ORIGINAL

IN THE UNITED STATES DISTRICT COURT FOR THE

NORTHERN DISTRICT OF TEXAS

Dallas Division

UNITED STATES OF AMERICA	)	_____-CR-_____ (____)
v.	)	
AVANOS MEDICAL, INC.,	)	3-21CR0307-E
Defendant.	)	

DEFERRED PROSECUTION AGREEMENT

Defendant Avanos Medical, Inc. (the "Company"), pursuant to authority granted by the Company's Board of Directors reflected in Attachment B, the United States Department of Justice, Criminal Division, Fraud Section (the "Fraud Section"), the United States Department of Justice, Civil Division, Consumer Protection Branch (the "CPB"), and the United States Attorney's Office for the Northern District of Texas (the "USAO-NDTX") (collectively, the "Offices") enter into this deferred prosecution agreement (the "Agreement"). The terms and conditions of this Agreement are as follows:

Criminal Information and Acceptance of Responsibility

1. The Company acknowledges and agrees that the Offices will file the attached one-count criminal Information in the United States District Court for the Northern District of Texas charging the Company with a felony violation of the Federal Food, Drug, and Cosmetic Act

("FDCA"), namely the introduction into interstate commerce of a device that is misbranded, in violation of Title 21, United States Code, Sections 331(a), 333(a)(2) and 352(a) (the "Information"). In so doing, the Company: (a) knowingly waives any right it may have to indictment on this charge, as well as all rights to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, Title 18, United States Code, Section 3161, and Federal Rule of Criminal Procedure 48(b); and (b) knowingly waives any objection with respect to venue to any charges by the United States arising out of the conduct described in the Statement of Facts attached hereto as Attachment A (the "Statement of Facts") and consents to the filing of the Information, as provided under the terms of this Agreement, in the United States District Court for the Northern District of Texas. The Offices agree to defer prosecution of the Company pursuant to the terms and conditions described below.

2. The Company admits, accepts, and acknowledges that it is responsible under United States law for the acts of its officers, directors, employees, and agents as charged in the Information, and as set forth in the Statement of Facts, and that the allegations described in the Information and the facts described in the Statement of Facts are true and accurate. The Company agrees that, effective as of the date it signs this Agreement, in any prosecution that is deferred by this Agreement, it will not dispute the Statement of Facts set forth in this Agreement, and, in any such prosecution, the Statement of Facts shall be admissible as: (a) substantive evidence offered by the government in its case-in-chief and rebuttal case; (b) impeachment evidence offered by the government on cross-examination; and (c) evidence at any sentencing hearing or other hearing. In addition, in connection therewith, the Company agrees not to assert any claim under the United States Constitution, Rule 410 of the Federal Rules of Evidence, Rule 11(f) of the Federal Rules of

Criminal Procedure, Section 1B1.1(a) of the United States Sentencing Guidelines ("USSG" or "Sentencing Guidelines"), or any other federal rule that the Statement of Facts should be suppressed or is otherwise inadmissible as evidence in any form.

Term of the Agreement

3. This Agreement is effective for a period beginning on the date on which the Information is filed and ending three years from that date (the "Term"). The Company agrees, however, that, in the event the Offices determine, in their sole discretion, that the Company has knowingly violated any provision of this Agreement or has failed to completely perform or fulfill each of its obligations under this Agreement, an extension or extensions of the Term may be imposed by the Offices, in their sole discretion, for up to a total additional time period of one year, without prejudice to the right of the Offices to proceed as provided in Paragraphs 29-33 below. Any extension of the Agreement extends all terms of this Agreement, including the terms of the reporting requirement in Attachment D, for an equivalent period. Conversely, in the event the Offices find, in their sole discretion, that there exists a change in circumstances sufficient to eliminate the need for the reporting requirement in Attachment D, and that the other provisions of this Agreement have been satisfied, the Agreement may be terminated early. If the Court refuses to grant exclusion of time under the Speedy Trial Act, Title 18, United States Code, Section 3161(h)(2), the Term shall be deemed to have not begun, and all the provisions of this Agreement shall be deemed null and void, except that the statute of limitations for any prosecution relating to the conduct described in the Statement of Facts shall be tolled from the date on which this Agreement is signed until the date the Court refuses to grant the exclusion of time plus six months, and except for the provisions contained within Paragraph 2 of this Agreement.

Relevant Considerations

4. The Offices enter into this Agreement based on the individual facts and circumstances presented by this case and by the Company, including:

a. The Company did not receive voluntary disclosure credit pursuant to the Corporate Enforcement Policy in the Department of Justice Manual 9-47.120, or pursuant to the Sentencing Guidelines, because it did not timely and voluntarily disclose to the Offices the offense conduct described in the Statement of Facts attached hereto as Attachment A ("Statement of Facts");

b. The Company received full credit for its cooperation with the investigation conducted by the Offices, including conducting a thorough internal investigation, meeting requests from the Offices promptly, making factual presentations to the Offices, voluntarily making a key foreign-based employee available for interview, and producing extensive documentation to the Offices, including documents located in foreign jurisdictions;

c. The Company provided to the Offices all relevant facts known to it, including information about the individuals involved in the conduct described in the attached Statement of Facts and conduct disclosed prior to the Agreement;

d. The Company engaged in extensive remedial measures, including: (i) changing the manufacturing process for the MicroCool surgical gowns to improve the quality of their sleeve seams; (ii) reorganizing its quality and regulatory departments so that they report directly to the CEO; (iii) substantially increasing the budget and headcount of its compliance and quality departments; (iv) creating a stand-alone Compliance Committee of the Board of Directors; (v) enhancing the independence, autonomy, and

resources of its compliance function by creating a stand-alone compliance department, and by appointing a full-time Chief Ethics and Compliance Officer who reports directly to the CEO and presents compliance reports to the Compliance Committee at least five times per year; (vi) enhancing compliance training for its employees, and (vii) implementing revised procedures for the review and approval of all medical device marketing material;

e. The Company has enhanced and has committed to continuing to enhance its compliance program and internal controls, including ensuring that its compliance program satisfies the minimum elements set forth in Attachment C to this Agreement (Corporate Compliance Program);

f. On April 30, 2018, the Company sold to a third-party company that had no involvement in the conduct discussed herein all assets related to the Company's Surgical and Infection Prevention ("S&IP") unit, including the name "Halyard Health, Inc." and all assets and employees related to the Company's surgical gown business, and the Company does not currently employ nor is it affiliated with any of the individuals who committed the conduct described in the Statement of Facts;

g. The Offices determined that an independent compliance monitor was unnecessary based on the following factors, among others: the Company's remediation; the state of the Company's compliance program; the Company's agreement to report to the Offices as set forth in Attachment D to this Agreement (Corporate Compliance Reporting); and the fact that the Company is no longer manufacturing or selling surgical gowns;

h. The Company has agreed to continue to cooperate with the Offices as described in Paragraph 5, below;

i. The nature and seriousness of the offense conduct, which involved the misbranding of the Company's "MicroCool" surgical gowns, which the Company falsely labeled as providing the highest level of protection against fluid and virus penetration. Employees and agents of the Company, including a senior R&D employee who was an internal expert on the gowns' construction and features, knew that they were misrepresenting the quality of the MicroCool surgical gowns. Through this conduct, hundreds of thousands of MicroCool surgical gowns sold by the Company to hospitals and other health care providers were misbranded. In addition, certain employees and agents of the Company obstructed a for-cause inspection conducted by the United States Food and Drug Administration ("FDA") into the Company's surgical gown business in July 2016. These specific agents and employees made numerous false entries in four documents that were requested by FDA investigators during the inspection;

j. Accordingly, after considering (a) through (i) above, the Offices believe that the appropriate resolution in this case is a Deferred Prosecution Agreement with the Company; a victim compensation payment of $8,939,000; a criminal monetary penalty in the amount of $12,600,000, which reflects a discount of twenty-five percent below the low end of the otherwise-applicable Sentencing Guidelines fine range; a disgorgement payment of $689,000; and the Company's agreement to report to the Offices as set forth in Attachment D to this Agreement.

