


<b>Facturar a:</b> <b>Aligntech de Mexico</b> <b>S.de R.L. de C.V.</b> <b>Boulevard</b> <b>Independencia No. 1951</b> <b>Parque Industrial</b> <b>Salvarcar</b> <b>Juarez, Chih. 32575</b> <b>Mexico</b>						<b>Orden de Compra</b>	
						<b>Numero PO:</b> 4100134653	
						<b>Contacto:</b> NA	
						SEP/17/2024	
				Página 1 de *			
<b>Proveedor</b>				<b>Enviar a</b>			
INDUSTRIAL ELECTRICA DE JUAREZ SA D AVE LOPEZ MATEOS 2050 F3 32390 CD JUAREZ Mexico VAT/Tax ID IEJ900913C38				Aligntech de Mexico S.de R.L. de C.V. Parque Industrial Salvarcar Boulevard Independencia 1951 32575 Cd. Juarez Mexico			
<b>Nombre del Contacto:</b> Pablo Medina <b>Telefono:</b> +4084701000 <b>Correo Electronico:</b> P-MEDINA@ALIGNTECH.COM							
<b>Terminos de Pago:</b> 30 days				<b>Terminos de Envio</b>		<b>Destino:</b>	
<b>Linea</b>	<b>Cantidad</b>	<b>Unidad de Medida</b>	<b>Material/Descripcion</b>	<b>Fecha de Entrega</b>		<b>Costo Unitario</b>	<b>Costo Total</b>
10	12.000	C/U	LDV80638-Reflector 030W 100-240V 5000k Requisition no: 1100139999 Requested by: Diana Pamela	SEP/20/2024	12.000	333.00 / EA	3,996.00
<b>Moneda :</b> MXN				<b>Impuesto Estimado</b>		639.36	
				<b>Total</b>		4,635.36	

# ALIGN'S STANDARD TERMS AND CONDITIONS OF PURCHASE

1. **COMPLETE AGREEMENT.** These Standard Terms and Conditions of purchase (the "Agreement") set forth the terms of purchase between Align Technology, Inc. or its subsidiary (except Align Technology, Ltd. and Align Technology do Brasil Ltda.) ("Align") and the seller and/or supplier identified in the Align purchase order ("Seller"). This Agreement is incorporated by reference in such purchase order ("P.O."). Additional terms may be set forth in the P.O., which may be accepted in writing or by specific performance (including, but not limited to, shipment of product, provision of services, acceptance of a purchase order, etc.). The P.O. and this Agreement set forth the entire agreement and understanding between the parties with respect to the purchase of products and/or services identified in the P.O., and no other additional or different terms or documents proposed by Seller, including any proposal, quotation, invoice, acknowledgement form or other written or oral communication, will be a part of the P.O. or this Agreement and are hereby expressly rejected, unless specifically agreed to in writing by Align. To the extent a valid written agreement is in existence covering the sale of the products and/or services covered hereby, the terms and conditions of said agreement shall govern and control, otherwise this Agreement shall govern. These terms apply to any repaired or replaced products or replaced services provided by Seller hereunder. Align is not obligated to any minimum purchase or future purchase obligations under the P.O. or this Agreement.
2. **PRICE.** Seller's acceptance of an Align P.O. constitutes a warranty that the prices charged for the products and/or services ordered will not exceed the prices referenced in the P.O. Align will only pay for quantities of product ordered and/or services rendered pursuant to the terms of the P.O. and will not have any liability for excess quantities or out-of-scope services. Unless otherwise specified in the P.O., the price includes all packaging, transportation costs to the delivery location, insurance, customs duties, and fees and applicable taxes, including, but not limited to, all sales, value added, use or excise taxes.
3. **CHANGES.** Seller agrees to notify Align and provide a written description of changes prior to implementation thereof in the products or services so Align may determine whether the changes may affect the quality of the product or finished product (incorporating the to-be-changed product) to meet a specified purchase requirement.
4. **PACKAGING AND DELIVERY.** Seller will package all products in an economical manner: (a) in accordance with good commercial practices, (b) acceptable to common carriers for shipment, (c) in accordance with governing regulations, and (d) adequate to ensure safe arrival of the products to the named delivery point. Each shipment must include a packing list referencing Align's P.O. number, Align's part number (if applicable), quantity, and description of products. The exterior packaging must include a label with Align's P.O. number, Align's part number (if applicable), Align's revision number and lot number (if applicable), and quantity in each box. The products must be delivered at Align's designated facility on the Request Date, which is listed on the applicable P.O. Align may issue changes, including but not limited to, a change to the Request Date, a change to the method or location for shipment without liability, provided such change is communicated in writing to Seller prior to shipment.
5. **DELIVERY AND RISK OF LOSS.** It is understood that TIME IS OF THE ESSENCE for the Seller's performance of its obligations under the P.O. The products ordered pursuant to the P.O. hereunder will be delivered via the carrier approved by Align, utilizing the account number approved by Align, FOB Align's designated facility or other destination approved by Align, freight collect. Title to the products passes to Align at Align's designated facility or other approved Align destination (the "delivery point").
6. **AMENDMENT AND MODIFICATION.** No change to the P.O. or this Agreement is binding upon Align unless it is in writing, specifically states that it amends this P.O. or this Agreement, and is signed by an authorized representative of Align.
7. **ACCEPTANCE AND INSPECTION.** This P.O. is not binding on Align until Seller accepts the P.O. in writing or Seller has commenced performance within 2 days of Seller's receipt of the P.O. Align may withdraw the P.O. at any time before it is accepted by Seller. All products and/or services are subject to inspection and acceptance at Align's designated facility within a reasonable time after delivery.

