SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS), (collectively, the "United States"); Essilor International, Essilor of America, Inc., Essilor Laboratories of America, Inc., and Essilor Instruments USA (collectively, "Essilor"); Laura Thompson, Lisa Brez, and Christie Rudolph (collectively, "Relators" and, collectively with the United States and Essilor, "the Parties"), through their authorized representatives.

RECITALS

- A. Essilor International is an international company that, through its various affiliates, designs, manufactures, markets, and distributes eye care equipment and products, including optical lenses, and provides various eye care services.
- B. Essilor of America, Inc. and Essilor Laboratories of America, Inc. are wholly owned subsidiaries of Essilor International that, among other things, manufacture and distribute optical lenses to independent eye care providers ("Providers") throughout the United States.
- C. During the time frame set out in paragraph G below, Essilor Instruments USA was an affiliate of Essilor International that, among other things, manufactured and distributed edging and finishing equipment, as well as other optical instruments, for in-store retail use by Providers.
- D. Optometrists and ophthalmologists provide prescriptions to patients, including those enrolled in Medicare and Medicaid, which can be used to purchase optical lenses. In most cases, opticians such as Providers subsequently advise those patients on frames and certain types of lenses and lens coatings, as well as help fit the eyeglasses properly. Providers submit claims for those services to commercial and government payers.

- E. Relators have filed the following actions against Essilor pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (collectively, the "Civil Actions"):
 - United States ex rel. Laura Thompson & Lisa Brez v. Essilor Int'l, No. 3:15-CV-2853-C (N.D. Tex.)
 - United States ex rel. Christie Rudolph v. Essilor Labs. of Am., Inc., No. 16-CV-0537 (WB) (E.D. Pa.)

Relators allege, among other things, that Essilor offered unlawful kickbacks to Providers in exchange for the Providers' agreement to order optical lenses from Essilor.

- F. The United States contends that Essilor caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395Ill ("Medicare"), and the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 ("Medicaid").
- G. The United States contends that it has certain civil claims against Essilor arising from Essilor's remunerative arrangements with Providers during the period from January 1, 2011 through December 31, 2016. Specifically, the United States contends that Essilor, through its Strategic Alliance, Practice Builder Loyalty, Practice Builder Elite, and Growth Financing programs (collectively, "Threshold Programs") knowingly and willfully offered or paid unlawful remuneration to Providers to induce Providers to order and purchase Essilor products in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b. The United States further contends that Essilor knowingly caused Providers to submit false claims to Medicare and Medicaid for Essilor products that were tainted by kickbacks that Essilor offered or paid to Providers enrolled in Threshold Programs between January 1, 2011 and December 31, 2016. That conduct is referred to below as the "Covered Conduct."

- H. This Agreement represents neither an admission of liability by Essilor nor a concession by the United States that the claims are not well-founded. Essilor denies the allegations in the Civil Actions and the United States' allegations in Paragraphs F and G above.
- I. Essilor has entered or will be entering into separate settlement agreements, described in Paragraph 1 below (the "Medicaid State Settlement Agreements") with certain states in settlement of the Covered Conduct. States with which Essilor executes a Medicaid State Settlement Agreement in the form to which Essilor and the state negotiating team ("State Team") have agreed, or in a form otherwise agreed to by Essilor and an individual State, shall be referred to as "Medicaid Participating States."
- J. Relators claim entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relators' reasonable expenses, attorneys' fees and costs.

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. Essilor shall pay to the United States and the Medicaid Participating States a total of twenty-two million dollars (\$22,000,000) (the "Total Settlement Amount"), plus interest on the Total Settlement Amount accruing at an annual rate of 0.875 percent from June 25, 2020, until the date of payment. The Total Settlement Amount shall be paid as follows:
 - (a) Essilor shall pay to the United States \$16,433,345.01, of which \$8,216,672.50 is restitution, plus accrued interest as set forth above (the "Federal Settlement Amount"), no later than ten business days after the Effective Date of this Agreement, as defined in paragraph 26, by electronic funds transfer pursuant to written

instructions to be provided by the Civil Division of the United States Department of Justice.