Future Cooperation and Disclosure Requirements

5. The Company and its subsidiaries and affiliates shall cooperate fully with the Offices in any and all matters relating to the conduct described in this Agreement and the attached Statement of Facts and other conduct under investigation by the Offices at any time during the Term, until the later of the date upon which all investigations and prosecutions arising out of such conduct are concluded, or the end of the Term. At the request of the Offices, the Company and its subsidiaries and affiliates shall also cooperate fully with other domestic or foreign law enforcement and regulatory authorities and agencies in any investigation of the Company, its subsidiaries, affiliates, or any of their present or former officers, directors, employees, and agents in any and all matters relating to the conduct described in this Agreement and the attached Statement of Facts and other conduct under investigation by the Offices at any time during the Term. The Company's and its subsidiaries' and affiliates' cooperation pursuant to this Paragraph is subject to applicable law and regulations, as well as valid claims of attorney-client privilege or attorney work product doctrine; however, the Company and its subsidiaries and affiliates must provide to the Offices a log of any information or cooperation that is not provided based on an assertion of law, regulation, or privilege, and the Company and its subsidiaries and affiliates bear the burden of establishing the validity of any such assertion. The Company and its subsidiaries and affiliates agree that their cooperation pursuant to this Paragraph shall include, but not be limited to, the following:

a. Upon request of the Offices, the Company and its subsidiaries and affiliates shall truthfully disclose all factual information with respect to their activities and those of their present and former directors, officers, employees, agents, and consultants, including any evidence or allegations and internal or external investigations, about which the

Company and its subsidiaries and affiliates have any knowledge or about which the Offices may inquire. This obligation of truthful disclosure includes, but is not limited to, the obligation of the Company and its subsidiaries and affiliates to provide to the Offices, upon request, any document, record or other tangible evidence about which the Offices may inquire of the Company and its subsidiaries and affiliates.

b. Upon request of the Offices, the Company and its subsidiaries and affiliates shall designate knowledgeable employees, agents, or attorneys to provide to the Offices the information and materials described in Paragraph 5(a) above on behalf of the Company and its subsidiaries and affiliates. It is further understood that the Company and its subsidiaries and affiliates must at all times provide complete, truthful, and accurate information.

c. The Company and its subsidiaries and affiliates shall use their best efforts to make available for interviews or testimony, as requested by the Offices, present or former officers, directors, employees, agents, and consultants of the Company and its subsidiaries and affiliates. This obligation includes, but is not limited to, sworn testimony before a federal grand jury or in federal trials, as well as interviews with domestic or foreign law enforcement and regulatory authorities. Cooperation under this Paragraph shall include identification of witnesses who, to the knowledge of the Company and its subsidiaries and affiliates, may have material information regarding the matters under investigation.

d. With respect to any information, testimony, documents, records, or other tangible evidence provided to the Offices pursuant to this Agreement, the Company and its

subsidiaries and affiliates consent to any and all disclosures to other governmental authorities, including United States authorities and those of a foreign government of such materials as the Offices, in their sole discretion, shall deem appropriate.

6. In addition to the obligations in Paragraph 5, during the Term, should the Company learn of any evidence or allegation of a violation of the FDCA or U.S. obstruction or fraud laws committed by the Company's employees or agents upon any domestic government agency (including the FDA), regulator, or any of the Company's customers, the Company shall promptly report such evidence or allegation to the Offices.

Total Criminal Monetary Amount

7. The Company and the Offices agree that the Total Criminal Monetary Amount to be paid by the Company pursuant to this Agreement is $22,228,000, which is comprised of the following components as further described below: (i) a victim compensation payment of $8,939,000 (the "Victim Compensation Amount"); (ii) a criminal monetary penalty of $12,600,000 (the "Criminal Monetary Penalty"); and (iii) a disgorgement payment of $689,000 (the "Criminal Disgorgement Amount").

Payment of Criminal Monetary Penalty

8. The Offices and the Company agree that application of the Sentencing Guidelines to determine the applicable fine range yields the following analysis:

a. The 2018 USSG are applicable to this matter.

b. Offense Level. Based upon USSG § 2B1.1, the total offense level is 30, calculated as follows:

(a)(2)	Base Offense Level	6
(b)(1)(J)	Loss of More Than $3,500,000	+18

(b)(2)(A)(i)	10 or more victims	+2
(b)(10)	Sophisticated Means	+2
(b)(16)(A)	Risk of death or serious bodily injury	+2
TOTAL		30

Base Fine. Based upon USSG §§ 8C2.4(a)(1) & (e)(1), the base fine is $10,500,000 (the fine amount from the Offense Level Fine Table of the 2014 USSG, which is greater than the pecuniary loss from the offense and the gain to the Company from the offense).

c. Culpability Score. Based upon USSG § 8C2.5, the culpability score is 8, calculated as follows:

(a)	Base Culpability Score	5
(b)(4)	The organization had 50 or more employees and an individual within substantial authority personnel participated in, condoned, or was willfully ignorant of the offense	+2
(e)	Obstruction	+3
(g)(2)	The organization fully cooperated in the investigation and clearly demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct	-2
TOTAL		8

Calculation of Fine Range:

Base Fine	$10,500,000
Multipliers	1.6 (min) / 3.2 (max)
Fine Range	$16,800,000 / $33,600,000

9. The Offices have determined that a Criminal Monetary Penalty in the amount of $12,600,000, which reflects a twenty-five percent discount off the low end of the applicable

Sentencing Guidelines fine range, is appropriate given the facts and circumstances of this case, including the Relevant Considerations described in Paragraph 4. The Company agrees to pay the Criminal Monetary Penalty of $12,600,000 to the United States Treasury no later than ten (10) business days after the Agreement is fully executed pursuant to payment instructions provided by the Offices in their sole discretion.

10. The Criminal Monetary Penalty is final and shall not be refunded. Furthermore, nothing in this Agreement shall be deemed an agreement by the Offices that $12,600,000 is the maximum penalty that may be imposed in any future prosecution, and the Offices are not precluded from arguing in any future prosecution that the Court should impose a higher fine, although the Offices agree that under those circumstances, it will recommend to the Court that any amount paid under this Agreement should be offset against any fine the Court imposes as part of a putative future judgment. The Company acknowledges that no tax deduction may be sought in connection with the payment of any part of the Criminal Monetary Penalty. The Company shall not seek or accept directly or indirectly reimbursement or indemnification from any source with regard to the penalty or disgorgement amounts that the Company pays pursuant to this Agreement or any other agreement entered into with an enforcement authority or regulator concerning the facts set forth in the Statement of Facts.

Payment of Criminal Disgorgement Amount

11. The Company hereby agrees to disgorge to the United States the sum of $689,000 (the "Criminal Disgorgement Amount"). The Company shall pay the Criminal Disgorgement Amount plus any associated transfer fees no later than ten (10) business days after the Agreement is fully executed, pursuant to payment instructions provided by the Offices in their sole discretion.

12. The Criminal Disgorgement Amount paid is final and shall not be refunded should the Offices later determine that the Company has breached this Agreement and commence a prosecution against the Company. In the event of a breach of this Agreement and subsequent prosecution, the Offices may pursue additional civil and criminal forfeiture in excess of the Criminal Disgorgement Amount. The Offices agree that in the event of a subsequent breach and prosecution, they will recommend to the Court that the amounts paid pursuant to this Agreement be offset against whatever forfeiture the Court shall impose as part of its judgment. The Company understands that such a recommendation will not be binding on the Court.

Payment of Victim Compensation Amount

13. The Company agrees to pay a total Victim Compensation Amount of $8,939,000 to purchasers of the misbranded MicroCool gowns between November 1, 2014 and January 15, 2015, that were directly and proximately harmed by the conduct described in the attached Statement of Facts. No later than ten (10) business days after the filing of the Information, the Company shall establish an escrow account ("Escrow Account") into which it shall deposit the full Victim Compensation Amount. No monies will be paid out of the Escrow Account without prior approval by the Offices.

14. The parties agree that the appointment of a Victim Compensation Claims Administrator (the "Administrator") is appropriate and necessary to determine the proper administration and disbursement of the Victim Compensation Amount that the Company will pay to the victims of the offense conduct.

15. The Administrator, consistent with a process imposed and required by the Offices, will make recommendations to the Offices regarding: (a) the purchasers who should receive

payments from Victim Compensation Amount; and (b) the compensation amounts that these purchasers should receive. Only the Offices shall be empowered to make final decisions regarding: (a) the purchasers who should receive the payments from the Victim Compensation Amount; and (b) the compensation amounts that these purchasers should receive.

16. The Company agrees to pay for all costs, fees, and expenses incurred by the Administrator. The Company shall execute an engagement letter with the Administrator that must be approved, in advance of execution, by the Offices.

