue for a sentence that varies from any of the terms of the Stipulated Sentence.

Exhibit 1

EXHIBIT 1

OLYMPUS MEDICAL SYSTEMS CORPORATION'S ADDITIONAL COMPLIANCE MEASURES AND REPORTING/CERTIFICATION OBLIGATIONS

With respect to all endoscope devices manufactured by Olympus Medical Systems Corporation ("OMSC") that are currently sold in the United States, including, but not limited to, the TJF-Q180V duodenoscope, OMSC reports that it has instituted and shall maintain policies and procedures designed to prevent future violations of the Federal Food, Drug, and Cosmetic Act ("FDCA") with respect to (a) medical device reporting ("MDR") and (b) device classification and market pathway. Following sentencing in this matter, OMSC agrees to do the following:

A. Notice to OMSC & OCA Employees

Within ten (10) days of being sentenced in this matter, OMSC shall communicate to all employees of OMSC and Olympus Corporation of the Americas ("OCA") that OMSC pleaded guilty to the Information and that OMSC agreed to the enhanced compliance measures and obligations set forth in this Exhibit 1. OMSC shall distribute copies of the Information and the Plea Agreement, including this Exhibit 1, to all such employees via link to USAO website.

B. MDR Compliance Measures

OMSC agrees to continue to develop, establish, and maintain policies and procedures that comply with the MDR obligations, as prescribed by the FDCA and its implementing regulations (hereinafter "MDR Compliance Measures"), including, but not limited to, the following actions:

i. Implement and maintain adequate written MDR procedures in compliance with 21 C.F.R. Part 803 and ensure that employees are trained on, understand, and properly implement the MDR requirements and procedures; and

ii. Maintain accurate and complete complaint files and establish and implement adequate written procedures for receiving, reviewing, and evaluating complaints in compliance with 21 C.F.R. Part 820.198.

C. MDR Expert Audit and Reporting

Within sixty (60) days of being sentenced in this matter, OMSC shall retain an independent person(s) (the "MDR Expert") to inspect and review OMSC's and OCA's then-current policies and procedures, to determine if the current policies and procedures are in compliance with the MDR requirements of the FDCA and its implementing regulations (hereinafter the "MDR Audit"). The MDR Expert shall be qualified by education, training, and experience to conduct the MDR Audit, and shall be without personal or financial ties (other than the retention agreement) to Olympus Corporation or its subsidiaries. OMSC shall notify the United States and the U.S. Food and Drug Administration's ("FDA's") Center for Devices and Radiological Health ("CDRH") in writing of the identity of the MDR Expert and the MDR Expert's qualifications within fifteen (15) days after retaining such MDR Expert.

If the MDR Expert resigns or is unable to serve the balance of his/her term under this Exhibit 1, a successor shall be selected by OMSC consistent with the above guidelines within forty-five (45) days. All provisions in this Exhibit shall apply to any

successor MDR Expert.

Within six (6) months of OMSC's being sentenced in this matter, the MDR Expert shall submit simultaneously to OMSC, the United States, and FDA-CDRH a complete written report of the MDR Audit (hereinafter "MDR Audit Report"), which shall include, but not necessarily be limited to:

i. Identifying in detail which MDR policies and procedures (including SOPs and similar documents) the MDR Expert reviewed and the MDR Expert's evaluation as to whether each such policies and procedures are currently in compliance with the MDR requirements of the FDCA and its implementing regulations; and

ii. If applicable, listing any observed deviations from compliance with the FDCA provisions, and its implementing regulations, governing MDR (hereinafter "MDR Deviations").

In the event the MDR Audit Report identifies MDR Deviations, within thirty (30) days after receiving the MDR Audit Report, OMSC shall submit a written report to the MDR Expert detailing the specific actions OMSC has taken and/or shall take to address the MDR Deviations (hereinafter "MDR Work Plan"). Furthermore, as the actions detailed in the MDR Work Plan are completed, OMSC shall notify the MDR Expert in writing, who shall promptly inspect and verify whether those actions have been completed in a manner that complies with the MDR requirements of the FDCA and its implementing regulations to the MDR Expert's satisfaction.