- (b) Essilor shall collectively pay to the Medicaid Participating States the total sum of \$5,566,654.99, plus accrued interest as set forth above (the "State Settlement Amount") pursuant to written instructions from the State Team and under the terms and conditions of the separate agreements that Essilor will enter into with the Medicaid Participating States.
- 2. Relators claim entitlement to attorney's fees, costs, and expenses allowable under 31 U.S.C. § 3730(d). Essilor reserves the right to challenge Relators' entitlement to such attorney's fees, costs and expenses on all available grounds, including but not limited to the first-to-file bar (31 U.S.C. § 3730(b)(5)) and the public disclosure bar (31 U.S.C. § 3730(e)(4)). Essilor and Relators, through their legal counsel, shall separately resolve, either through negotiated resolution or through proceedings before the Court, Relators' entitlement to any attorney's fees, costs, and expenses allowable under 31 U.S.C. § 3730(d).
- 3. Subject to the exceptions in Paragraph 6 (concerning excluded claims) below, and conditioned upon Essilor's full payment of the Federal Settlement Amount, the United States releases Essilor, together with any 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, other than Shamir USA, Inc., Shamir Optical Industry, Ltd., Shamir Optica Holdings, A.C.S. Ltd., or Shamir Insight, Inc., from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 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.

4. Conditioned upon Essilor's full payment of the Federal Settlement Amount and the amounts specified in Paragraph 1 above, Relators, for themselves and for their heirs, successors, attorneys, agents, representatives and assigns, fully and finally release, waive and forever discharge Essilor and its predecessors, together with its current and former parent companies, direct and indirect subsidiaries, affiliated companies, brother and sister corporations, divisions, current or former corporate owners, all of its directors, officers, employees, general and limited partners, heirs, successors, attorneys, agents, and representatives, and the successors and assigns of any of them from any and all claims, of every kind and however denominated, for damages, fines, and penalties, that any of them has asserted, could have asserted, or may assert in the future, for themselves or on behalf of the United States, under the False Claims Act, 31 U.S.C. §§ 3729-3733, with respect to the allegations set forth in the Civil Actions and the Covered Conduct. Nothing in this Agreement shall be construed to preclude any claims (1) in the matter before the Superior Court of the State of California entitled State of California and Christie Rudolph v. Essilor Laboratories of America, Inc., Essilor of America, Inc., Empire Optical of California, Inc., and John Does # 1-25 (No. CGC-16-551940), under the California Insurance Frauds Prevention Act, Cal. Ins. Code § 1871.7, et seq., (2) in the matter before the United States District Court for the Central District of California entitled *United States*, et al., ex rel. Richard Mark v. Shamir USA, Inc., Shamir Optical Industry, Ltd., Shamir Optica Holdings, A.C.S. Ltd., and Shamir Insight, Inc. (No. 2:18-cv-09426-RGK-PLA), under the False Claims Act, 31 U.S.C. §§ 3729-3733, or (3) in any other matter, whether pending or potential, involving individuals other than Relators who have or may have claims against Shamir USA, Inc., Shamir Optical Industry, Ltd., Shamir Optica Holdings, A.C.S. Ltd., and Shamir Insight, Inc., under the California Insurance Frauds Prevention Act, Cal. Ins. Code § 1871.7, et seq.