of the products or completion of services. If any products and/or services are defective (in material, workmanship, design, construction, or manufacture), are subject to infringement claims, does not meet the applicable specifications or warranties, or is not in conformity with the requirements of the P.O., Align may, at its option: (i) reject the products and/or services, and Seller must promptly replace or rework the rejected products and/or services at Seller's expense, (ii) require Seller to promptly correct the defective, infringing or nonconforming products and/or services by repair, rework or replacement at no cost to Align, (iii) return the defective, infringing or nonconforming products to Seller at Seller's expense and recover from Seller the P.O. price thereof, or (iv) correct the defective, infringing or nonconforming products and/or services (itself or on its behalf) and charge Seller with the cost of such correction. If pursuant to subsection (i) or (ii) above, Seller fails to promptly replace or correct any defective or infringing products and/or services, then Align may at its sole discretion (a) replace or correct the products and/or services and charge to Seller the cost occasioned thereby, (b) immediately cancel the P.O. without liability to Align, or (c) adjust the P.O. to indicate a reduction in price for the defective, infringing or nonconforming products and/or services.

**8. WARRANTY.** Seller warrants, for a period of at least one year (or longer as specified in the P.O.) from the date of Align acceptance at the products or services, that such products or services (i) will be free from defects in workmanship, design, material and manufacture, (ii) will comply with the requirements of the P.O. and this Agreement (iii) will comply with specifications, composition, formulation, component specifications, software specifications and/or other instructions provided or agreed by Align, (iv) will be free from any liability, including, but not limited to, royalties, license fees, mechanics' liens or other encumbrances, and (v) the products and/or services do not infringe upon any third party's Intellectual Property Rights (as defined below). Seller warrants that the services provided under the P.O. and this Agreement will be performed in a professional and workmanlike manner, and Seller and the products and services will comply with all applicable federal, state and local laws. To the extent that it may do so, Seller agrees to pass through any warranties of any supplier whose component product is included in the products delivered to Align. All warranties run to the benefit of Align and its customers.

**9. TERMINATION.** The parties agree that this Agreement and the P.O. may be terminated as follows:

- Termination Prior to Shipment. Align reserves the right to cancel the P.O., in whole or in part, and without liability at any time prior to delivery of the products and/or services ordered.

- Termination By Align. Additionally, Align may terminate the P.O. in whole or part, after delivery of the products and/or performance of the services by providing written notice to Seller.

- Termination for Default. If Align terminates the P.O. for Seller's default of the P.O. this Agreement, Align may procure at its sole discretion, products and/or services substantially similar to those ordered pursuant to the P.O., and Seller will be liable to Align for any reasonable excess costs for the replacement products and/or services.

- Procedures Upon Termination. Upon termination of the P.O. in whole or in part, Seller will, upon Align's direction and at the times specified by Align, stop work under the terminated portion of the P.O. place no further orders for materials or services under the terminated portion of the P.O., settle (with Align's prior approval) any third party claims relating to the products and/or services (including payment owed to third party sub-contractors), safeguard property related to the products and/or services, transfer title and make delivery to Align of all deliverables and/or work in process relating to the products and/or services under the terminated portion of the P.O., deliver materials acquired for performance of the P.O., and preserve records documentation, and other materials relating to the products and/or services. Seller shall at all times proceed with any portion of P.O. that has not been terminated.

