

## SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into among: (1) the United States of America, acting through the United States Attorney’s Office for the Eastern District of Pennsylvania, on behalf of (a) for the Medicare and Medicaid programs, the Office of Inspector General (“OIG-HHS”) of the U.S. Department of Health and Human Services (HHS), and (b) for the TRICARE program, the Defense Health Agency (“DHA”) (collectively the “United States”); (2) Medicea USA Inc. (“MUSAC”) and Medicea International (“MI”), (collectively “Medicea”); and (3) Dory Frain (“Relator”), through their authorized representatives. The United States, Medicea, and Relator are hereafter collectively referred to as “The Parties.”

### RECITALS

A. Medicea manufactures—and markets and sells within the United States and elsewhere, including in the Eastern District of Pennsylvania—medical devices used to treat spinal diseases, including scoliosis and other disorders requiring spinal fusion.

B. MI, the parent company of MUSAC, is headquartered in Lyon, France. MUSAC is headquartered in the State of New York.

C. The United States contends that Medicea caused claims to be submitted for payment to: (1) the Medicare Program (“Medicare”) (Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1), which provides health insurance for qualified persons age 65 or older and certain disabled persons; (2) the Medicaid Program (“Medicaid”) (42 U.S.C. §§ 1396-1396w-5), which provides health insurance for certain persons with limited income and resources; and (3) the TRICARE Program

(“TRICARE”) (10 U.S.C. §§ 1071-1110b), which provides health insurance for uniformed military service members, retirees, and their families.

D. In mid-to-late September 2013, Medicea hosted a variety of events surrounding meetings at the Scoliosis Research Society’s Congress in Lyon, France (“the 2013 SRS Conference”). Medicea provided certain transportation, meals, drinks, and entertainment to various United States-based physicians who attended the 2013 SRS Conference as well as some of these Medicea-hosted events in France.

E. The following conduct is referred to in this Agreement as the “Covered Conduct”:

1. The United States contends that it has certain civil claims against Medicea arising from the companies’ provision of benefits—specifically meals, alcoholic beverages, entertainment, and travel expenses—to U.S.-based physicians who attended events in France surrounding the 2013 SRS Conference and occurring between September 18 and 21, 2013, in return for some of the physicians purchasing or ordering—or arranging for or recommending the purchasing or ordering of—Medicea’s medical devices that were to be paid for, in whole or in part, under a federal healthcare program. The United States contends that this conduct violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(1)(B) (“AKS”), and resulted in claims submitted to, or purchases made by, federal healthcare programs between October 1, 2013 and December 31, 2015, including claims for payment to Medicare, Medicaid, and TRICARE.

2. The United States further contends that it has claims against Medicea under the then newly-passed Open Payments Program (“OPP”), 42 U.S.C. § 1320a-7h, and associated regulations, 42 C.F.R. §§ 403.900-.914 (“OPP Regulations”),

which the Centers for Medicare & Medicaid Services (“CMS”—an HHS operating division) administers. The OPP and OPP Regulations required Medicea—as a manufacturer of medical devices for which payment has been available under Medicare—to disclose to CMS: (a) certain payments or other transfers of value that Medicea made after August 1, 2013 to physicians, such as the U.S.-based surgeons attending the 2013 SRS Conference; and (b) specifically, through the OPP web portal, Medicea’s provision of meals, alcoholic beverages, entertainment, and travel expenses to U.S.-based physicians at various events surrounding that conference. The United States contends that Medicea, however, in violation of the OPP and OPP Regulations, only partially disclosed to CMS such payments or other transfers of value that the companies provided. The United States’ OPP and OPP Regulation claims arise from Medicea’s alleged knowing and/or reckless failures to report fully to CMS, between April 1, 2014 and March 29, 2018, the full value of Medicea’s reportable payments or transfers of value to U.S.-based physicians attending the 2013 SRS Conference.

F. On April 27, 2016, Relator filed a *qui tam* action in the United States District Court for the Eastern District of Pennsylvania—captioned *United States of America, et al., ex rel. Dory Frain v. Medicea USA Corporation*, Civil Action No. 16-1986—under the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) and various State statutes (the “Civil Action”). In her *qui tam* complaint, Relator alleged, among other things, that MUSAC—in order to induce referrals, recommendations, and arrangements for purchase of the company’s spinal products—violated the AKS and other statutes by providing to some surgeons various benefits and perquisites that included not only paid travel to France but also meals and beverages for surgeons and

some of their family members. Relator further alleged that these and other violations caused the submission of false and fraudulent claims to federal and state health care programs.

G. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the Federal FCA Settlement Amount (defined below) and to Relator's reasonable expenses, attorneys' fees, and costs.

H. Medicea has entered, or will be entering into, separate agreements described below in paragraph 1.a. ("Medicaid State Settlement Agreements") with several States ("Medicaid Participating States") in settlement of the conduct released in those separate Medicaid State Settlement Agreements. Relator claims entitlement under 31 U.S.C. § 3730(d), and State equivalents, to a share of the proceeds of the Medicaid State Settlement Agreements.

I. This Agreement is not an admission of liability by Medicea, nor is it a concession by the United States that its claims are not well founded.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows:

#### TERMS AND CONDITIONS

1. Medicea shall pay to the United States, and to the Medicaid Participating States, in total, the sum of Two Million Dollars (\$2,000,000.00) plus interest at the rate of 0.75% per annum, calculated monthly, from October 23, 2020, and continuing until and including the date of payment (collectively, the "Settlement Amount"). That Settlement Amount shall be paid, subject to the provisions of Paragraph 12, as follows:

a. With respect to the conduct described in Paragraph E(1) above:

(i) Medicea shall pay to the United States the sum of \$585,028.90 of which \$277,264.88 is restitution, plus pro rata interest as set forth above (the “Federal FCA Settlement Amount”), no later than ten business days after the Effective Date of this Agreement, by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney’s Office for the Eastern District of Pennsylvania; and (ii) Medicea shall pay to the Medicaid Participating States, collectively, the sum of \$414,971.10 of which \$196,668.77 is restitution, plus pro rata interest as set forth above (the “Medicaid State FCA Settlement Amount”), pursuant to written instructions from the National Association of Medicaid Fraud Control Units (“NAMFCU”) State Team and under the terms and conditions of the separate agreements that Medicea has entered into, or will enter into, with the Medicaid Participating States.

b. With respect to the conduct specified in Paragraph E(2) above, Medicea shall pay to the United States the sum of One Million Dollars (\$1,000,000.00), plus pro rata interest as set forth above (the “Federal OPP Settlement Amount”), no later than ten business days after the Effective Date of this Agreement, by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney’s Office for the Eastern District of Pennsylvania.

2. Conditioned upon the United States receiving from Medicea the portion of the Settlement Amount payable to the United States that is set forth in Paragraph 1(a) above (*i.e.*, the Federal FCA Settlement Amount), and as soon as feasible after its receipt, the United States shall pay \$128,706.36 to Relator, through Relator’s counsel, by electronic funds transfer.

3. Except as provided in a separate agreement that Medicea has entered into with the Relator for her fees and costs pursuant to 31 U.S.C. § 3730(d), each party shall bear its own legal and other costs incurred with this matter including the preparation and performance of this Agreement.

4. a. Subject to the exceptions in Paragraph 6 (concerning excluded claims) below, and conditioned upon Medicea’s full payment pursuant to Paragraph 1(a) above, the United States releases Medicea—together with its current and former parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors and assigns of any of them (collectively, “the Medicea Entities”)—from any civil or administrative monetary claim the United States has for the Covered Conduct in Paragraph E(1) above under the False Claims Act (“FCA”), 31 U.S.C. §§ 3729–3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801–3812; or the common law theories of payment by mistake, unjust enrichment, and fraud. This Agreement does not release any claims of any State.

b. Subject to the exceptions in Paragraph 6 (concerning excluded claims) below, and conditioned upon Medicea’s full payment pursuant to Paragraph 1(b) above, the United States releases the Medicea Entities from any civil or administrative monetary claim the United States has for the Covered Conduct in Paragraph E(2) above under the OPP or OPP Regulations.

5. Subject to the exceptions in Paragraph 6, below, and conditioned upon Medicea’s full payment to the United States of the Federal FCA Settlement Amount, and full payment to Relator of the Fee Amount set forth in Paragraph 3, Relator, for herself

and for her heirs, successors, attorneys, agents, and assigns, fully and completely releases and discharges the Medicea Released Parties, as well as Pierre Olivier and Denys Sournac, from: (a) any civil monetary claim the Relator has on behalf of the United States or herself for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; (b) to the extent related in any way to the Civil Action, all of Relator's and her attorneys' reasonable expenses, necessarily incurred; reasonable attorneys' fees; costs; and fees claimed or that could be claimed pursuant to 31 U.S.C. § 3730(d); and (c) all liability, claims, demands, actions, or causes of action whatsoever, whether known or unknown, fixed or contingent, in law or in equity, in contract or in tort, under any federal or State statute or regulation, or in common law, that Relator, her heirs, successors, attorneys, agents, and assigns otherwise would have standing to bring as of the effective date of this Agreement, including any liability to Relator arising from or relating to the claims Relator asserted or could have asserted in the Civil Action.