- 5. In consideration of the obligations of Essilor in this Agreement and the Corporate Integrity Agreement ("CIA"), entered into between OIG-HHS and Essilor, and upon the United States' receipt of full payment of the Settlement Amount, plus interest due under Paragraph 1, the OIG-HHS shall release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Essilor under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in this paragraph and in Paragraph 6 (concerning reserved claims), below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Essilor from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 6, below.
- 6. Notwithstanding the releases given in paragraphs 3, 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;
 - 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 of individuals;
- g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- h. Any liability for failure to deliver goods or services due; and
- Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.
- 7. Relators and their 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). In connection with this Agreement and these Civil Actions, Relators and their heirs, successors, attorneys, agents, and assigns agree that neither this Agreement, nor any intervention by the United States in the Civil Actions in order to dismiss the Civil Actions, nor any dismissal of the Civil Actions shall waive or otherwise affect the ability of the United States to contend that provisions in the False Claims Act, including 31 U.S.C. §§ 3730(d)(3) and 3730(e), bar Relators from sharing in the proceeds of this Agreement. Moreover, the United States and Relators and their heirs, successors, attorneys, agents, and assigns agree that they each retain all of their rights pursuant to the False Claims Act on the issue of the share percentage, if any, that Relators should receive of any proceeds of the settlement of their claim(s).
- 8. Essilor waives and shall not assert any defenses Essilor 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

Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

- 9. Essilor fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Essilor 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 Covered Conduct and the United States' investigation and prosecution thereof.
- 10. Subject to the provisions of Paragraph 2, Essilor fully and finally releases the Relators from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Essilor has asserted, could have asserted, or may assert in the future against the Relators, related to the Covered Conduct and the Relators' investigation and prosecution thereof. Nothing in this Agreement shall be construed to preclude Essilor or any affiliated Essilor entity from asserting any right, defense (affirmative or otherwise) or argument with respect to any claims, including requests for expenses, attorneys' fees or costs, (1) in the matter before the Superior Court of the State of California entitled State of California and Christie Rudolph v. Essilor Laboratories of America, Inc., Essilor of America, Inc., Empire Optical of California, Inc., and John Does # 1-25 (No. CGC-16-551940), under the California Insurance Frauds Prevention Act, Cal. Ins. Code § 1871.7, et seq., (2) in the matter before the United States District Court for the Central District of California entitled *United States, et al., ex* rel. Richard Mark v. Shamir USA, Inc., Shamir Optical Industry, Ltd., Shamir Optica Holdings, A.C.S. Ltd., or Shamir Insight, Inc. (No. 2:18-cv-09426-RGK-PLA), under the False Claims Act, 31 U.S.C. §§ 3729-3733, or (3) in any other matter, whether pending or potential, involving individuals other than Relators who have or may have claims against Shamir USA, Inc., Shamir

Optical Industry, Ltd., Shamir Optica Holdings, A.C.S. Ltd., and Shamir Insight, Inc., under the California Insurance Frauds Prevention Act, Cal. Ins. Code § 1871.7, et seq.

- 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, carrier), Medicaid contractor (e.g., Medicaid fiscal intermediary, carrier, or managed care organization) or any other state payer, related to the Covered Conduct; and Essilor agrees not to resubmit, or encourage any Providers enrolled in Essilor's Threshold Programs to resubmit, to any Medicare contractor, Medicaid contractor, or any state payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.
 - 12. Essilor agrees to the following:
- a. <u>Unallowable Costs Defined</u>: 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 Essilor, its present or former officers, directors, employees, shareholders, and agents in connection with:
 - (1) the matters covered by this Agreement;
 - the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;
 - (3) Essilor's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
 - (4) the negotiation and performance of this Agreement;

- (5) the payment Essilor makes to the United States pursuant to this Agreement and any payments that Essilor may make to Relators, including costs and attorneys' fees; and
- (6) the negotiation of, and obligations undertaken pursuant to the CIA to: (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (ii) prepare and submit reports to the OIG-HHS

are unallowable costs for government contracting purposes and under Medicare and Medicaid (hereinafter referred to as Unallowable Costs). However, nothing in paragraph 12.a.(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to Essilor.