- Payment Upon Termination. Payment for completed products and/or services delivered to and accepted by Align under the P.O. will be at the P.O. price. Seller must promptly submit any outstanding invoices for such products and/or services have accepted by Align. Align will not have any liability whatsoever as to any products or services not invoiced within forty-five (45) days of the termination date.

- 10. PAYMENT TERMS AND INVOICE.** Seller shall invoice Align no later than seven (7) days following Align's acceptance of delivered products and/or rendered services. Align agrees to pay Seller all undisputed amounts as set forth in the P.O. in USD or local currency, as applicable, on the first Thursday or the third Thursday of the month following sixty(60)days (unless otherwise agreed in writing as a condition of purchase) from Align's receipt of a properly issued and correct invoice. Seller's invoice(s) must include the Seller Name, Address, Invoice Number, Invoice Date, P.O. number, Quantity, Unit Price and Extended price, Description/Item Number, Ship to address, and additional charges such as freight and handling and tax. Align's payment of an invoice will not constitute acceptance of the products and/or services. Invoices shall be subject to review for errors, shortages, defects, or other related failure of Seller to meet the requirements of a P.O.
- 11. SETOFF.** Without prejudice to any other right or remedy it may have, Align reserves the right to set off, at any time, any amount owed to it by Seller against any amount payable by Align to Seller.
- 12. ACH PAYMENT.** All payments due and owing pursuant to a properly issued and correct invoice or under this Agreement shall be made through automated clearing house("ACH") transfers, unless otherwise agreed upon by both parties in writing. Seller shall provide Align with ACH payment details whereby, Align shall initiate the ACH transfers to Seller in the amount required pursuant to a properly issued and correct invoice or under this Agreement. Each party shall undertake any and all required actions and execute any required documents, instruments or agreements required to effectuate the requirements of this Section 12.
- 13. WAIVER; REMEDIES.** The failure of Align to require performance of any provision under this Agreement or the P.O. will not affect in any way the full right to require such performance at any time thereafter. Align's remedies stated herein are in addition to all other remedies at law or in equity.
- 14. INDEMNIFICATION.** Seller agrees to defend, indemnify and hold harmless Align, its agents, customers, successors and assigns against any claims, actions, proceedings, losses, damages, and liabilities (including costs and expenses) which arise from or are attributable to allegations of infringement of any patent, copyright, trademark, and/or other intellectual property (including right trade secret rights) ("Intellectual Property Right") by the products and/or services provided, however, that Align must promptly notify Seller of the claim, action or proceeding and tender Seller control of the defense and settlement of the claim with counsel reasonably satisfactory to Align. Align, at its own expense, may participate in the defense of any such claim, action or proceeding with counsel of its own choice. Seller may not settle or compromise any claim in a manner that imposes any material restrictions or obligations on Align without Align's prior written consent.
- 15. LIMITATION OF LIABILITY.** EXCEPT FOR PAYMENT FOR PRODUCTS AND/OR SERVICES DELIVERED AND ACCEPTED BY ALIGN, IN NO EVENT WILL ALIGN'S TOTAL CUMULATIVE LIABILITY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE P.O. (UNDER ANY THEORY OF LAW) EXCEED THE SUM OF FEES PAID BY ALIGN UNDER THE APPLICABLE P.O. THE EXISTENCE OF ONE OR MORE CLAIMS SHALL NOT EXPAND SUCH LIMIT. IN NO EVENT SHALL ALIGN HAVE ANY LIABILITY TO SELLER FOR ANY INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES, LOST PROFITS, LOSS OF DATA, LOSS OF USE OR COST OF PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES HOWEVER CAUSED AND UNDER ANY THEORY OF LIABILITY (WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), OR OTHERWISE) WHETHER OR NOT SELLER HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.
- 16. CONFIDENTIAL INFORMATION.** "Confidential Information" means all tangible and intangible non-public information: (a) disclosed by either party or otherwise made available or accessible by such party to the other party, regardless of the manner or medium of disclosure or access, and (b) is labeled as "proprietary" or "confidential" or would be considered as confidential or proprietary under the circumstances. Confidential Information shall include, but is not limited to, this Agreement, the P.O., specifications, drawings, samples, ideas, concepts, prototypes, materials and equipment, capacities, inventions, manufacturing processes, pricing and financial information, business plans, marketing and development plans, software, products and services.

