

General Terms and Conditions (ToCs)

1. General/Scope of Application

- 1.1 These General Terms and Conditions (ToCs) govern the business relationship between EC Certification Service GmbH, Sandgasse 29a, A-9300 Sankt Veit an der Glan (hereinafter referred to as "ECC"), and the Customer (hereinafter referred to as "Customer") in the version in effect at the time of the order.
For questions, complaints and claims, the Customer can contact ECC at +43 4212 6094 during business hours or via email at office@ec-c.at.
- 1.2 All legal transactions with ECC are governed by Austrian law. The provisions of international private law are expressly excluded. ECC endeavors to avoid disputes or resolve them amicably. In case of legal disputes, the place of jurisdiction shall be Klagenfurt.
- 1.3 Should any provision of these Terms and Conditions become or be deemed invalid, the validity of the remaining provisions shall not be affected. In place of the provision, a valid provision shall apply that most closely reflects the intended purpose. This also applies in case of any gaps in the provisions.
- 1.4 The Customer accepts the Terms that are in effect at the time of ordering services or products. The Customer is informed of these Terms at the time of the order and confirms by placing the order that they have read, understood, and agreed to them.
- 1.5 Any terms proposed by the Customer that deviate from these Terms are not recognized by ECC, even if ECC does not expressly object to them, unless ECC agrees to their applicability in writing.

2. Customers, Conclusion of Contract

- 2.1 The presentation of products on the website and in catalogs does not constitute a legally binding offer, but rather an invitation to submit an order. Product descriptions in ECC's catalogs or on the website do not constitute guarantees or warranties. ECC reserves the right to make changes and correct any errors.
- 2.2 All orders, except for custom-made products (see section 2.3), may be placed in writing via email, fax, or by phone. Offers from ECC do not constitute an acceptance of an order. Orders become binding only when confirmed in writing or fulfilled by shipment of the medical devices. ECC's acceptance of an order is made either through the issuance of an order confirmation via email to the Customer or, where the Customer has not consented to receiving a confirmation email, through the passage of time and shipment of medical devices. Oral agreements are only valid if confirmed in writing by ECC.
- 2.3 Orders for custom-made products are placed by submitting all necessary documents (see Section 6.2). Once the documents are complete, the Customer will receive an order confirmation, and the order for the creation of a treatment plan is considered accepted by ECC.
- 2.4 ECC's product offerings are directed exclusively to business operators and healthcare professionals, and, therefore, the right of withdrawal is excluded.
- 2.5 Reselling ECC products under a different name (i.e. relabeling) is permitted only with prior written consent from ECC. Any alteration of product labeling is prohibited without such consent.
- 2.6 Additional provisions for direct sales to healthcare professionals:
 - 2.6.1 The healthcare professional guarantees that they hold the necessary licenses to perform their respective services in the country in which they practice. If the professional's license is revoked or suspended during treatment, the products may no longer be used.
 - 2.6.2 It is the responsibility of the healthcare professional to identify and properly assess clinical risks. Additionally, the healthcare professional must ensure that patients are informed about the risks associated with using ECC products before starting treatment.
 - 2.6.3 The healthcare professional must familiarize themselves with the instructions for use of the products and ensure they stay updated on any changes, especially regarding contraindications and risk factors. The professional is also responsible for ensuring that products are used only on patients with no contraindications and who are fully informed of the associated risks.
In case of aligners, the healthcare professional must provide patients with the necessary care instructions and ensure they understand them.
- 2.7 Additional provisions for sales to business operators (i.e., distributor):
 - 2.7.1 The distributor is responsible for familiarizing themselves with the specifications, application areas, and instructions for use of the products.
 - 2.7.2 The distributor must ensure compliance with all relevant legal and regulatory requirements for distributing medical devices.
 - 2.7.3 The distributor must ensure that all employees handling the products are adequately trained and informed.
 - 2.7.4 The distributor must retain documentation for all products delivered and ensure complete traceability of the products.
 - 2.7.5 ECC provides instructions for use in English and German. The responsibility for translating them into other languages lies with the distributor.
 - 2.7.6 The distributor must promptly report any incidents involving the use of ECC products to ECC.
 - 2.7.7 The distributor must ensure that the products are stored and handled according to ECC's prescribed conditions to maintain their quality and safety.
 - 2.7.8 The distributor is responsible for ensuring that products are only supplied to authorized Customers who possess the necessary qualifications for handling them.
 - 2.7.9 The distributor must forward any complaints related to ECC products to ECC.
 - 2.7.10 The distributor must ensure that any advertising for ECC products complies with all applicable legal requirements and ECC's guidelines.