17. Within twenty (20) business days after the filing of the Information, the Company shall submit a written proposal identifying three (3) candidates to serve as the Administrator, setting forth the candidates' qualifications and credentials. The Offices retain the right, in their sole discretion, to choose the Administrator from among the candidates proposed by the Company. Any submission or selection of the Administrator by either the Company or the Offices shall be made without unlawful discrimination against any person or class of persons. The Offices and the Company will use their best efforts to complete the selection process within thirty (30) calendar days of when the candidates have been submitted to the Offices.

18. The Company agrees that it will not employ or be affiliated with the Administrator for a period of not less than two years from the date on which the Administrator's term expires. Nor will the Company discuss with the Administrator the possibility of further employment or affiliation during the Administrator's term. Upon agreement by the parties, this prohibition will not apply to other claims administration responsibilities that the Administrator may undertake in connection with resolutions with foreign or other domestic authorities.

19. Within five (5) business days of the Administrator being selected, the Company shall provide the Administrator with a list of all purchasers of the MicroCool surgical gowns from the Company between November 1, 2014 and January 15, 2015.

20. The Administrator shall provide written notice to all such purchasers of the process and procedure for submitting a claim for victim compensation. The Administrator shall send the initial notice 60 days after the effective date of this Agreement (or 30 days after the Administrator is selected, whichever is later), and a follow-up notice 60 days later.

21. Any purchaser that believes it is a victim entitled to compensation must submit a claim to the Administrator within one year of the Administrator being selected, pursuant to the process and procedure outlined by the Administrator in the written notice.

22. Any portion of the Victim Compensation Amount that (i) has not been paid out to victims within one year of the Administrator being selected and (ii) is not subject to a pending claim submitted to the Administrator, shall be paid into the Crime Victims Fund. Any portion of the Victim Compensation Amount that is subject to a pending claim submitted to the Administrator shall remain in escrow until the claim is fully resolved, after which the remaining funds, if any, shall be paid into the Crime Victims Fund. No portion of the Victim Compensation Amount shall revert to the Company.

Conditional Release from Liability

23. Subject to Paragraphs 29-33, the Offices agree, except as provided in this Agreement, that they will not bring any criminal or civil case against the Company relating to any of the conduct as described in the attached Statement of Facts or the Information filed pursuant to this Agreement. The Offices, however, may use any information related to the conduct described

in the attached Statement of Facts against the Company: (a) in a prosecution for perjury or obstruction of justice that was not part of the Offices' investigation; (b) in a prosecution for making a false statement that was not part of the Offices' investigation; (c) in a prosecution or other proceeding relating to any crime of violence; or (d) in a prosecution or other proceeding relating to a violation of any provision of Title 26 of the United States Code.

a. This Agreement does not provide any protection against prosecution for any future conduct by the Company.

b. In addition, this Agreement does not provide any protection against prosecution of any individuals, regardless of their affiliation with the Company.

Corporate Compliance Program

24. The Company represents that it has implemented and will continue to implement a compliance and ethics program designed, implemented, and enforced to prevent and detect violations of the FDCA and U.S. obstruction and fraud laws throughout its operations, including those of its subsidiaries, affiliates, agents, and joint ventures, and those of its contractors and subcontractors whose responsibilities relate to the Company's interactions with domestic government agencies (including the FDA), regulators, and its customers, as well as the Company's testing and labeling of its devices, including, but not limited to, the minimum elements set forth in Attachment C.

25. In order to address any deficiencies in its internal controls, policies, and procedures, the Company represents that it has undertaken, and will continue to undertake in the future, in a manner consistent with all of its obligations under this Agreement, a review of its existing internal controls, policies, and procedures regarding compliance with the FDCA and U.S. obstruction and

fraud laws, focusing on the Company's interactions with domestic government agencies (including the FDA), regulators, and its customers, as well as the Company's testing and labeling of its devices. Where necessary and appropriate, the Company agrees to adopt a new compliance program, or to modify its existing one, including internal controls, compliance policies, and procedures in order to ensure that it maintains an effective compliance program, including a system of internal controls, designed to effectively detect and deter violations of the FDCA and U.S. obstruction and fraud laws. The compliance program, including the internal controls system, will include, but not be limited to, the minimum elements set forth in Attachment C.

Corporate Compliance Reporting

26. The Company agrees that it will report to the Offices annually during the Term regarding remediation and implementation of the compliance measures described in Attachment C. These reports will be prepared in accordance with Attachment D.

Deferred Prosecution

27. In consideration of the undertakings agreed to by the Company herein, the Offices agree that any prosecution of the Company for the conduct set forth in the attached Statement of Facts or Information will be and hereby is deferred for the Term. To the extent there is conduct disclosed by the Company that is not set forth in the attached Statement of Facts or Information, such conduct will not be exempt from further prosecution and is not within the scope of or relevant to this Agreement.

28. The Offices further agree that if the Company fully complies with all of its obligations under this Agreement, the Offices will not continue the criminal prosecution against the Company described in Paragraph 1 and, at the conclusion of the Term, this Agreement shall

expire. Six months after the Agreement's expiration, the Offices shall seek dismissal with prejudice of the Information filed against the Company described in Paragraph 1, and agree not to file charges in the future against the Company based on the conduct described in this Agreement, the attached Statement of Facts, or the Information. If, however, the Offices determine during this six-month period that the Company breached the Agreement during the Term, as described in Paragraphs 29-33, the Offices' ability to extend the Term, as described in Paragraph 3, or to pursue other remedies, including those described in Paragraphs 29-33, remains in full effect.

Breach of the Agreement

29. If, during the Term, (a) the Company commits any felony under U.S. federal law; (b) the Company provides in connection with this Agreement deliberately false, incomplete, or misleading information, including in connection with its disclosure of information about individual culpability; (c) the Company or its subsidiaries and affiliates fail to cooperate as set forth in Paragraphs 5 and 6 of this Agreement; (d) the Company fails to implement a compliance program as set forth in Paragraphs 24-25 of this Agreement and Attachment C; or (e) the Company and its subsidiaries and affiliates otherwise fail to completely perform or fulfill each of their obligations under the Agreement, regardless of whether the Offices become aware of such a breach after the Term is complete, the Company and its subsidiaries and affiliates shall thereafter be subject to prosecution for any federal criminal violation of which the Offices have knowledge, including, but not limited to, the charges in the Information described in Paragraph 1, which may be pursued by the Offices in the United States District Court for the Northern District of Texas or any other appropriate venue. Determination of whether the Company has breached the Agreement and whether to pursue prosecution of the Company and its subsidiaries and affiliates shall be in the

Offices' sole discretion. Any such prosecution may be premised on information provided by the Company, its subsidiaries and affiliates, or their personnel. Any such prosecution relating to the conduct described in the attached Statement of Facts or relating to conduct known to the Offices prior to the date on which this Agreement was signed that is not time-barred by the applicable statute of limitations on the date of the signing of this Agreement may be commenced against the Company, or its subsidiaries and affiliates, notwithstanding the expiration of the statute of limitations, between the signing of this Agreement and the expiration of the Term plus one year. Thus, by signing this Agreement, the Company agrees that the statute of limitations with respect to any such prosecution that is not time-barred on the date of the signing of this Agreement shall be tolled for the Term plus one year. In addition, the Company agrees that the statute of limitations as to any violation of U.S. federal law that occurs during the Term will be tolled from the date upon which the violation occurs until the earlier of the date upon which the Offices are made aware of the violation or the duration of the Term plus five years, and that this period shall be excluded from any calculation of time for purposes of the application of the statute of limitations.

30. In the event the Offices determine that the Company has breached this Agreement, the Offices agree to provide the Company with written notice of such breach prior to instituting any prosecution resulting from such breach. Within thirty days of receipt of such notice, the Company shall have the opportunity to respond to the Offices in writing to explain the nature and circumstances of such breach, as well as the actions the Company has taken to address and remediate the situation, which explanation the Offices shall consider in determining whether to pursue prosecution of the Company.