When the MDR Expert determines that all of the actions identified in the MDR

Work Plan have been completed to his or her satisfaction, the MDR Expert shall provide simultaneously to OMSC, the United States, and FDA-CDRH a written certification that all of the MDR Deviations have been corrected and that, based on the MDR Expert's inspection(s) and review(s), OMSC's policies and procedures are in compliance with the MDR requirements of the FDCA and its implementing regulations (hereinafter the "MDR Expert's Completion Certification"). The MDR Expert's Completion Certification shall include a report of the results of the MDR Expert's inspection(s) and review(s).

D. MDR Review

Following submission of the MDR Expert's Completion Certification, OMSC shall have the MDR Expert conduct a review of OMSC's then-current MDR Compliance Measures to determine and ensure continued compliance with the MDR requirements of the FDCA and its implementing regulations (hereinafter the "MDR Review"), including a review of a statistically valid sample of MDR records from the same time period as the MDR Review. The MDR Expert shall submit simultaneously to OMSC, the United States, and FDA-CDRH the results of each MDR Review. The report should identify in detail which MDR policies, procedures, and records the MDR Expert reviewed and state the MDR Expert's evaluation as to whether such policies, procedures, and/or records currently are in compliance with the MDR requirements of the FDCA and its implementing regulations.

The first MDR Review period shall cover the one-year period following the date of the MDR Expert's Completion Certification, and the report shall be submitted

to OMSC, the United States, and FDA-CDRH no later than fifteen (15) months after submission of the MDR Expert's Completion Certification. The second MDR Review period shall cover the thirteenth (13th) through twenty-fourth (24th) months after submission of the MDR Expert's Completion Certification, and the report shall be submitted to OMSC, the United States, and FDA-CDRH no later than twenty-seven (27) months after submission of the MDR Expert's Completion Certification.

The MDR Expert's and OMSC's reports under Sections (C), (D), and (E) of this Exhibit will likely include proprietary, financial, confidential, and competitive business information. Moreover, public disclosure of the reports could discourage cooperation and undermine the objectives of the Compliance Measures. For these reasons, among others, the reports and their contents are intended to remain and shall remain non-public, except as otherwise agreed to by the parties in writing, or except to the extent that the United States determines in its sole discretion that disclosure would be in furtherance of the United States's discharge of its duties and responsibilities or is otherwise required by law.

E. Device Classification & Market Pathway Reviews/Audits and Reporting

OMSC shall conduct a review and audit of all Letters to File for all endoscope device types manufactured by OMSC (not including accessories or surgical tools) that are scopes intended for use in the sterile body cavity, including primarily duodenoscopes, bronchoscopes, and ureteroscopes, and that are currently sold in the United States ("In-Scope Devices") to assess and evaluate the respective devices' classification and regulatory status (hereinafter the "Classification/Marketing

Review"). This Classification/Marketing Review shall include review of OMSC's systems, processes, policies, and procedures relating to the classification, pathway to market, and regulatory status of all In-Scope Devices, including evaluating any decisions whether or not to file premarket approval applications and/or premarket notifications.

The first Classification/Marketing Review shall be conducted within six (6) months of the date of OMSC's sentencing and shall cover the time period from January 1, 2015, to the date of sentencing. OMSC shall submit a report to the United States and FDA-CDRH regarding the first Classification/Marketing Review within seven (7) months after sentencing. The second Classification/Marketing Review shall cover the period from the date of sentencing through twelve (12) months following the date of the MDR Expert's Completion Certification, and the report shall be submitted to the United States and FDA-CDRH no later than fifteen (15) months after submission of the MDR Expert's Completion Certification. The third Classification/Marketing Review period shall cover the thirteenth (13th) through twenty-fourth (24th) months after submission of the MDR Expert's Completion Certification, and the report shall be submitted to the United States and FDA-CDRH no later than twenty-seven (27) months after submission of the MDR Expert's Completion Certification.