The receiving party shall:(a) use the Confidential Information solely to perform its obligations and exercise its rights under this Agreement ("Purpose");(b) restrict disclosure of the Confidential Information to its officers,directors,employees, accountants, attorneys and affiliates (collectively, "Representatives")who (i) need access to Confidential Information for the Purpose,(ii) are informed of its confidential nature of the Confidential Information, and (iii) are bound by confidentiality obligations no less protective than the obligations set forth in this Agreement;(c) protect all Confidential Information with the same degree of care it accords its own confidential information of a similar nature ,but not less than a reasonable degree of care,against unauthorized disclosure and dissemination; (d) not reverse engineer ,disassemble, or decompile any Confidential Information,including any prototypes, software or other tangible objects which embody the Confidential Information and provide the disclosing party with proof of its return ordestruction. The receiving party will be responsible for any breach of this Agreement caused by its Representatives.

The receiving party's obligations under this Section 16 shall not apply ,or shall cease to apply, after such time that the receiving party can document that the Confidential Information: (a) is publicly known through no act or fault of the receiving party; (b) was known by the receiving party free of any confidentiality obligation prior to receipt of or access to the Confidential Information from the disclosing party; (c) is obtained by the receiving party from a third party on a non-confidential basis without breach of any direct or indirect confidentiality obligation to the disclosing party; or (d) was or is independently developed by the receiving party without use of or reference to such Confidential Information.

If the receiving party is legally compelled to disclose the disclosing party's Confidential Information, the receiving party shall promptly notify the disclosing party,if legally permissible,and use reasonable efforts to assist the disclosing party in seeking a protective order or other appropriate remedy. The receiving party will furnish only that portion of the Confidential Information that is legally required to be disclosed and use reasonable efforts to ensure that it is afforded confidential treatment.

## **17. INTELLECTUAL PROPERTY RIGHTS AND OWNERSHIP.**

17.1 Intellectual Property Rights. For purposes of this Agreement: (a) "Intellectual Property" means all intellectual property, including, without limitation,inventions, works of authorship,and know-how, process method, machine, design, composition, trade secrets, computer software, proprietary information and data; and (b) "Intellectual Property Rights"has the meaning in Section 14.

17.2 Align Property. "Align Property" means the following: (1) Align's Intellectual Property and Intellectual Property Rights therein that Align owns prior to the effective date of the P.O. or acquires separately or develops independently of the P.O.; (2) Intellectual property conceived, created or developed by Seller, whether directly or indirectly or alone or jointly with others, in connection with or pursuant to Seller's performance of the P.O. or this Agreement; and (3) other products or services that are made or performed by Seller throughthe use of Align's equipment, supplies,facilities, materials, Align's Confidential Information and/or Align's proprietary information. Seller hereby assigns to Align all of its right (including all Intellectual Property Rights), title, and interest in and to the Align Property,and Align solely owns all right (including all Intellectual Property Rights), title and interest in and to the Align Property. Subject to the terms and conditions of this Agreement, Align grants Seller, during the term of this Agreement, a non-exclusive, paid-up and royalty-free, non-transferable,non-sublicensable license to use the Align Property solely to the extent necessary for Seller to provide products and/or services in accordance with the P.O. Except as expressly set forth in this Agreement, Align grants no rights or licenses (whether by implication or otherwise) to the Align Property and its Confidential Information.

17.3 **Seller Property.** "Seller Property" means: (a) Intellectual Property (i) created or acquired by Seller before the effective date of the P.O. and not assigned to Align pursuant to a P.O. or this Agreement or (ii) independently developed by or for Seller as part of Seller's normal business and not developed for or paid for by Align under a P.O. or this Agreement; and the Intellectual Property Rights therein. Seller Property may be incorporated into or embodied by the products or services provided under a P.O. To the extent any Seller Property is incorporated into or embodied by such products or services, Seller hereby grants Align a royalty-free and fully-paid up, perpetual and irrevocable, world-wide, transferable, sublicensable and non-exclusive license to: (1) reproduce, prepare derivative works of, publicly display, publicly perform, digitally transmit, distribute and otherwise use the Seller Property for any purpose in connection with Align's products and services; (2) disclose and use the Seller Property for any purpose in connection with Align's products and services; and (3) make, have made, use, offer to sell, sell, import, and otherwise dispose of any purpose in connection with Align's products and services.