- b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Essilor, and Essilor 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 Essilor, Essilor's subsidiaries or affiliates, or providers enrolled in any of Essilor's Threshold Programs, to Medicare or Medicaid.
- c. Treatment of Unallowable Costs Previously Submitted for Payment:

 Essilor further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare fiscal intermediaries, carriers, and/or contractors, and Medicaid 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 Essilor, Essilor's subsidiaries or affiliates, or Providers enrolled in Essilor's Threshold Programs, 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. Essilor agrees that the United States, at a minimum, shall be entitled to recoup from Essilor, any of its subsidiaries or affiliates, or Providers enrolled in Essilor's Threshold Programs, 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 Essilor or Providers enrolled in Essilor's Threshold Programs, or any of Essilor's subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Essilor 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 Essilor's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.
- 13. Essilor agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Essilor shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Essilor further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of

interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

- 14. 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 Paragraphs 3 and 4, above, and Paragraph 15 (waiver for beneficiaries paragraph), below.
- 15. Essilor 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 payors based upon the claims defined as Covered Conduct.
- 16. Upon receipt of the payment described in Paragraph 1, above, the relevant Parties shall promptly sign and file in the Civil Actions joint stipulations of dismissal dismissing each civil action pursuant to Rule 41(a)(1). The dismissal by Relators shall be with prejudice. However, the Relators' claims for attorneys' fees, expenses, and costs under 31 U.S.C. § 3730(d) and the Relators' claims for a share of the settlement amount shall not be dismissed. Both of those claims are expressly preserved and shall be resolved either by the Court or through a separate agreement between the respective Parties. The dismissal by the United States shall be with prejudice with respect to the Covered Conduct and otherwise without prejudice. The dismissal by the Medicaid Participating States shall be addressed in separate agreements with those entities. The dismissal by any states other than the Medicaid Participating States, and by the County of Allegheny, County of Broward, City of Chicago, County of Miami-Dade, City of New York, and City of Philadelphia, who are not parties to this Agreement, shall be without prejudice.

- 17. Other than Relators' rights, if any, to seek reasonable attorneys' fees, expenses and costs from Essilor, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
- 18. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.
- 19. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Northern District of Texas. 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.
- 20. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.
- 21. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.
- 22. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.
 - 23. This Agreement is binding on Essilor's successors, transferees, heirs, and assigns.
 - 24. This Agreement is binding on Relators' successors, transferees, heirs, and assigns.
- 25. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.
- 26. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED:	BY:	Diana Cieslak Trial Attorney Commercial Litigation Branch Civil Division United States Department of Justice
DATED:	BY:	Braden Civins Assistant United States Attorney Northern District of Texas
DATED:	BY:	Paul Kaufman Assistant United States Attorney Eastern District of Pennsylvania
DATED: <u>03/07/20</u> 22	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

THE UNITED STATES OF AMERICA

DATED:	BY:	Diana Cieslak Trial Attorney Commercial Litigation Branch Civil Division United States Department of Justice
DATED: <u>4/1/2022</u>	BY:	Braden Civins Assistant United States Attorney Northern District of Texas
DATED: <u>4/4/2022</u>	BY:	Paul Kaufman Assistant United States Attorney 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

ESSILOR

DATED: 3/1/2022	BY:	Docusigned by: Alexander Lunshof Essilor International
DATED: <u>2/23/2022</u>	BY:	Rick Gadd Essilor of America, Inc.
DATED: <u>2/23/2022</u>	BY:	Pick Gadd Rick Gadd Essilor Laboratories of America, Inc.
DATED: <u>3/1/2022</u>	BY:	Jean Unistophe Paris Jean-Christophe Paris Essilor Instruments USA
DATED: 3/31/2022	BY:	Sean Cenawood Counsel for Essilor International, Essilor of America, Inc., Essilor Laboratories of America, Inc., and Essilor

Instruments USA

RELATORS LAURA THOMPSON AND LISA BREZ

DATED: 2/23/2022

BY: Laura thompson

Laura Thompson

DATED: 2/23/2022

DocuSigned by:

BY:

BY:

Lisa Brez

DATED: 2/23/2022

DocuSigned by:

Christopher L. Nelson Christopher L. Nelson

Counsel for Laura Thompson and Lisa Brez

RELATOR CHRISTIE RUDOLPH

DATED: Feb-23-2022

BY: Christic Kudolph

Christie Rudolph

DATED: Feb-24-2022

BY: Docusigned by:

W. Scott Simmer

W. Scott Simmer

Counsel for Christie Rudolph