F. Certification by OMSC

During the same periods and by the same deadlines set forth in section D above for the MDR Reviews and reports, the President of OMSC shall submit to the United States a signed certification stating that, to the best of his or her knowledge based on a

reasonable review of the MDR Compliance Measures and the Classification/Marketing Review, during the specified time period, OMSC: (1) maintained all necessary MDR Compliance Measures described in section B above; and (2) conducted an effective Classification/Marketing Review. These certifications shall summarize the President's review of OMSC's operations, and further shall be sworn to under the penalty of perjury and shall state that the representations contained therein may be provided to, relied upon, and material to the government of the United States, and that a knowingly false statement could result in criminal or civil liability for the signatory.

If the President of OMSC is unable to provide any of these certifications, the President shall provide a detailed explanation of why MDR Compliance Measures were not maintained and/or why the Classification/Marketing Review was not effective, and shall also state what steps OMSC is taking to resolve any deficiencies.

G. Resolution by OMSC's Board of Directors

The Board of Directors of OMSC, or a designated Committee thereof (the "Board"), shall review the effectiveness of OMSC's MDR Compliance Measures and the Classification/Marketing Review with respect to In-Scope Devices. This review shall include, but not be limited to, updates and reports by the quality officer responsible for quality issues for OMSC ("OMSC Quality Officer") and other quality personnel. The review shall evaluate the Quality Management System, including, among other means, by receiving updates about the activities of the OMSC Quality Officer and other company personnel and updates about adoption and implementation of policies, procedures, and practices designed to ensure compliance with applicable FDCA

requirements.

These reviews shall cover the same time periods set forth in section D above for the MDR Reviews. By the same deadlines set forth in section D above for the MDR Review reports, the Board shall submit to the United States a resolution (the "Board Resolution") that summarizes its review and oversight of OMSC's MDR Compliance Measures and the Classification/Marketing Review, and, at a minimum, includes the following language:

> The Board of Directors has made a reasonable inquiry into the content and operations of OMSC's MDR Compliance Measures and the Classification/Marketing Review with respect to In-Scope Devices manufactured by OMSC that are sold by Olympus in the United States for the time period [insert time period], including the performance of the OMSC Quality Officer and other quality personnel employed by OMSC. The Board has concluded that, to the best of its knowledge, OMSC has implemented MDR Compliance Measures and a Classification/Marketing Review designed to exercise due diligence to prevent, detect, and remediate violations of the Federal Food, Drug, and Cosmetic Act and its implementing regulations, and is promoting an organizational culture that encourages ethical conduct and a commitment to compliance with the law.
>
> OMSC's MDR Compliance Measures and Classification/Marketing Review continued to include the policies and procedures referenced in the MDR Expert's report dated [MONTH/DAY,] 20[ ].

If the Board is unable to provide any part of this statement, it shall include in the resolution an explanation of the reasons why it is unable to provide such a statement about OMSC's MDR Compliance Measures and Classification/Marketing Review.

H. Contact Information for Certifications, Submissions, and/or Filings[1]

Certifications, submissions, reports, or filings to the United States shall be sent to the following addresses:

Chief, Health Care & Government Fraud Unit
United States Attorney's Office
District of New Jersey
970 Broad Street, 7th Floor
Newark, NJ 07102

Director
Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044

Submissions, reports, or filings to FDA-CDRH shall be sent to the following address:

Bryan H. Benesch
Center for Devices and Radiological Health
Food and Drug Administration
White Oak, Bldg. 66 Rm. 3678
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