- 18. ASSIGNMENTS.** No right or obligation under this Agreement and/or the P.O. may be assigned or delegated by Seller without Align's prior written consent, and any attempted assignment without such consent will be null and void. Align may freely assign the P.O. and/or assign or delegate any of its rights or obligations under this Agreement at any time.
- 19. DELAYS.** Whenever any event delays or threatens to delay the timely performance of the P.O., Seller will immediately notify Align in writing furnishing all relevant details. Receipt by Align of such notice will not constitute a waiver of the Request Date or other due dates agreed by the parties.
- 20. RELATIONSHIP OF THE PARTIES.** The relationship between the parties is that of independent contractors. Nothing contained in the P.O. or this Agreement shall be construed as creating any agency, partnership, joint venture, or other form of joint enterprise, employment or fiduciary relationship between the parties, and neither party shall have authority to contract for or bind the other party in any manner whatsoever. No relationship of exclusivity shall be construed from this P.O.
- 21. THIRD-PARTY BENEFICIARIES.** This Agreement is for the sole benefit of the parties hereto and their respective successors and permitted assigns. Nothing herein, express or implied, is intended to or shall confer upon any other person or entity any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of these terms.
- 22. APPLICABLE LAW.** The validity, interpretation, enforceability, and performance of this Agreement and/or the P.O. will be governed by and construed substantively and procedurally (by excluding expressly the applicability of UCITA, or by the United Nations Conventions on Contracts for the International Sale of Goods) as follows:

<b>WHERE SERVICE OR GOOD IS PROVIDED:</b>	<b>APPLICABLE GOVERNING LAW:</b>	<b>EXCLUSIVE JURISDICTION</b>
United States, Canada or any other location not named	State of California	The state and federal courts located in Santa Clara County, California; the Parties consent to the exclusive Jurisdiction of those courts.
EMEA, except for as specified below for Israel	Switzerland	. * Any dispute will be resolved by arbitration in Zurich, Switzerland in accordance with the International Chamber of Commerce (“ICC”) rules of arbitration by a single arbitrator if the requested relief is under €2,000,000, or a tribunal of three arbitrators. if the requested relief is €2,000,000 or more. The place of arbitration shall be Zurich and the language of arbitration shall be English.
LATAM	State of California, unless all parties are from the same country, in which case the law from that country governs	Any dispute will be resolved by arbitration in the State of California in accordance with the American Arbitration Association (“AAA”) rules of arbitration by a single arbitrator if the requested relief is under \$2,000,000, or a tribunal of three arbitrators if the requested relief is \$2,000,000 or more. The place of arbitration shall be San Francisco, CA, USA, and the language of arbitration shall be English.
Israel	Israel	Competent courts of Tel-Aviv, Israel
The Peoples' Republic of China,	People's Republic of China	Competent courts of the people's Republic of China
Hong Kong	Hong Kong	Competent courts of Hong Kong
Taiwan	Taiwan	Taipei District Court
Japan	Japan	Tokyo District Court
ASEAN, Republic of Korea, Bangladesh, Nepal, India, Sri Lanka or any other location in Asia Pacific	Singapore	*Any dispute will be resolved by arbitration in Singapore in accordance with the Arbitration Rules of the Singapore International Arbitration Centre (“SIAC”) by a single arbitrator if the requested relief is under \$2,000,000, or a tribunal of three arbitrators. if the requested relief is \$2,000,000 or more. The place of arbitration shall be Singapore and the language of arbitration shall be English.
Australia, New Zealand	Australia	Competent courts of New South Wales, Australia.

All disputes will be resolved in English unless otherwise agreed to by the parties. Notwithstanding the foregoing, a party may seek injunctive relief in any court competent jurisdiction at any time and for any purpose.