6. Notwithstanding the releases given in Paragraphs 4 and 5 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory or permissive exclusion from Federal health care programs;

- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- g. Any liability for failure to deliver goods or services due;
- h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; or
- i. Any liability of individuals.

7. Relator and her heirs, successors, attorneys, agents, and assigns shall not object to this Agreement, but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B).

Conditioned upon Relator's receipt of the payment from the United States described in Paragraph 2, Relator and her heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

8. Medicea waives and shall not assert any defenses Medicea may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the U.S. Constitution, or under the Excessive Fines Clause in



the Eighth Amendment of the U.S. Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

9. Medicea fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including for attorney's fees, costs, and expenses of every kind and however denominated) that Medicea has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Civil Action and the United States' investigation and prosecution thereof.

10. Medicea fully and finally releases the Relator and her heirs, successors, attorneys, agents, and assigns from any claims (including for attorney's fees, costs, and expenses of every kind and however denominated) that Medicea has asserted, could have asserted, or may assert in the future against the Relator, related to the Civil Action and the Relator's investigation and prosecution thereof.

11. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, TRICARE or FEHBP carrier or payer) or any State payer, related to the Covered Conduct; and Medicea agrees not to resubmit to any Medicare contractor, TRICARE or FEHBP carrier or payer, or any State payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals

12. Medicea agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the

Social Security Act, 42 U.S.C. §§ 1395-1395lll-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Medicea, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil investigation of the matters covered by this Agreement;
- (3) Medicea's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement;
- (5) the payment Medicea makes to the United States pursuant to this Agreement and any payments that Medicea may make to Relator, including costs and attorneys' fees,

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs will be separately determined and accounted for by Medicea, and Medicea shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Medicea or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for

Payment: Medicea further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Medicea or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Medicea agrees that the United States, at a minimum, shall be entitled to recoup from Medicea any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Medicea or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Medicea or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Medicea's books and records to

determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

13. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 5 (relator's release of certain additional parties on behalf of relator only) and Paragraph 14 (waiver for beneficiaries paragraph).

14. Medicea agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payers based upon the claims defined as Covered Conduct.

15. On or after the Effective Date of this Agreement (as defined in Paragraph 25, below), the United States will file a notice of intervention in the Civil Action with regard to the Covered Conduct, and, upon the United States' receipt from Medicea of the payments described in Paragraph 1, above, the United States and Relator shall promptly sign and file in the Civil Action a Joint Notice of Dismissal of the Civil Action pursuant to Rule 41(a)(1). The dismissal shall be with prejudice to the Relator as to all claims and without prejudice to the United States except as to the Covered Conduct.

16. Except as expressly set forth herein, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

17. Each party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

18. The laws of the United States govern this Agreement. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Eastern District of Pennsylvania. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

19. This Agreement constitutes the complete agreement between and among the Parties with respect to the issues covered by this Agreement. This Agreement may not be amended except by written consent of the Parties.

20. The undersigned represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

21. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which constitute one and the same Agreement.

22. This Agreement is binding on Medicrea's successors, transferees, heirs, and assigns.

23. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

24. All parties consent to the United States' disclosure to the public of this Agreement and of information about this Agreement.

25. This Agreement is effective on the date of signature of the last signatory to the Agreement ("Effective Date"). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

[Remainder of page left intentionally blank; signatures follow]

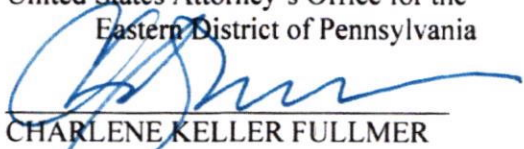
**THE UNITED STATES OF AMERICA**

DATED: \_\_\_\_\_ BY: LOUIS LAPPEN Digitally signed by LOUIS LAPPEN  
Date: 2021.05.13 10:59:13 -04'00'

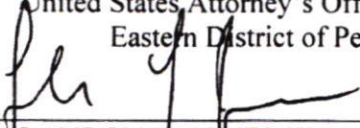
JENNIFER ARBITTIER WILLIAMS  
Acting United States Attorney  
Eastern District of Pennsylvania

DATED: \_\_\_\_\_ BY: GREGORY DAVID Digitally signed by GREGORY DAVID  
Date: 2021.05.19 11:38:07 -04'00'