3. Prices, Minimum Quantities

- 3.1 All prices stated in the price list or other documents are net prices in EUR, exclusive of VAT and shipping costs, which will be added according to the applicable rates at the time of delivery. Minimum order quantities are based on individual agreements.
- 3.2 Prices for aligner treatments are net prices including shipping costs, unless otherwise stated.

4. Ordering of Services, such as Authorized Representative, Consulting

- 4.1 ECC's offers for Authorized Representative or consulting services related to the European Medical Device Regulation (MDR) and the implementation of EN ISO 13485 are non-binding. A contract is formed when the Customer accepts the offer. Acceptance is deemed to occur either through written confirmation of the offer or by the Customer utilizing the service.
- 4.2 The Customer may place an order for services in writing directly with ECC. The contract will be considered concluded, and the offer accepted when the Customer proceeds to utilize the services at the agreed time.
- 4.3 ECC commits to providing the services outlined in the contract with reasonable care and diligence.
- 4.4 The scope of services is defined in the service description provided in the offer or contract. Any changes or additions to the services require a written agreement.
- 4.5 In the event the Customer fails to follow ECC's instructions, resulting in diminished service quality, ECC is entitled to charge the Customer for the full service as outlined in the offer. Furthermore, ECC reserves the right to charge for any additional costs incurred in providing the service again.

5. Custom-made Orders

- 5.1 No right of withdrawal exists for the purchase of aligners specifically manufactured according to the individual requirements of the user, or brackets made custom for the Customer. These are explicitly excluded from the right of withdrawal.
- 5.2 In the event of defective products or deliveries, the Customer is entitled to request either rectification or replacement of the medical devices. The manufacturer reserves the right to determine the method of remedying the defect.
- 5.3 With respect to aligners, ECC guarantees their fit based on the model produced on the company's proprietary 3D printers from the digital scan or model impression submitted. If the dental model has been digitally modified and the Customer was informed of this upon receiving the treatment plan, ECC is only liable for the fit of the aligners on the 3D print of the digitally modified dental model. ECC is not liable for any issues arising from the digital modification of the model.
- 5.4 ECC guarantees that its products are free from manufacturing defects. ECC offers a guarantee on the fit of the aligners for a period of up to 30 days after shipment. This guarantee becomes void if the aligners are improperly applied, altered, or used in combination with third-party products. Any defects must be reported in writing immediately, but no later than 30 days after receipt of the medical devices.
- 5.5 To claim the warranty, the defect must be documented with photographs. In case of incorrect fit, the aligners should be photographed in the patient's mouth to clearly show the affected areas. Upon ECC's request, the aligners must also be returned for inspection.
- 5.6 ECC assumes no liability for treatment results or complications arising during the treatment, as the treatment is carried out by a qualified professional, and ECC has no influence over the instructions given to the patient or their compliance. Furthermore, the treatment must be regularly monitored by the professional at appropriate intervals.
- 5.7 Orthodontists or dental practices are assigned an individual Customer number for ordering aligners. The sharing of this Customer number with third parties for joint use is prohibited. Sharing customer numbers or access details with third parties is strictly prohibited and constitutes a breach of legal and ethical standards.