31. In the event that the Offices determine that the Company has breached this Agreement: (a) all statements made by or on behalf of the Company or its subsidiaries and affiliates to the Offices or to the Court, including the attached Statement of Facts, and any testimony given by the Company or its subsidiaries and affiliates before a grand jury, a court, or any tribunal, or at any legislative hearings, whether prior or subsequent to this Agreement, and any leads derived from such statements or testimony, shall be admissible in evidence in any and all criminal proceedings brought by the Offices against the Company or its subsidiaries and affiliates; and (b) the Company or its subsidiaries and affiliates shall not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, Section 1B1.1(a) of the USSG, or any other federal rule that any such statements or testimony made by or on behalf of the Company prior or subsequent to this Agreement, or any leads derived therefrom, should be suppressed or are otherwise inadmissible. The decision whether conduct or statements of any current director, officer, or employee, or any person acting on behalf of, or at the direction of, the Company or its subsidiaries and affiliates will be imputed to the Company for the purpose of determining whether the Company has violated any provision of this Agreement shall be in the sole discretion of the Offices.

32. The Company acknowledges that the Offices have made no representations, assurances, or promises concerning what sentence may be imposed by the Court if the Company breaches this Agreement and this matter proceeds to judgment. The Company further acknowledges that any such sentence is solely within the discretion of the Court and that nothing in this Agreement binds or restricts the Court in the exercise of such discretion.

33. On the date that the period of deferred prosecution specified in this Agreement expires, the Company, by the Chief Executive Officer of the Company and the Chief Financial Officer of the Company, will submit the certification set forth in Attachment E and certify to the Offices that the Company has met its disclosure obligations pursuant to Paragraph 6 of this Agreement. Each certification will be deemed a material statement and representation by the Company to the executive branch of the United States for purposes of Title 18, United States Code, Sections 1001 and 1519, and it will be deemed to have been made in the judicial district in which this Agreement is filed.

Sale, Merger, or Other Change in Corporate Form of the Company

34. Except as may otherwise be agreed by the parties in connection with a particular transaction, the Company agrees that in the event that, during the Term, it undertakes any change in corporate form, including if it sells, merges, or transfers business operations that are material to the Company's operations, or to the operations of any subsidiaries or affiliates involved in the conduct described in the attached Statement of Facts, as they exist as of the date of this Agreement, whether such sale is structured as a sale, asset sale, merger, transfer, or other change in corporate form, it shall include in any contract for sale, merger, transfer, or other change in corporate form a provision binding the purchaser, or any successor in interest thereto, to the obligations described in this Agreement. The purchaser or successor in interest must also agree in writing that the Offices' ability to breach under this Agreement is applicable in full force to that entity. The Company agrees that the failure to include these provisions in the transaction will make any such transaction null and void. The Company shall provide notice to the Offices at least thirty (30) days prior to undertaking any such sale, merger, transfer, or other change in corporate form. The Offices

shall notify the Company prior to such transaction (or series of transactions) if they determine that the transaction(s) will have the effect of circumventing or frustrating the enforcement purposes of this Agreement. At any time during the Term the Company engages in a transaction(s) that has the effect of circumventing or frustrating the enforcement purposes of this Agreement, the Offices may deem it a breach of this Agreement pursuant to Paragraphs 29-33 of this Agreement. Nothing herein shall restrict the Company from indemnifying (or otherwise holding harmless) the purchaser or successor in interest for penalties or other costs arising from any conduct that may have occurred prior to the date of the transaction, so long as such indemnification does not have the effect of circumventing or frustrating the enforcement purposes of this Agreement, as determined by the Offices.

Public Statements by the Company

35. The Company expressly agrees that it shall not, through present or future attorneys, officers, directors, employees, agents, or any other person authorized to speak for the Company make any public statement, in litigation or otherwise, contradicting the acceptance of responsibility by the Company set forth above or the facts described in the attached Statement of Facts. Any such contradictory statement shall, subject to cure rights of the Company described below, constitute a breach of this Agreement, and the Company thereafter shall be subject to prosecution as set forth in Paragraphs 29-33 of this Agreement. The decision whether any public statement by any such person contradicting a fact contained in the attached Statement of Facts will be imputed to the Company for the purpose of determining whether it has breached this Agreement shall be at the sole discretion of the Offices. If the Offices determine that a public statement by any such person contradicts, in whole or in part, a statement contained in the attached Statement of Facts,

the Offices shall so notify the Company, and the Company may avoid a breach of this Agreement by publicly repudiating such statement(s) within five business days after notification. The Company shall be permitted to raise defenses and to assert affirmative claims in other proceedings relating to the matters set forth in the attached Statement of Facts provided that such defenses and claims do not contradict, in whole or in part, a statement contained in the attached Statement of Facts. This Paragraph does not apply to any statement made by any present or former officer, director, employee, or agent of the Company in the course of any criminal, regulatory, or civil case initiated against such individual, unless such individual is speaking on behalf of the Company.

36. The Company agrees that if it, or any of its direct or indirect subsidiaries or affiliates, issues a press release or holds any press conference in connection with this Agreement, the Company shall first consult with the Offices to determine (a) whether the text of the release or proposed statements at the press conference are true and accurate with respect to matters between the Offices and the Company; and (b) whether the Offices have any objection to the release.

37. The Offices agree, if requested to do so, to bring to the attention of law enforcement and regulatory authorities the facts and circumstances relating to the nature of the conduct underlying this Agreement, including the nature and quality of the Company's cooperation and remediation. By agreeing to provide this information to such authorities, the Offices are not agreeing to advocate on behalf of the Company, but rather are agreeing to provide facts to be evaluated independently by such authorities.

Limitations on Binding Effect of the Agreement

38. This Agreement is binding on the Company, the Fraud Section, the CPB and the USAO-NDTX, but specifically does not bind any other component of the United States

Department of Justice, other federal agencies, or any state, local or foreign law enforcement or regulatory agencies, or any other authorities, although the Offices will bring the cooperation of the Company and its compliance with its other obligations under this Agreement to the attention of such agencies and authorities if requested to do so by the Company.

Notice

39. Any notice to the Offices under this Agreement shall be given by personal delivery, or overnight delivery by a recognized delivery service, addressed to the following:

a. Chief of the Market Integrity and Major Frauds Unit and Chief of the Strategy, Policy, and Training Unit, United States Department of Justice, Criminal Division, Fraud Section, 1400 New York Avenue N.W., Washington, D.C., 20005;

b. Director, Consumer Protection Branch, United States Department of Justice, Civil Division, 450 Fifth Street, N.W., Room 6400-South, Washington, D.C. 20001; and

c. Criminal Division Chief, United States Attorney's Office, Northern District of Texas, 1100 Commerce, Suite 300, Dallas, Texas 75242.

Any notice to the Company under this Agreement shall be given by personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail, addressed to Avanos General Counsel. Notice shall be effective upon actual receipt by the Fraud Section/CPB/USAO-NDTX or the Company. Notice shall also be given by email to any email addresses provided by the Offices or the Company.

Complete Agreement

40. This Agreement, including its attachments, sets forth all the terms of the agreement between the Company, the Fraud Section, CPB and the USAO-NDTX. No amendments, modifications, or additions to this Agreement shall be valid unless they are in writing and signed by the Fraud Section, CPB the USAO-NDTX, the attorneys for the Company, and duly authorized representatives of the Company.

* * *

AGREED:

FOR AVANOS MEDICAL, INC.:

Date: 7/6/2021 By: _____

Joseph F. Woody
Chief Executive Officer
AVANOS MEDICAL, INC.

Date: _____ By: _____

Joshua S. Levy
Laura G. Hoey
Ropes & Gray LLP
Counsel for Avanos Medical, Inc.

AGREED:

FOR AVANOS MEDICAL, INC.:

Date: _____ By: _____

Joseph F. Woody
Chief Executive Officer
AVANOS MEDICAL, INC.

Date: 7-6-21 By: _____

Joshua S. Levy
Laura G. Hoey
Ropes & Gray LLP
Counsel for Avanos Medical, Inc.

AGREED:

FOR THE UNITED STATES DEPARTMENT OF JUSTICE:

Date: July 6, 2021

GUSTAV W. EYLER
Director, Consumer Protection Branch
Civil Division

By: Allan Gordus /JPS
Allan Gordus
Senior Litigation Counsel

David Gunn
Max Goldman
Trial Attorneys

Date: July 6, 2021

JOSEPH S. BEEMSTERBOER
Acting Chief, Fraud Section
Criminal Division

By: John Scanlon
John "Fritz" Scanlon
Trial Attorney

Date: July 6, 2021

PRERAK SHAH
Acting United States Attorney
Northern District of Texas

By: Katherine Miller
Katherine Miller
Assistant U.S. Attorney

COMPANY OFFICER'S CERTIFICATE

I have read the Agreement and carefully reviewed its terms and attachments with inside and outside counsel for Avanos Medical, Inc. (the "Company"). I understand the terms of the Agreement and voluntarily agree, on behalf of the Company, to each of its terms. Before signing the Agreement, I consulted inside and outside counsel for the Company. Counsel fully advised me of the rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into this Agreement.