- 23. NOTICES.** Any notice or other communication to be provided hereunder must be evidenced by a delivery receipt and will be effective upon receipt.
- 24. SEVERABILITY.** If any term or provision of this Agreement and/or the P.O. is invalid, illegal or unenforceable in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Agreement and/or the P.O.
- 25. SURVIVAL.** Any provision of this Agreement or P.O. which, by its nature, should survive any termination or expiration of the Agreement or P.O. shall so survive, including, but not limited to, the following provisions: Warranty, Indemnification, Confidential Information, Intellectual Property and Ownership, Applicable Law and Survival.
- 26. INSURANCE.** Seller must procure and maintain, at its sole expense, a policy or policies of insurance at levels sufficient to support its obligations under this Agreement and the P.O. and Seller shall promptly notify Align of any change, cancellation, or non-renewal of the insurance. Upon request by Align, Seller shall provide a Certificate of Insurance or other evidence satisfactory to Align.
- 27. FORCE MAJEURE.** Neither party shall be deemed to be in breach of this Agreement for any failure or delay in performance caused by reasons beyond its reasonable control if such party makes reasonable efforts to perform.
- 28. QUALITY CLAUSES.**
- GENERAL: Based on the type of products and/or services provided to Align, the following quality clauses apply to all purchases that have the potential to impact the quality of the products and/or services provided by Align's Quality Management System (QMS). Any conflict between the terms in the P.O. and these Quality Clauses (which relate to Quality Clauses themselves) shall be resolved in favor of these Quality Clauses.
- MANAGEMENT RESPONSIBILITY: Seller's management shall provide the resources necessary to implement and maintain a QMS, including monitoring of its effectiveness, continual improvement and customer focus.
- SUB-CONTRACTING: Seller shall not subcontract any of the work subject to the P.O. as previously agreed by both parties and any future sub-contract shall not be performed without prior written approval by Align.
- REGULATORY SUPPORT: Upon request, Seller shall provide information necessary for Align to obtain regulatory approval for the marketing, sale, and distribution of Align products into which the Seller's Products or Services are incorporated. Such information may include specific details relating to raw materials, composition, ingredients, etc.
- QUALITY MANAGEMENT SYSTEM: Seller, during fulfillment of all accepted P.O.s, shall maintain, demonstrate, and/or control of QMS that monitors all aspects of the work performed. QMS activities include such as documented procedures as required by the QMS, documents needed by the organization to ensure the effective planning, operation and control of its processes, and records required by the QMS. Additional QMS activities include internal audits, Corrective and Preventive Action (CAPA), complaint handling/files, purchasing controls, etc. to ensure compliance with its QMS, procedures, any applicable standards and Align requirements.
- RECORDS: Seller shall keep complete records that provide evidence of conformity to all requirements of the QMS. Records shall be maintained in a manner that allows them to be readily retrievable and to prevent deterioration, damage or loss. Electronic approval and storage of records is readily available for traceability. Unless record retention, responsibilities are otherwise agreed with Align, Seller shall maintain records for 15 years, or a time-period as required by applicable laws, rules or regulations, whichever is greater. Records shall be made available for inspection by Align, its representatives, any relevant regulatory authority such as a Notified Body or FDA, or a government authority.
- COMPETENCY OF PERSONNEL: Seller shall provide adequate and competent personnel for the fulfillment of the PO.
- WORK ENVIRONMENT: Seller shall maintain an appropriate infrastructure, work environment, and cleanliness of personnel to prevent adverse effects on product or service quality.
- CONTROL OF SPECIFICATIONS: Seller shall control the distribution and use of all specifications and documents pertaining to the P.O. To the extent there is a conflict between product specifications provided to Seller by Align and the requirements herein, the product Specifications shall govern.
- IDENTIFICATION AND TRACEABILITY: Seller shall maintain identification and traceability of raw materials, components and products during all stages of receipt, production and distribution.



CONFORMANCE TO REQUIREMENTS: Seller warrants that the products and/or services will be free from defects in materials, workmanship and design and are supplied to Align in accordance with the specifications, drawings and other written instructions provided with this P.O. For services purchased from Seller, all such services shall be performed in a good and efficient manner, consistent with all applicable industry standards.

CONTROL OF NONCONFORMING PRODUCT: Seller shall have an established process for the control of nonconforming products and/or services at all stages of Seller's operations, which includes identification, documentation, evaluation, segregation and disposition of the nonconforming product or service conditions. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organization responsible for the nonconformance.

ESCAPES: In the event Seller discovers a nonconformance that affects products already shipped or services performed, Seller shall promptly notify Align. Seller shall fully cooperate with all investigation and containment actions. Seller shall reimburse all costs and expenses incurred by Align in connection with use of nonconforming products and/or services. Align may return all nonconforming products to Seller, at Seller's expenses.

CAPA: Seller shall have an established process for CAPA. Where a product or service is identified by Align as nonconforming, Align may issue a Seller CAPA. Seller shall complete all necessary CAPA activities within mutually agreed timeframes.