6. Creation of Treatment Plans / Aligner Treatment

- 6.1 The creation of a treatment plan is done concurrently with the preparation of the offer for the aligner treatment. Although the aligners are not necessarily required to be ordered thereafter, ECC will charge a fee for the creation of the treatment plan (see section 8.6.1).
- 6.2 To create a treatment plan for aligner therapy, the Customer must provide the manufacturer with all necessary documentation. This includes dental models of the upper and lower jaws in digital STL format or as plaster models, at least one frontal photograph of the face, an occlusal image of the upper and lower jaws, a frontal close-up image of the closed jaw, images of the lateral molar regions on both sides, and a current panoramic X-ray.
- 6.3 If the documentation is incomplete or inaccurate, ECC reserves the right to refuse to create the treatment plan.
- 6.4 The date of submission of the order is the day on which all required documentation is received in proper form.
- 6.5 ECC commits to sending the treatment plan to the Customer within 10 working days of receiving all necessary documentation. This is a guideline; the exact time of dispatch is not essential for contract fulfillment.
- 6.6 The Customer is required to provide all information and documentation in complete and correct form. Incomplete or incorrect documentation may result in delays or errors in planning, for which the manufacturer is not responsible.
- 6.7 Express Delivery: If the complete planning data is received by 9.00 a.m (CET), that day is considered the first working day of the processing period. Delivery in case of express planning will be made within five working days, provided that no queries or additional information is required. Additional charges apply for express processing; these are listed separately in the respective offer.
- 6.8 If the Customer requests a new treatment plan for the same patient after an initial plan has already been prepared, this will be charged separately, as a new plan requires reworking.
- 6.9 ECC assumes no liability if the dental models or 3D scans used to create the treatment plan do not accurately represent the patient's actual dental condition.
- 6.10 If the dental models show minor defects that can be corrected digitally, ECC reserves the right to charge for the additional work at an hourly rate.
- 6.11 Upon receipt of all necessary documentation, ECC will create an individual treatment plan, detailing the planned treatment steps, estimated duration, and the required aligners.
- 6.12 The treatment plan will be submitted to the Customer electronically, together with the offer, for review and approval. The Customer has the opportunity to provide feedback or request amendments after receiving the plan. It is the Customer's responsibility to thoroughly review the treatment plan before approving it. The offer for the production of the aligners is valid for 28 days.
- 6.13 Any changes to the treatment plan after the production approval by the doctor may incur additional costs and extend the treatment duration.
- 6.14 ECC will provide the link to the treatment plan for a period of at least three months. After this period, the plan must be requested again from ECC.
- 6.15 After confirmation of the treatment plan, the aligners will be shipped within ten working days. This is a guideline; the exact time of dispatch is not essential for contract fulfillment.
- 6.16 If no order is placed for a treatment plan (i.e., if the case is canceled), ECC will charge for the treatment plan. A cancellation occurs either upon written communication from the Customer or after a period of 90 days from the submission of the treatment plan.
- 6.17 If a case has been cancelled – whether by the Customer or due to the expiration of the time period – and the cancellation has already been invoiced, the cancellation fee may be credited against the cost of resuming the case upon reordering the aligners, provided no new treatment plan is required.

- 6.18 ECC does not assume liability for the accuracy of the treatment plan or the effectiveness of the subsequent treatment, as the diagnosis of the patient and the final approval of the treatment lie with the treating orthodontist (i.e., the Customer).
6.19 ECC shall not be liable for the progress or the results of the treatment.
6.20 In the event that the patient refuses the aligner treatment after receiving the aligners, no refund shall be due.

7. Delivery, Transport, Packaging

- 7.1 ECC reserves the right to withhold performance if the Customer is in arrears with any outstanding obligations.
7.2 Delivery of the medical devices shall be made from ECC's registered office in Sankt Veit an der Glan. All delivery dates provided by ECC are non-binding. Partial deliveries requested by the Customer will be invoiced and delivered separately.
7.3 In the event that certain items are unavailable at the time of order, they will be automatically backordered and delivered at the earliest possible time, unless an alternative arrangement is made with the Customer.
7.4 In the case of a delayed delivery due to the seller's fault, delay is only deemed to occur after the setting of a reasonable grace period of at least two weeks.
7.5 When selecting the shipping method and route, ECC takes into account the customer's preferences and interests regarding the shipping method and route and selects the most cost-effective shipping solution where possible. All shipments – with the exception of aligners – are automatically insured by ECC for transport. The insurance costs are listed separately in the order confirmation. For postal deliveries, the general shipping terms and conditions of the respective postal service provider apply.
7.6 If the customer does not wish to take on transport insurance, this must be communicated to ECC in writing prior to shipment.
7.7 Aligners are not automatically covered by transport insurance. However, insurance can be arranged and offered upon the customer's explicit request.
7.8 If the customer has their own account with a transport company and the shipment is made via this account, transport insurance will be handled through the respective transport company. In this case, ECC does not list the insurance costs separately in the quotation.
7.9 Subsequent deliveries caused by ECC shall be at ECC's expense.
7.10 ECC shall not be liable for any obligations arising from incomplete or incorrect delivery address information provided by the Customer.
7.11 Unless otherwise agreed, aligners are delivered directly to the address of the purchaser.
7.12 Should a package be undeliverable due to reasons such as the Customer's absence (e.g., vacation), ECC reserves the right to charge for re-shipment and assumes no responsibility for timely delivery.
7.13 ECC shall not be liable for any delays in delivery caused by postal services or courier companies.

