



ALIGN'S STANDARD TERMS AND CONDITIONS OF PURCHASE

1. **COMPLETE AGREEMENT.** This agreement contains Align Technology, Inc. and its subsidiaries (except Align Technology do Brasil Ltda.) ("Align") Standard Terms and Conditions of Purchase (the "Agreement") and sets forth the terms of purchase between the Align entity and the seller and/or supplier identified in the Align Purchase Order ("Seller"), which this Agreement is attached to or 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 parties acknowledge and agree the P.O. and this Agreement sets forth the entire agreement and understanding between the parties, and no other additional or different terms or documents proposed by Seller, including Seller's 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, current, and executed written agreement is in existence covering the sale of the goods and/or services covered hereby, the terms and conditions of said agreement shall govern and control, otherwise this Agreement shall govern.
2. **PRICE.** Seller's acceptance of an Align P.O. constitutes a warranty that the prices charged for the goods and/or services ordered will not exceed the prices referenced on the P.O. Align will only pay for quantities ordered and/or services rendered pursuant to the terms of the P.O. and will not have any liability for over-shipments.
3. **CHANGES.** Seller agrees to notify Align and provide a written description of changes prior to implementation in the good or service so Align may determine whether the changes may affect the quality of a finished device or purchased product to meet a specified purchase requirement.
4. **PACKAGING AND DELIVERY.** Seller will package all goods 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 goods at the named destination. Each shipment must include a packing list referencing Align's P.O. number, Align's part number (if applicable), quantity, and description of goods. The exterior packaging must include a label with Align's P.O. number, Align's part number, Align's revision number and lot number (if applicable), and quantity in each box. The order is due 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 any liability to Align, 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 P.O. since the goods and/or services are required for products and/or services necessary to satisfy Align's expanding market. The goods ordered 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. The title passes to Align at Align's designated facility or other approved Align destination, the packing slips and/or bill of lading must reference Align's Purchase Order Number, Item Number and list the name of the carrier and tracking number.
6. **INSPECTION AND ACCEPTANCE.** All goods and/or services are subject to inspection and acceptance at Align's designated facility within a reasonable time after delivery of goods or completion of services. In the event any goods and/or services are defective (in material, workmanship, design, construction, or manufacture), has claims alleging infringement, does not meet the specifications or applicable warranties, and/or is not in conformity with the requirements of the P.O., Align may, at its option: (i) reject the goods and/or services, and Seller must promptly replace or rework the rejected goods and/or services at Seller's expense, (ii) require Seller to promptly correct the defective, infringing or nonconforming goods and/or services by repair, rework or replacement at no cost to Align, (iii) return the defective, infringing or nonconforming goods to Seller at Seller's expense and recover from Seller the order price thereof, or (iv) correct the defective, infringing or nonconforming goods and/or services itself and charge Seller with the cost of such correction. If under (i) or (ii) above Seller, after being requested by Align, fails to promptly replace or correct any defective or infringing goods and/or services, then Align may at its sole discretion (i) replace or correct the goods and/or services and charge to Seller the cost occasioned thereby, (ii) immediately cancel the P.O. without liability to Align, or (iii) adjust the P.O. to indicate a reduction in price for the defective, infringing or nonconforming goods and/or services.
7. **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 Align's designated facility that all goods and/or services delivered (i) will be free from defects in workmanship, design, construction, material and manufacture (whether latent or patent), (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, a royalty, mechanics' lien or other encumbrance, and (v) the goods and/or services do not infringe upon any third party's Intellectual Property (as defined below). Seller warrants that the goods and/or services provided under the P.O. and this Agreement will be delivered in a professional and workmanlike manner and will comply with all applicable federal, state and local laws. Seller agrees to pass through warranties of any subcomponent supplier's product included in the goods delivered to Align. All warranties run to the benefit of Align and its customers.
8. **TERMINATION.** The parties agree that this Agreement and the P.O. may be terminated as follows:
 - o 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 goods and/or services ordered.
 - o Termination By Align. Additionally, Align may terminate the P.O. in whole or part, after shipment of the goods and/or delivery of the services by providing written notice to Seller.