PROCESS CONTROL: Seller shall control processes that effect products or services quality and performance, including but not limited to: approval of processes and process equipment including qualification and where appropriate, validation, monitoring and control of process parameters, including a documented control plan, if required, and compliance with all specified reference standards. Align reserves the right to review and approve Seller's qualification/validation plans and reports.

EQUIPMENT CONTROL, MAINTENANCE AND CALIBRATION: Seller shall have an established system in place to ensure process and test equipment are controlled, maintained, and calibrated at stated frequencies, to ensure they are suitable for their intended purpose and is capable of producing valid results. Product potentially impacted by use of out of calibration equipment shall be treated as nonconforming product. Calibration standards shall be traceable to recognized national and/or international standards.

CONTROL OF SUB-TIER SELLERS: Seller shall maintain controls, commensurate with risk, for the quality of all products and/or services procured in connection with the performance of work subject to the P.O. Controls shall include, as applicable, the flow down of applicable Align requirements and ensuring action is taken when sub-tier performance is not acceptable.

ACCEPTANCE ACTIVITIES: Seller shall maintain processes to ensure products and/or services conform to Align requirements, including as appropriate, incoming, in-process and final acceptance activities. Records of acceptance activities shall be maintained. Records shall include the acceptance activity performed, date performed, the results, the individual conducting the acceptance activity and the equipment used. Where required by Align, Seller shall provide a Certificate of Conformance and/or Analysis for each lot or batch of product shipped, or for the service provided.

CHANGE CONTROL: Any process changes, design changes or deviations considered by the Seller and/or sub-tier must be submitted to Align for review, and must include a detailed description of the change and its effects to the Products and/or Services characteristics.

AUDITS/INSPECTIONS: Seller agrees that Align, any government, notified body, commission, board, regulatory agency, court or other instrumentality having any jurisdiction over all aspects of the design, manufacturing and distribution of the products ("Authority"), shall have access to and the right to inspect or audit any pertinent product manufacturing or quality processes, and associated documentation or records. The Seller may specifically be subject to scheduled or unannounced audits (per EU Recommendation 2013/473/EU). During unannounced audits, the Seller must allow the Authority to witness the testing of product samples, and/or if requested, provide samples of product(s) for independent testing by the Authority. If issues or findings are identified during an audit that potentially impact product or service quality, performance or availability, Seller shall promptly notify Align and agree to cooperate regarding communications with FDA, regulatory, or government authority.

LABELING, PACKAGING, HANDLING & STORAGE: Seller shall ensure that packaging and shipping containers are of adequate design and construction to protect product from damage, deterioration or alteration during handling, storage and distribution. Expiration dates and any required storage conditions shall be clearly recorded on the labelling, packaging and shipping documents. Seller shall create and store labels and perform labelling operations in a way that prevents an incorrect label from being used.

SHIPMENT: Seller shall have systems in place to control shipment of products so that only products approved for release are shipped. Seller shall ensure that no obsolete, rejected, expired or deteriorated products are shipped.

COMPLAINTS: Seller shall provide assistance and information requested by Align in relation to the investigation of complaints Align receives from its customers, and to fulfil its regulatory reporting obligations. Where the complaint is confirmed to be attributed to the product or service provided, Seller shall follow the CAPA process.

RESTRICTED SUBSTANCES/MATERIAL DECLARATION: Products and/or services supplied to Align are expected to meet all applicable requirements of country, federal, state and local environmental regulations. Sellers of packaging, components and finished devices (products) are expected to provide information about the specific composition (e.g. trade or chemical name, color, grade, etc.), including quantity of all constituents used in the product(s) and packaging and/or provide specific certifications to Align upon request. This detailed information, declaring the raw materials and process chemicals used to manufacture the product(s) and packaging is required to fulfill Regulatory Body requirements for approval for use and other environmental reporting obligations.

RECALLS: Seller shall promptly notify Align in writing in the event products and/or services provided become subject to a Seller or Authority initiated recall and shall cooperate with Align requests for information related to the recall. Align has the sole authority for decisions related to any of its products in the field, including any field corrective action.

SURVIVAL: All quality requirements which are continuing in nature, including, but not limited to, CAPA, nonconforming product, escapes, authority audits & inspections, record retention, complaints, recalls, shall survive termination or cancellation of the P.O.