I have carefully reviewed the terms of this Agreement with the Board of Directors of the Company. I have advised and caused outside counsel for the Company to advise the Board of Directors fully of the rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into the Agreement.

No promises or inducements have been made other than those contained in the Agreement. Furthermore, no one has threatened or forced me, or to my knowledge any person authorizing the Agreement on behalf of the Company, in any way to enter into the Agreement. I am also satisfied with outside counsels' representation in this matter. I certify that I am the Chief Executive Officer for the Company and that I have been duly authorized by the Company to execute the Agreement on behalf of the Company.

Date: 7/6/2021 By: _____

Joseph F. Woody
Chief Executive Officer
AVANOS MEDICAL, INC.

CERTIFICATE OF COUNSEL FOR AVANOS MEDICAL, INC.

I am counsel for Avanos Medical, Inc. (the "Company") in the matter covered by this Agreement. In connection with such representation, I have examined relevant Company documents and have discussed them with the Company's Board of Directors. Based on my review of the foregoing materials and discussions, I am of the opinion that the representative of the Company has been duly authorized to enter into the Agreement on behalf of the Company and that the Agreement has been duly and validly authorized, executed, and delivered on behalf of the Company and is a valid and binding obligation of the Company. Further, I have carefully reviewed the terms of the Agreement with the Board of Directors and the Chief Executive Officer. I have fully advised them of the rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions and of the consequences of entering into the Agreement. To my knowledge, the decision of the Company to enter into the Agreement, based on the authorization of the Board of Directors, is an informed and voluntary one.

Date: 7-6-21

By: Joshua S. Levy by Sgh
Laura G. Hoey

Joshua S. Levy
Laura G. Hoey
ROPES & GRAY LLP
Counsel for Avanos Medical, Inc.

ATTACHMENT A

STATEMENT OF FACTS

1. The following Statement of Facts is incorporated by reference as part of the Deferred Prosecution Agreement (the "Agreement") between the United States Department of Justice, Criminal Division, Fraud Section (the "Fraud Section"), the United States Department of Justice, Civil Division, Consumer Protection Branch (the "CPB") and the United States Attorney's Office for the Northern District of Texas (the "USAO-NDTX") (collectively, the "Offices") and Avanos Medical, Inc. ("Avanos" or the "Company"). The Company hereby agrees and stipulates that the following information is true and accurate. The Company admits, accepts, and acknowledges that it is responsible for the acts of its officers, directors, employees, and agents as set forth below. Should the Offices pursue the prosecution that is deferred by this Agreement, the Company agrees that it will neither contest the admissibility of, nor contradict, this Statement of Facts in any such proceeding. The following facts establish beyond a reasonable doubt the charge set forth in the Information attached to this Agreement:

At all times relevant to this Statement of Facts, with all dates being approximate and inclusive:

Relevant Individuals and Entities

2. Avanos Medical, Inc. ("Avanos") was a U.S.-based multinational corporation that was created on October 31, 2014, when Company 1 spun off its health care business unit into a separate, publicly traded company that began trading on the New York Stock Exchange on November 3, 2014 as "Halyard Health, Inc." Avanos (then-known as "Halyard Health, Inc.") engaged in, among other things, the design, manufacture and sale of medical devices, including

disposable surgical gowns. Avanos marketed and sold such surgical gowns directly to hospitals and other health care providers (and through third-party distribution channels) throughout the United States and abroad. On April 30, 2018, Avanos (then known as "Halyard Health, Inc.") sold to a third-party company that had no involvement in the conduct discussed herein all assets related to the Company's Surgical and Infection Prevention unit, including the name "Halyard Health, Inc." and all assets related to the Company's surgical gown business. In June 2018, the Company changed its name from Halyard Health, Inc. to Avanos Medical, Inc.

3. Employee 1 was employed as a Technical Leader in the Research and Development department of Avanos from the time when the Company was spun off from Company 1 through the period relevant to this Statement of Facts. Prior to his employment with Avanos, Employee 1 was employed as a Research Scientist and then a Senior Specialist in the Research and Engineering department of Company 1 from approximately October 2004 until the spin off in October 2014.

4. Employee 2 was employed as a Quality Engineer in Technical Quality and Quality Technical Leader at Avanos from the time when the Company was spun off from Company 1 through the period relevant to this Statement of Facts. Prior to her employment with Avanos, Employee 2 was employed as a Quality Specialist in Sterility Assurance at Company 1 from approximately November 2012 until the spin off in October 2014.

5. Agent 1 was an agent of Avanos who was hired as a Technical Writer through a staffing agency in approximately July 2015. Agent 1 remained in this position until voluntarily leaving the Company in September 2016.

AAMI Level 4 Standard

6. In the United States, surgical gowns are subject to regulation by the United States Food and Drug Administration ("FDA"), the federal agency responsible for protecting the health and safety of the American public by enforcing the Federal Food, Drug, and Cosmetic Act ("FDCA").

7. In or about 2004, the FDA recognized the American National Standards Institute ("ANSI") and Association for the Advancement of Medical Instrumentation ("AAMI") system of classification for surgical gowns, known as the "ANSI/AAMI PB70 standard." The ANSI/AAMI PB70 standard, first established in or about 2003, described the barrier protection levels (ranging from 1 to 4) of surgical gowns and specified the testing necessary to verify each level of protection.

8. Under the ANSI/AAMI PB70 standard, the highest protection level for surgical gowns—"AAMI Level 4"—was reserved for gowns intended for surgeries and other high risk medical procedures on patients suspected of having infectious diseases. Level 4 surgical gowns were intended to protect both health care workers and patients from potential blood-borne pathogens and exposure to such diseases.

9. To qualify for an AAMI Level 4 rating under the ANSI/AAMI PB70 standard, a surgical gown needed to pass certain tests conducted on all critical zones—the areas on a surgical gown where direct contact with blood, body fluids, and other potentially infectious materials were mostly likely to occur. To establish compliance with the standard, a surgical gown needed to demonstrate blood-borne pathogen resistance in each of those zones by preventing fluids from penetrating the gown. The sleeve seam was a critical zone on surgical gowns.

MicroCool Surgical Gowns

10. Company 1 developed the "MicroCool Breathable High-Performance Surgical Gown" (hereinafter, "MicroCool gown") as "sterile, single use surgical apparel intended to be worn by healthcare professionals to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate matter."

11. On or about December 23, 2010, the FDA notified Company 1 that it could legally market and sell MicroCool gowns as AAMI Level 4 gowns. Pursuant to FDA regulations, however, Company 1 was required to monitor the MicroCool gown's continuous compliance with the requirements of AAMI Level 4 in the 2003 ANSI/AAMI PB70 standard.

12. Employee 1 contributed to the development of the MicroCool gown and served as an expert on the gown's construction and features at both Company 1 and later Avanos. In that role, Employee 1 participated in efforts to improve the MicroCool gown's performance and profitability, worked closely with Honduras plant workers on sampling and testing the gowns, provided MicroCool data and information to the Company's marketing and sales divisions, in certain circumstances, and acted as a Company representative to certain hospital customers by providing assurances about the MicroCool gown's compliance and protection level.

Problems with the MicroCool Gown Sleeve Seam

A. The Flawed Bar-Sealing Manufacturing Process

13. Company 1 manufactured the gown's fabric in the United States. Company 1 and then later Avanos converted the fabric into finished gowns at a plant in Honduras. As part of the finishing process, Company 1 and then later Avanos used Thermal Impulse Sealers, also known as "bar sealer machines," to seal the sleeve seams on MicroCool gowns.

14. The bar sealer machines were highly variable and unstable. Operators of the machines were unable to find any fixed time and temperature control settings that consistently resulted in properly sealed seams. As a result, Company 1 and later Avanos were unable to validate the bar sealer machines at fixed settings. The plant workers in Honduras instead used a visual inspection process to try to ensure that all seams were properly sealed on approximately 80,000 gowns (160,000 sleeves) per week. Improperly sealed sleeve seams could develop cracks or holes in the seams or come apart.