I. Remedies for Breach

OMSC recognizes that each of the terms in this Exhibit 1 constitutes a material term of this Exhibit 1. As a contractual remedy, OMSC and the United States agree that failure to comply with the obligations set forth in this Exhibit 1 may lead to the imposition of the following monetary penalties (hereinafter "Stipulated Penalties") in accordance with the following provisions:

i. A Stipulated Penalty of $5,000 per day for each day OMSC fails to

[1] Consistent with the Department of Justice's ("DOJ's") respective Freedom of Information Act ("FOIA") procedures, the government shall make reasonable effort to notify OMSC prior to any release by DOJ of information submitted by OMSC pursuant to its obligations under this Exhibit 1 and identified upon submission by OMSC as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, OMSC shall have the rights set forth under said procedures.

comply with any of the obligations set forth above. With regard to the certifications and board resolution, the Stipulated Penalty shall begin to accrue on the first day after the date the document was due, subject to the provisions for extension of time for compliance and the opportunity to cure set forth below.

ii. OMSC may submit a timely written request for an extension of time to provide any certification or board resolution required in this Exhibit 1. A written request is timely if received by the U.S. Attorney's Office for the District of New Jersey and the U.S. Department of Justice's Consumer Protection Branch at least five (5) business days prior to the date by which the certification or board resolution is due. Timely requests for extension shall not be unreasonably denied. If an extension of time is granted in writing, Stipulated Penalties shall not accrue until one day after OMSC fails to meet the revised deadline. If not granted, Stipulated Penalties shall not begin to accrue until three (3) business days after OMSC receives the United States' written denial of such request, or the original due date, whichever is later.

iii. Upon the United States' reasonable determination that OMSC has failed to comply with any of the obligations described herein, the United States shall notify OMSC in writing of OMSC's failure to comply and the United States' exercise of its contractual right to demand payment of the Stipulated Penalties (the "Demand Letter"). The Demand Letter

shall set forth: (1) the provision breached; (2) the date of the breach; (3) a description of the breach sufficient to permit OMSC to cure (as described below); and (4) the amount of Stipulated Penalties claimed by the United States as of the date of the Demand Letter.

iv. Within fourteen (14) business days after receipt of a Demand Letter, or such other period as the United States and OMSC may agree in writing, OMSC shall have the opportunity to cure the breach to the United States' reasonable satisfaction ("Cure Period"). If OMSC cures the breach within the Cure Period, no Stipulated Penalties shall be due. If OMSC fails to cure the breach during the Cure Period, Stipulated Penalties calculated from the date of breach to the date of payment shall be immediately payable to the United States. The Stipulated Penalties shall be paid by electronic fund transfer according to wire instructions that shall be provided by the United States. A joint reasonable determination by the United States Attorney for the District of New Jersey and the Director of the Consumer Protection Branch regarding OMSC's failure to comply with any of the obligations described herein shall be final and non-appealable. OMSC agrees that the United States District Court for the District of New Jersey shall have jurisdiction over any action to collect such a penalty.

J. Miscellaneous Provisions

OMSC agrees that nothing regarding the requirements of sections B – G above

is intended to: (i) relieve OMSC of any of its obligations under the FDCA or its implementing regulations, including with regard to violative devices; or (ii) limit FDA's authority to inspect OMSC pursuant to 21 U.S.C. § 374.

OMSC further agrees that the absence of a violation notice from the United States is not, and shall not be construed as, evidence of compliance with this Exhibit 1, federal healthcare program requirements, the FDCA or its implementing regulations, or any other applicable laws, policies, or procedures. OMSC also agrees that nothing in this Exhibit 1 precludes any other civil, criminal, or administrative claims that the government may have or bring in the future against Olympus Corporation or any of its subsidiaries, in connection with, or relating to, any activities involving FDA-regulated products, excluding the conduct alleged in the Information.

Exhibit 2

U.S. Department of Justice
Civil Division

Assistant Attorney General

November 26, 2018

Ms. Rachael Honig
Attorney for the United States
Acting Under Authority
Conferred by 28 U.S.C. § 515
District of New Jersey
970 Broad Street, 7th Floor
Newark, New Jersey 07102

Attention: Jacob T. Elberg
Assistant United States Attorney

Re: Global Plea Agreement for Olympus Medical Systems Corporation

Dear Ms. Honig:

This is in response to your request for authorization to enter into a global agreement with Olympus Medical Systems Corporation (Olympus).