- o Termination for Default. If termination is for Seller's default, Align may procure at its sole discretion, goods and/or services substantially similar to those ordered and Seller will be liable to Align for any reasonable excess costs for the replacement goods and/or services.
 - o Procedures Upon Termination. Upon termination, 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 goods and/or services (including payment owed to third party sub-contractors), safeguard property related to the goods and/or services, transfer title and make delivery to Align of all deliverables and/or work in process relating to the goods 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 goods and/or services. Seller shall at all times proceed with any portion of P.O. that has not been terminated.
 - o Payment Upon Termination. Payment for completed goods and/or services delivered to and accepted by Align under this paragraph will be the P.O. price. Seller must promptly submit any outstanding invoices for goods and/or services. Align will not have any liability whatsoever as to any goods or services not invoiced within forty-five (45) days of the termination date.
9. **PAYMENT TERMS AND INVOICE.** Seller shall invoice Align no earlier than and no later than sixty (60) days following shipment of goods and/or delivery of the services. Align agrees to pay Seller all undisputed amount as set forth in the P.O. in USD or local currency, as applicable, within sixty (60) days (unless otherwise agreed in writing as a condition of purchase) from Align's receipt of goods and/or completion of services and a correct invoice, if required. Seller's invoice(s) must include the Supplier Name, Address, Invoice Number, Invoice Date, Purchase Order 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 goods 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.
10. **ACH PAYMENT.** The Parties agree that all payments due and owing under this Agreement shall be made through automated clearing house ("**ACH**") transfers, unless otherwise agreed upon by both Parties in writing. Seller shall deliver to Align the ACH payment details whereby, Align shall initiate the ACH transfers to Seller in the amount required under this Agreement. The Parties hereby agree to undertake any and all required actions and execute any required documents, instruments or agreements required to effectuate the requirements of this Section 10.
11. **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. The remedies stated herein are in addition to all other remedies at law or in equity.
12. **INDEMNIFICATION.** Seller agrees to indemnify Align, its agents, customers, successors and assigns against any loss, damage, and liability (including costs and expenses) which arise from or are attributable to allegations of infringement of any patent, copyright, trademark or other intellectual property ("Intellectual Property") arising from the goods and/or services provided, however, that Align must promptly notify Seller of the claim and allow Seller control over 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 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.
13. **LIMITATION OF LIABILITY.** EXCEPT FOR PAYMENT FOR GOODS AND/OR SERVICES DELIVERED AND ACCEPTED BY ALIGN, IN NO EVENT WILL ALIGN'S TOTAL CUMULATIVE LIABILITY ARISING OUT OF 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), INDEMNITY OR OTHERWISE) WHETHER OR NOT SELLER HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.
14. **CONFIDENTIAL INFORMATION & OWNERSHIP.** "Confidential Information" means all tangible and intangible information disclosed by Align or otherwise made available or accessible whether intentionally or inadvertently regardless of the manner or medium of disclosure or access that is described as proprietary or confidential or considered as confidential or proprietary and shall include but is not limited to: this Agreement, the P.O., Intellectual Property, specifications, drawings, samples, ideas, concepts, prototypes, materials and equipment, capacities, inventions, manufacturing processes, pricing and financial information, business plans, marketing and development plans, and products. Align owns all deliverables, Intellectual Property, Confidential Information, work product and results developed or created by Seller under this Agreement whether such development occurs with or without contribution by Align.
15. **ASSIGNMENTS.** No right or obligation under this Agreement and/or the P.O. may be assigned by Seller without Align's prior written consent, and any attempted assignment without such consent will be null and void. Align may assign the P.O. at any time to any party which assumes Align's obligations hereunder.
16. **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.
17. **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 Products) as follows:

WHERE SERVICE OR GOOD IS PROVIDED:	APPLICABLE GOVERNING LAW:	EXCLUSIVE JURISDICTION
United States, Canada or any other location not named	State of California	Santa Clara County, California
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 an arbitral tribunal of three arbitrators. 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 International Chamber of Commerce ("ICC") rules of arbitration by an arbitral tribunal of three arbitrators. The place of arbitration shall be San Francisco, CA 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	People's Republic of China
Hong Kong	Hong Kong	Courts of Hong Kong
Taiwan	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 panel of three arbitrators. 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.

18. NOTICES. Any notice or other communication to be provided hereunder must be evidenced by a delivery receipt and will be effective upon receipt.

19. 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.

20. QUALITY CLAUSES.

GENERAL: Based on the type of goods and/or services provided to Align, the following quality clauses apply to all purchases that have the potential to impact the quality of the goods and/or services provided by Align's Quality Management System (QMS). Any conflict between the terms in the PO these Quality Clauses relate to and the 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 this PO as previously agreed by both parties and any future subcontract 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 POs, 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 PO. 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 goods 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 PO. 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 goods 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 goods 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 goods and/or services. Align may return all nonconforming goods 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 affect goods or service 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 is controlled, maintained, and calibrated at stated frequencies, to ensure it is suitable for its 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 goods and/or services procured in connection with the performance of work subject to the PO. 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 goods 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 goods ("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 good(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 goods so that only goods approved for release are shipped. Seller shall ensure that no obsolete, rejected, expired or deteriorated goods 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: Goods 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 good(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 good(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 goods 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 PO.