15. As a contributor to the development of the MicroCool gown and an expert on the MicroCool gowns' construction and features, Employee 1 knew that the bar sealer operators were unable to find any fixed controls and settings on the sealers that consistently resulted in properly sealed sleeve seams on the gowns.

B. Failed Testing

16. To monitor the MicroCool gown's compliance with the AAMI Level 4 standard after receiving the FDA's clearance, Company 1 implemented (and Avanos continued) a monthly, liquid-penetration monitoring test that measured the protective quality of each critical zone of the gown, including the sleeve seams. Beginning in or about 2012 and continuing through in or about 2015, the MicroCool gowns repeatedly failed the monthly liquid-penetration monitoring test at the sleeve seam critical zone. Employee 1 knew that the MicroCool gowns were failing these monthly monitoring tests at the sleeve seam.

17. In or about 2012, ANSI and AAMI revised the ANSI/AAMI PB70 standard. The revisions required a more rigorous testing of gowns labeled as AAMI Level 4. In response to this change, Company 1 established an initiative to test the MicroCool gowns under the revised and

more rigorous 2012 ANSI/AAMI PB70 standard. The MicroCool gowns failed several of the viral-penetration tests that were performed on the gowns' sleeve seams in connection with this initiative to test the MicroCool gowns to the more rigorous 2012 ANSI/AAMI PB70 standard. Employee 1 knew that the MicroCool gowns were failing these viral-penetration tests at the sleeve seam.

C. Efforts to Fix the Flawed Bar-Sealing Manufacturing Process

18. In or about early 2013, Employee 1 was assigned responsibility for a Corrective and Preventive Action ("CAPA") intended to find a solution to the problems with the MicroCool gowns' sleeve seams.

19. As a part of the investigation triggered by the CAPA, Employee 1, along with Company 1 managers, determined that the solution was to replace the bar sealer machines, which could not be validated, with new and different machines in the Honduras manufacturing plant, which they believed could be validated. The new machines were called "Continuous Band Sealers" (hereinafter, "band sealers").

20. Although the decision to replace the bar sealer machines with band sealers was made in or about early 2013, the band sealers were not used to seal MicroCool gowns' sleeve seams until mid-January 2015.

21. Employee 1 made statements about the replacement of the bar sealer machines with the band sealers, including on or around September 9, 2013, Employee 1 wrote to other employees of Company 1 that "[s]ealing technology is not a new gown opportunity – it's a manufacturing upgrade to our current sleeve seaming technology used for AAMI-4 MicroCool and Ultra AAMI-3 gowns to be in compliance with AAMI claims. It's a compliance remediation project."

22. On or around September 25, 2014, Employee 1 wrote to other employees of Company 1 that "[m]y position is that [the change in the manufacturing method for sealing the MicroCool sleeve seams] is not a design change per the criteria in 5.10. The established attributes/requirements addressed by this Change Control were that the sleeve seam was not meeting the PB70 Level 4 requirement of ASTM-1671, which is now being met with the change."

Avanos, through Employee 1, Introduced
Misbranded MicroCool Gowns into Interstate Commerce with the Intent to Defraud

23. From on or about November 1, 2014, through on or about January 15, 2015, Avanos, through Employee 1, with the intent to defraud and mislead, knowingly introduced and caused the introduction into interstate commerce medical devices, namely MicroCool surgical gowns, that were misbranded within the meaning of Title 21, United States Code, Section 352(a), in that the labeling of the gowns as "AAMI Level 4" under the 2012 ANSI/AAMI PB70 standard was false and misleading.

24. At all times relevant to this Statement of Facts, Employee 1 was acting within the scope of his employment and with the intention, at least in part, to benefit Avanos.

25. Employee 1 helped other Avanos employees and agents devise marketing materials, presentations, and letter communications to customers about the MicroCool gowns' purported classification as AAMI Level 4.

26. Employee 1 also made direct misrepresentations about the MicroCool gowns' purported high quality and compliance with the requirements of AAMI Level 4 under the 2012 ANSI/AAMI PB70 standard in meetings and phone conferences with hospital customers.

27. For example, in or about November 2014, certain hospitals and other potential purchasers of MicroCool gowns requested that Avanos provide assurances that its MicroCool

gowns met the AAMI Level 4 standard in all critical zones. The hospitals and other potential purchasers stated that the reasons for such requests included (1) the filing of a class action lawsuit alleging that the MicroCool gowns were defective and/or (2) the need to obtain surgical gowns for use in responding to the outbreak of the disease caused by the Ebola virus.

28. Employee 1 was part of a team that coordinated the response to these requests by providing assurances to customers over the phone and contributing to letters sent by an Avanos employee to these customers stating that the MicroCool gowns met AAMI Level 4 standards.

29. Employee 1 reviewed and contributed to four such letters sent to customers in November 2014 that falsely claimed that the MicroCool gowns met the requirements of the revised and more rigorous 2012 ANSI/AAMI PB70 standard—a standard that Employee 1 knew the gowns had never met. To support this claim, Employee 1 inserted into the letters AAMI Level 4 test results for the MicroCool sleeve seams that he had manipulated by, among other things, pre-selecting and pre-testing the sleeve seams used in the testing.

30. From on or about November 1, 2014, through on or about January 15, 2015, Avanos continued to use the bar sealer machines to manufacture hundreds of thousands of misbranded MicroCool gowns that were labeled as complying with the 2012 ANSI/AAMI PB70 standard for classification as AAMI Level 4.

31. From on or about November 1, 2014, through on or about January 15, 2015, Avanos sold approximately $8,939,000 worth of misbranded MicroCool gowns labeled AAMI Level 4 to customers all over the United States and abroad.

Alteration and Falsification of Records During FDA Inspection

32. In or about July 2016, the FDA conducted a for-cause inspection of Avanos's surgical gown business. As part of that for-cause inspection, FDA investigators requested that Avanos create a chart summarizing product stability tests conducted on the MicroCool gowns, as well as summaries of product stability tests conducted on other surgical gowns manufactured and sold by Avanos.

33. Employee 2 was part of the group who assisted in fulfilling the FDA investigators' request for a chart summarizing stability tests conducted on the MicroCool gowns and other surgical gowns manufactured and sold by Avanos.

34. Employee 2 directed Agent 1 to assist in preparing the summaries of the stability test results, which were put in Excel spreadsheet format. Each stability testing summary spreadsheet contained information regarding dozens of stability testing results.

35. Agent 1 or another employee of Avanos prepared the initial drafts of each stability testing summary spreadsheet. These initial drafts contained testing results for failed stability tests that were highlighted in red and labeled "fail" or "inconclusive." These initial drafts also showed that certain stability tests were not performed on the gowns. For such not-performed tests, the results were labeled "not tested" and highlighted in red.

36. Employee 2 made multiple false entries in three separate testing summary spreadsheets that were requested by the FDA investigators. These false entries included but were not limited to the following: changing (i) notations for failing or not-performed test results that were highlighted in red and labeled "fail," "not tested" or "inconclusive" to (ii) notations for test results that were highlighted in green and labeled "pass" or "inconclusive," along with references

to associated remediation reports. The row labeled "Pass/Fail" in the final versions of each testing summary spreadsheet contained only results that were highlighted in green and labeled "pass" or "inconclusive." The term "fail" did not appear in the row labeled "Pass/Fail" in the final version of any of the three testing summary spreadsheets requested by the investigators, even though the gowns failed many of the product stability tests performed.

37. Employee 2 informed Agent 1 in July 2016 that the purpose for making these changes to the stability testing summary spreadsheets was to avoid tipping off the investigators that there were failures of stability tests performed on the surgical gowns.

38. For each of the test result notations that Employee 2 changed in the manner discussed above, Employee 2 inserted a reference to a remediation report in which the failing or not-performed stability tests were discussed. Employee 2 instructed Agent 1 to ensure that all the referenced remediation reports contained some rationale for the failed or not-performed stability tests.

39. On at least one occasion, Agent 1 copied and pasted a rationale from (a) a remediation report addressing one type of stability test failure related to the MicroCool surgical gown into (b) a remediation report referenced in one of the stability testing summary spreadsheets requested by the FDA investigators that addressed a different type of stability test failure related to a different type of surgical gown. Agent 1 did not make any effort to ensure that the rationale was valid or true for the latter type of stability test failure and surgical gown. By doing so, Agent 1 made false entries in the remediation report referenced in the stability testing summary spreadsheet requested by the FDA investigators.