I hereby approve the terms of the Plea Agreement with Olympus, including the provisions on pages 4-5, through which the United States agrees not to initiate further criminal proceedings against Olympus for the conduct at issue, with the exceptions and conditions noted within those paragraphs and elsewhere within the Plea Agreement.

You are authorized to make this approval a matter of record in this proceeding.

Sincerely,

Joseph H. Hunt
Assistant Attorney General

Exhibit 3

CERTIFICATE OF CORPORATE RESOLUTIONS OF OLYMPUS MEDICAL SYSTEMS CORPORATION

At a duly held meeting on November 20, 2018, the Board of Directors (the "Board") of Olympus Medical Systems Corporation (the "Company") resolved as follows:

WHEREAS, the Company, through its legal counsel, has been engaged in discussion with the United States Department of Justice, Criminal Division, Consumer Protection Branch and the U.S. Attorney's Office for the District of New Jersey in connection with their investigation into potential criminal violations related to the TJF-Q180V duodenoscope (the "Investigation");

WHEREAS, both Company management and external legal counsel have reported to the Board the terms and conditions of a proposed resolution of the Investigation;

WHEREAS, the Board has been advised by its legal counsel of the terms of the Information and Plea Agreement with attachments (collectively, the "Plea Agreement"), as provided to the Board, which include payment of a criminal fine and forfeiture, communication of the substance of the Plea Agreement to TJF-Q180V customers, and implementation of compliance measures; and

WHEREAS, the Board acknowledges that the Plea Agreement fully sets forth the Company's agreement with the United States Department of Justice, Consumer Protection Branch and the U.S. Attorney's Office for the District of New Jersey with respect to criminal violations identified during the Investigation and that no additional promises or representations have been made to the Company by any officials of the United States Department of Justice, Consumer Protection Branch or the U.S. Attorney's Office for the District of New Jersey in connection with the disposition of the Investigation, other than those set forth in the Plea Agreement.

THEREFORE, this Board hereby **RESOLVES** that:

1. The Board approves and agrees to the Plea Agreement;
2. The Board approves and agrees that it is in the best interests of the Company to enter the guilty plea provided for, and agrees to the other terms provided in the Plea Agreement with the United States Department of Justice, Consumer Protection Branch and the U.S. Attorney's Office for the District of New Jersey in substantially the form and substance set forth in the Plea Agreement presented to this Board;
3. The directors of the Company and legal counsel for the Company are hereby each individually authorized, empowered and directed, on behalf of the Company, to execute and deliver the Plea Agreement, substantially in such form as reviewed by this Board, with such changes as such directors or legal counsel may approve;
4. The directors of the Company and legal counsel for the Company are hereby each individually authorized, empowered, and directed to take any and all actions as may be necessary or appropriate, and to approve the forms, terms, or provisions of any agreement or other documents as may be necessary or appropriate to carry out and effectuate the

purpose and intent of the foregoing resolution (including execution and delivery of any such agreement or document on behalf of the Company);

5. Akihiro Okubo is hereby authorized to act and speak on behalf of the Company, in any proceeding or as otherwise necessary, for the purpose of executing the Plea Agreement, including entry of a guilty plea in court on behalf of the Company;
6. All of the actions of the directors of the Company and legal counsel for the Company, which actions would have been within the scope of and authorized by the foregoing resolution except that such actions were taken prior to the adoption of such resolutions, are hereby severally ratified, confirmed, approved, and adopted as actions on behalf of the Company; and
7. The representative directors of the Company are individually authorized, empowered or directed, to provide to the United States Department of Justice, Consumer Protection Branch and the U.S. Attorney's Office for the District of New Jersey a certified copy of this resolution.

I hereby certify that the above is a true and accurate copy of the resolution of the Board of the Company passed on November 20, 2018.

A. Okubo

Akihiro Okubo
President and Representative Director
Olympus Medical Systems Corporation