GREGORY B. DAVID  
Assistant United States Attorney  
Chief, Civil Division  
United States Attorney's Office for the Eastern District of Pennsylvania

DATED: \_\_\_\_\_ BY: 

CHARLENE KELLER FULLMER  
Assistant United States Attorney  
Deputy Chief, Civil Division  
United States Attorney's Office for the Eastern District of Pennsylvania

DATED: 5/6/2021 BY: 

LONDON Y. JONES III  
GERALD B. SULLIVAN  
Assistant United States Attorneys  
United States Attorney's Office for the Eastern District of Pennsylvania

DATED: \_\_\_\_\_ BY: \_\_\_\_\_

LISA M. RE  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
United States Department of Health and Human Services

DATED: \_\_\_\_\_ BY: \_\_\_\_\_

SALVATORE M. MAIDA  
General Counsel  
Defense Health Agency  
United States Department of Defense

**THE UNITED STATES OF AMERICA**

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

JENNIFER ARBITTIER WILLIAMS  
Acting United States Attorney  
Eastern District of Pennsylvania

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

GREGORY B. DAVID  
Assistant United States Attorney  
Chief, Civil Division  
United States Attorney's Office for the  
Eastern District of Pennsylvania

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

CHARLENE KELLER FULLMER  
Assistant United States Attorney  
Deputy Chief, Civil Division  
United States Attorney's Office for the  
Eastern District of Pennsylvania

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

LANDON Y. JONES III  
GERALD B. SULLIVAN  
Assistant United States Attorneys  
United States Attorney's Office for the  
Eastern District of Pennsylvania

DATED: 4/14/2021

BY: 

LISA M. RE  
Assistant Inspector General for Legal  
Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
United States Department of Health  
and Human Services

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

SALVATORE M. MAIDA  
General Counsel  
Defense Health Agency  
United States Department of Defense

**THE UNITED STATES OF AMERICA**

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

JENNIFER ARBITTIER WILLIAMS  
Acting United States Attorney  
Eastern District of Pennsylvania

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

GREGORY B. DAVID  
Assistant United States Attorney  
Chief, Civil Division  
United States Attorney's Office for the  
Eastern District of Pennsylvania

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

CHARLENE KELLER FULLMER  
Assistant United States Attorney  
Deputy Chief, Civil Division  
United States Attorney's Office for the  
Eastern District of Pennsylvania

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

LANDON Y. JONES III  
GERALD B. SULLIVAN  
Assistant United States Attorneys  
United States Attorney's Office for the  
Eastern District of Pennsylvania

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

LISA M. RE  
Assistant Inspector General for Legal  
Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
United States Department of Health  
and Human Services

DATED: 04/09/2021

BY: \_\_\_\_\_

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SALVATORE M. MAIDA  
General Counsel  
Defense Health Agency  
United States Department of Defense

for



**DORY FRAIN - RELATOR**

DATED: 4/12/2021 | 4:23 PM PDT  
\_\_\_\_\_

BY:

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*Dory Frain*  
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DORY FRAIN

DATED: 4/12/2021 | 7:05 PM EDT  
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BY:

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*Michael A. Filoromo, III*  
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Michael A. Filoromo, III  
Katz, Marshall & Banks, LLP  
Counsel for Dory Frain

DATED: 4/12/2021 | 6:08 PM EDT  
\_\_\_\_\_

BY:

DocuSigned by:  
*Ryan Allen Hancock, Esq.*  
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\_\_\_\_\_  
Ryan Allen Hancock  
Willig Williams & Davidson  
Counsel for Dory Frain

MEDICREA USA, INC.

DATED: April 28, 2021 BY: \_\_\_\_\_

*Nadège*

Nadège Bourdois  
Directrice Juridique et Ressources Humaines  
Medicrea International

DATED: April 28, 2021 BY: \_\_\_\_\_

*Marc S. Raspanti*

Marc S. Raspanti, Esquire  
Pamela Coyle Brecht, Esquire  
Erik R. Giannitrapani, Esquire  
Pietragallo Gordon Alfano  
Bosick & Raspanti, LLP

**MEDICREA INTERNATIONAL**

DATED: April 28, 2021

BY:

Nadège Bourdois  
Nadège Bourdois  
Directrice Juridique et Ressources Humaines  
Medicrea International

DATED: April 28, 2021

BY:

Marc S. Raspanti  
Marc S. Raspanti  
Pamela Coyle Brecht  
Erik R. Giannitrapani  
Pietragallo Gordon Alfano  
Bosick & Raspanti, LLP