40. At all times relevant to this Statement of Facts, Employee 2 and Agent 1 were acting within the scope of their employment and with the intention, at least in part, to benefit Avanos.

* * *

ATTACHMENT B

CERTIFICATE OF CORPORATE RESOLUTIONS

WHEREAS, Avanos Medical, Inc. (the "Company") has been engaged in discussions with the United States Department of Justice, Criminal Division, Fraud Section (the "Fraud Section"), the United States Department of Justice, Civil Division, Consumer Protection Branch (the "CPB") and the United States Attorney's Office for the Northern District of Texas (the "USAO-NDTX") (collectively, the "Offices") regarding issues arising in relation to the Offices' investigation of violations of the Federal Food, Drug, and Cosmetic Act ("FDCA") and U.S. obstruction and fraud laws by certain of the Company's employees;

WHEREAS, in order to resolve such discussions, it is proposed that the Company enter into a deferred prosecution agreement with the Offices (the "Agreement");

WHEREAS, the Company's Senior Vice President, General Counsel (Interim), and Corporate Secretary, S. Ross Mansbach, together with outside counsel for the Company, have advised the Board of Directors of the Company of its rights, possible defenses, the Sentencing Guidelines' provisions, and the consequences of entering into such agreement with the Offices;

Therefore, the Board of Directors has RESOLVED that:

1. The Company (a) acknowledges the filing of the one-count Information charging the Company with a felony violation of the FDCA, namely the introduction into interstate commerce of a device that is misbranded, in violation of Title 21, United States Code, Sections 331(a), 333(a)(2) and 352(a); (b) waives indictment on such charge and enters into a deferred prosecution agreement with the Offices; and (c) agrees to pay a Total Criminal Monetary Amount of $22,228,000 under the Agreement with respect to the conduct described in the Information;

2. The Company accepts the terms and conditions of the Agreement, including, but not limited to, (a) a knowing waiver of its rights to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, Title 18, United States Code, Section 3161, and Federal Rule of Criminal Procedure 48(b); and (b) a knowing waiver for purposes of the Agreement and any charges by the United States arising out of the conduct described in the Statement of Facts attached to the Agreement of any objection with respect to venue and consents to the filing of the Information, as provided under the terms of the Agreement, in the United States District Court for the Northern District of Texas; and (c) a knowing waiver of any defenses based on the statute of limitations for any prosecution relating to the conduct described in the Statement of Facts attached to the Agreement and Information or relating to conduct known to the Offices prior to the date on which the Agreement is signed that is not time-barred by the applicable statute of limitations on the date of the signing of this Agreement;

3. The Chief Executive Officer of the Company, Joseph F. Woody, is hereby authorized, empowered and directed, on behalf of the Company, to execute the Agreement substantially in such form as reviewed by this Board of Directors at this meeting with such changes as the Chief Executive Officer of the Company, Joseph F. Woody, may approve;

4. The Chief Executive Officer of the Company, Joseph F. Woody, is hereby 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 resolutions; and

5. All of the actions of the Chief Executive Officer of the Company, Joseph F. Woody, which actions would have been authorized by the foregoing resolutions 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.

Date: 7/6/21 By: _____

S. Ross Mansbach
Corporate Secretary
AVANOS MEDICAL, INC.

ATTACHMENT C

CORPORATE COMPLIANCE PROGRAM

In order to address any deficiencies in its internal controls, compliance program, policies, and procedures relating to violations of the Federal Food, Drug, and Cosmetic Act ("FDCA") and U.S. obstruction and fraud laws in connection with interactions with any domestic government agency (including the FDA), regulator, or any of its customers, Avanos Medical, Inc. (the "Company") agrees to continue to conduct, in a manner consistent with all of its obligations under this Agreement, appropriate reviews of its existing internal controls, policies, and procedures.

Where necessary and appropriate, the Company agrees to adopt a new or to modify its existing compliance program, including internal controls, compliance policies, and procedures in order to ensure that it maintains an effective compliance program that is designed, implemented, and enforced to effectively deter and detect violations of the FDCA and U.S. obstruction and fraud laws. At a minimum, this should include, but not be limited to, the following elements to the extent they are not already part of the Company's existing internal controls, compliance program, policies, and procedures:

Commitment to Compliance

1. The Company will ensure that its directors and senior management provide strong, explicit, and visible support and commitment to its corporate policy against violations of the FDCA and U.S. obstruction and fraud laws and its compliance codes, and demonstrate rigorous adherence by example. The Company will also ensure that middle management, in turn, reinforces those

standards and encourages employees to abide by them. The Company will create and foster a culture of ethics and compliance with the law in its day-to-day operations.

Policies and Procedures

2. The Company will develop and promulgate clearly articulated and visible corporate policies against violations of the FDCA and U.S. obstruction and fraud laws, which policies shall be memorialized in a written compliance code.

3. The Company will develop and promulgate compliance policies and procedures designed to reduce the prospect of violations of the FDCA and U.S. obstruction and fraud laws and the Company's compliance code, and the Company will take appropriate measures to encourage and support the observance of ethics and compliance policies and procedures against violation of the FDCA and U.S. obstruction and fraud laws by personnel at all levels of the Company. These policies and procedures shall apply to all directors, officers, and employees and, where necessary and appropriate, outside parties acting on behalf of the Company, including, but not limited to, agents, consultants, and joint venture partners (collectively, "agents and business partners"). The Company shall notify all employees that compliance with the policies and procedures is the duty of individuals at all levels of the Company.

Periodic Risk-Based Review

4. The Company will develop these compliance policies and procedures on the basis of a periodic risk assessment addressing the individual circumstances of the Company.

5. The Company shall review its compliance policies and procedures regarding the FDCA and U.S. obstruction and fraud laws no less than annually and update them as appropriate

to ensure their continued effectiveness, taking into account relevant developments in the field and evolving industry standards.

Proper Oversight and Independence

6. The Company will assign responsibility to one or more senior corporate executives of the Company for the implementation and oversight of the Company's compliance code, policies, and procedures regarding the FDCA and U.S. obstruction and fraud laws. Such corporate official(s) shall have the authority to report directly to independent monitoring bodies, including internal audit, the Company's Board of Directors, or any appropriate committee of the Board of Directors, and shall have an adequate level of stature and autonomy from management as well as sufficient resources and authority to maintain such autonomy.

Training and Guidance

7. The Company will implement mechanisms designed to ensure that its compliance code, policies, and procedures regarding the FDCA and U.S. obstruction and fraud laws are effectively communicated to all directors, officers, employees, and, where necessary and appropriate, agents and business partners. These mechanisms shall include: (a) periodic training for all directors and officers, all employees in positions of leadership or trust, any positions that require such training (*e.g.*, internal audit, sales, legal, compliance, finance), and, where necessary and appropriate, agents and business partners; and (b) corresponding certifications by all such directors, officers, employees, agents and business partners, certifying compliance with the training requirements. The Company will conduct training in a manner tailored to the audience's size, sophistication, or subject matter expertise and, where appropriate, will discuss prior compliance incidents.

8. The Company will maintain, or where necessary establish, an effective system for providing guidance and advice to directors, officers, employees, and, where necessary and appropriate, agents and business partners, on complying with the Company's compliance code, policies, and procedures regarding the FDCA and U.S. obstruction and fraud laws, including when they need advice on an urgent basis.

Internal Reporting and Investigation

9. The Company will maintain, or where necessary establish, an effective system for internal and, where possible, confidential reporting by, and protection of, directors, officers, employees, and, where appropriate, agents and business partners concerning violations of the FDCA and U.S. obstruction and fraud laws or the Company's compliance code, policies, and procedures regarding the FDCA and U.S. obstruction and fraud laws.

10. The Company will maintain, or where necessary establish, an effective and reliable process with sufficient resources for responding to, investigating, and documenting allegations of violations of the FDCA and U.S. obstruction and fraud laws or the Company's compliance code, policies, and procedures regarding the FDCA and U.S. obstruction and fraud laws. The Company will handle the investigations of such complaints in an effective manner, including routing the complaints to proper personnel, conducting timely and thorough investigations, and following up with appropriate discipline where necessary.

Enforcement and Discipline

11. The Company will implement mechanisms designed to effectively enforce its compliance code, policies, and procedures, including appropriately incentivizing compliance and disciplining violations.

12. The Company will institute appropriate disciplinary procedures to address, among other things, violations of the FDCA and U.S. obstruction and fraud laws and the Company's compliance code, policies, and procedures regarding the FDCA and U.S. obstruction and fraud laws by the Company's directors, officers, and employees. Such procedures should be applied consistently and fairly, and in a manner consistent with the violation, regardless of the position held by, or perceived importance of, the director, officer, or employee. The Company shall implement procedures to ensure that where misconduct is discovered, reasonable steps are taken to remedy the harm resulting from such misconduct, and to ensure that appropriate steps are taken to prevent further similar misconduct, including assessing the internal controls, compliance code, policies, and procedures and making modifications necessary to ensure the overall compliance program regarding the FDCA and U.S. obstruction and fraud laws is effective.

Mergers and Acquisitions

13. The Company will develop and implement policies and procedures for mergers and acquisitions requiring that the Company conduct appropriate risk-based due diligence on potential new business entities, including appropriate due diligence regarding the FDCA and U.S. obstruction and fraud laws by legal, accounting, and compliance personnel.

14. The Company will ensure its compliance code, policies, and procedures regarding the FDCA and U.S. obstruction and fraud laws apply as quickly as is practicable to newly-acquired businesses or entities merged with the Company, and will promptly (a) train the directors, officers, employees, agents, and business partners consistent with Paragraphs 7 and 8; and (b) where warranted, conduct an audit of all newly acquired or merged businesses as quickly as is practicable concerning compliance with the FDCA and U.S. obstruction and fraud laws.

Monitoring, Testing, and Remediation

15. In order to ensure that its compliance program does not become stale, the Company will conduct periodic reviews and testing of its compliance code, policies, and procedures regarding the FDCA and U.S. obstruction and fraud laws designed to evaluate and improve their effectiveness in preventing and detecting violations of the FDCA and U.S. obstruction and fraud laws and the Company's code, policies, and procedures regarding the FDCA and U.S. obstruction and fraud laws, taking into account relevant developments in the field and evolving industry standards. The Company will ensure that compliance and control personnel have sufficient direct and indirect access to relevant sources of data to allow for timely and effective monitoring and/or testing. Based on such review and testing and its analysis of any prior misconduct, the Company will conduct a thoughtful root cause analysis and timely and appropriately remediate to address the root causes.

ATTACHMENT D

COMPLIANCE REPORTING REQUIREMENTS

Avanos Medical, Inc. (the "Company") agrees that it will report to the United States Department of Justice, Criminal Division, Fraud Section (the "Fraud Section"), the United States Department of Justice, Civil Division, Consumer Protection Branch (the "CPB") and the United States Attorney's Office for the Northern District of Texas (the "USAO-NDTX") (collectively, the "Offices") periodically, at no less than twelve-month intervals during a three-year term, regarding remediation and implementation of the compliance program and internal controls, policies, and procedures described in Attachment C. During this three-year period, the Company shall: (1) conduct an initial review and submit an initial report, and (2) conduct and prepare at least two (2) follow-up reviews and reports, as described below:

a. With respect to the initial review and report, after consultation with the Offices, the Company shall prepare the first written work plan within sixty (60) calendar days of the date this Agreement is executed, and the Offices shall provide comments within thirty (30) calendar days after receipt of the written work plan. With respect to each follow-up review and report, after consultation with the Offices, the Company shall prepare a written work plan within forty-five (45) calendar days of the submission of the prior report, and the Offices shall provide comments within thirty (30) calendar days after receipt of the written work plan. Any disputes between the Company and the Offices with respect to any written work plan shall be decided by the Offices in their sole discretion. All written work plans shall identify with reasonable specificity the activities the Company plans to undertake in execution of the enhanced self-reporting obligations.

b. By no later than one year from the date this Agreement is executed, the Company shall submit to the Offices a written report setting forth a complete description of its remediation efforts to date, its proposals reasonably designed to improve the Company's internal controls, policies, and procedures for ensuring compliance with the FDCA and U.S. obstruction and fraud laws, and the proposed scope of the subsequent reviews. The report shall be transmitted to the following:

i. Chief of the Market Integrity and Major Frauds Unit and Chief of the Strategy, Policy, and Training Unit, United States Department of Justice, Criminal Division, Fraud Section, 1400 New York Avenue N.W., Washington, D.C., 20005;

ii. Director, Consumer Protection Branch, United States Department of Justice, Civil Division, 450 Fifth Street, N.W., Room 6400-South, Washington, D.C. 20001; and

iii. Criminal Division Chief, United States Attorney's Office, Northern District of Texas, 1100 Commerce, Suite 300, Dallas, Texas 75242.

The Company may extend the time period for issuance of the report with prior written approval of the Offices.

c. The Company shall undertake at least two follow-up reviews, incorporating the Offices' views on the Company's prior reviews and reports, to further monitor and assess whether the Company's policies and procedures are reasonably designed to detect and prevent violations of the FDCA and U.S. obstruction and fraud laws.

c. The first follow-up review and report shall be completed by no later than one year after the initial review. The second follow-up review and report shall be completed by no later than one year after the completion of the preceding follow-up review. The final follow-up review and report shall be completed and delivered to the Offices no later than thirty days before the end of the Term.

d. The reports will likely include proprietary, financial, confidential, and competitive business information. Moreover, public disclosure of the reports could discourage cooperation, impede pending or potential government investigations and thus undermine the objectives of the reporting requirement. For these reasons, among others, the reports and the contents thereof 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 Offices determine in their sole discretion that disclosure would be in furtherance of the Offices' discharge of its duties and responsibilities or is otherwise required by law.

e. The Company may extend the time period for submission of any of the follow-up reports with prior written approval of the Offices.

ATTACHMENT E

CERTIFICATION

To: United States Department of Justice
Criminal Division, Fraud Section
Attention: Chief of the Fraud Section

United States Department of Justice
Civil Division, Consumer Protection Branch
Attention: Director of the Consumer Protection Branch

United States Attorney's Office for the Northern District of Texas
Attention: Criminal Division Chief

Re: Deferred Prosecution Agreement Disclosure Certification

The undersigned certify, pursuant to Paragraph 33 of the Deferred Prosecution Agreement ("DPA") filed on July __, 2021 in the United States District Court for the Northern District of Texas, by and between the United States of America and Avanos Medical, Inc. (the "Company"), that undersigned are aware of the Company's disclosure obligations under Paragraph 6 of the DPA, and that the Company has disclosed to the United States Department of Justice, Criminal Division, Fraud Section (the "Fraud Section"), the United States Department of Justice, Civil Division, Consumer Protection Branch (the "CPB") and the United States Attorney's Office for the Northern District of Texas (the "USAO-NDTX") (collectively, the "Offices") any and all evidence or allegations of conduct required pursuant to Paragraph 6 of the DPA, which includes evidence or allegations of any violation of the Federal Food, Drug, and Cosmetic Act ("FDCA") or U.S. obstruction or fraud laws committed by the Company's employees and agents upon any domestic government agency (including the FDA), regulator, or any of the Company's customers ("Disclosable Information"). This obligation to disclose information extends to any and all

Disclosable Information that has been identified through the Company's compliance and controls program, whistleblower channel, internal audit reports, due diligence procedures, investigation process, or other processes. The undersigned further acknowledge and agree that the reporting requirements contained in Paragraph 6 and the representations contained in this certification constitute a significant and important component of the DPA and of the Offices' determination whether the Company has satisfied its obligations under the DPA.

The undersigned hereby certify that they are the Chief Executive Officer and the Chief Financial Officer of the Company, respectively, and that each has been duly authorized by the Company to sign this Certification on behalf of the Company.

This Certification shall constitute a material statement and representation by the undersigned and by, on behalf of, and for the benefit of, the Company to the executive branch of the United States for purposes of 18 U.S.C. § 1001, and such material statement and representation shall be deemed to have been made in the Northern District of Texas. This Certification shall also constitute a record, document, or tangible object in connection with a matter within the jurisdiction of a department and agency of the United States for purposes of 18 U.S.C. § 1519, and such record, document, or tangible object shall be deemed to have been made in the Northern District of Texas.

Date: _____ Name (Printed): _____

Name (Signed): _____
Chief Executive Officer
AVANOS MEDICAL, INC.

Date: _____ Name (Printed): _____

Name (Signed): _____
Chief Financial Officer
AVANOS MEDICAL, INC.