8. Payment, Cancellation

- 8.1 The invoice shall be issued on the date of delivery or provision of the medical devices.
8.2 Unless otherwise stated, invoices are payable in full and without deduction upon receipt of the invoice. ECC also offers payment via SEPA direct debit or PayPal. Deliveries to foreign countries are made subject to prepayment. In the case of unauthorized deductions of bank charges for transfers, ECC reserves the right to reclaim these charges.
8.3 In the event of a delay in payment, interest at the rate of 3% per month will be charged, without prejudice to the right to claim further damages.
8.4 In the event of payment delay or reasonable doubt regarding the Customer's financial ability or creditworthiness, ECC is entitled, without prejudice to any other rights, to request security or advance payment for outstanding deliveries and to make all claims arising from the business relationship immediately due and payable.
8.5 In the event of default, the contracting party agrees to reimburse ECC for any reminder and collection fees incurred, insofar as they are necessary for appropriate legal enforcement. If the reminders are handled directly by ECC, the contracting party agrees to pay a fee of EUR 8.00 per reminder letter issued.
8.6 Upon the Customer's acceptance of an offer, the order becomes binding. The Customer may withdraw from the order, but may be subject to cancellation fees of 5% of the offer amount.
8.6.1 Custom-made orders: If the Customer cancels the order after submission of the treatment documentation but before the treatment plan is created, no fees will be charged. If a treatment plan has already been created and is cancelled (i.e., not confirmed) by the Customer, the orthodontist will be charged for the plan. If an order is canceled up to one week before the scheduled delivery date, a fee of 70% of the net price will be charged. After this point, the full offer price will be invoiced.

9. Force Majeure

- 9.1 In the event of force majeure, such as operational disruptions, strikes, lockouts, government measures, delayed deliveries from suppliers etc., the delivery and acceptance deadlines shall be extended for the duration of the hindrance. In such cases, claims for damages due to delayed delivery are excluded.
9.2 If circumstances that form the basis of the contract change significantly after the conclusion of the contract and the parties would not have concluded the contract, or would have concluded it with different terms, had they foreseen these changes, an adjustment of the contract may be requested, provided it is unreasonable for one party to adhere to the unchanged contract, taking into account all the circumstances, particularly the contractual or legal risk allocation.
9.3 If an adjustment of the contract is not possible or unreasonable for one party, the disadvantaged party may withdraw from the contract.

10. Transfer of Risk, Retention of Title

- 10.1 The risk of damage or loss of the medical devices passes to the Customer upon delivery (see Section 7.5.)
10.2 The delivered medical devices remain the property of ECC until all claims against the Customer, regardless of the legal basis, are fully satisfied. In the case of partial payment, this applies to the payment of the final installment. The Customer agrees to insure goods subject to retention of title against fire, theft, and water damage. Any third-party claims that affect ECC's ownership must be reported to ECC immediately.
10.3 Pledging or transferring goods subject to retention of title to third parties is excluded. In case of seizure, the Customer must expressly reference the retention of title and inform ECC without delay.

11. Credit, Set-off

- 11.1 Retaining due invoice amounts is generally not permitted. Offsetting is only allowed with claims that are undisputed and legally confirmed.
11.2 Unless otherwise required by law, returns for credit require prior written approval from ECC. For goods returned to ECC for credit, ECC reserves the right to deduct a processing fee of 25%. Credits are generally applied to the following order. Custom-made items are excluded from return for credit.

12. Warranty, Complaints, Returns

- 12.1 ECC delivers goods that are free of defects and quality-checked. With the exception of custom-made products (see sections 5.3, 5.4, 5.5), the customer agrees to inspect the goods immediately upon delivery and submit complaints in writing no later than 14 days after receipt, including the invoice number and, in the case of aligners, the case number.
- 12.2 The warranty will primarily be fulfilled through repair or replacement of the medical devices within a reasonable time during regular business hours.
- 12.3 Warranty does not apply to damage caused by external influences or failure to comply with the storage instructions on the label. It also does not apply in the case of improper, unsuitable use, or normal wear and tear.
- 12.4 For returns of products, the following conditions apply:
- Items must be unused, complete, in their original packaging, and in a condition that allows for resale.
 - The Customer bears the shipping costs for returns. It is recommended to insure the shipment for the invoice amount.
 - A copy of the original invoice or delivery note must be included with the return.
 - Custom-made items are excluded from return.

13. Liability and Compensation

- 13.1 The Customer assumes full responsibility for the proper use of ECC products and is liable for it. This includes decisions about the use and ongoing application of the products, approval of the treatment plan for aligner treatment, and continuous patient care to achieve the desired treatment results.
- 13.2 ECC is only liable for damages caused by gross negligence or willful misconduct, with the Customer bearing the burden of proof. Liability for minor negligence, consequential damages, financial losses, lost profits, unachieved savings, or interest losses is excluded. ECC is not liable for claims from third parties.
- 13.3 The Customer is obligated to inform ECC without delay, and no later than within ten days, of any events that concern the use of ECC products in a patient and which the Customer or ECC must report to a government or Competent Authority. All relevant information must be provided.
- 13.4 Under the product liability law, ECC is liable for personal injury or property damage caused by a defective product to an end-user/patient. Business Customers have no claims under product liability law.
- 13.5 Claims for damages arising from incidents are subject to a statute of limitations of twelve months from the date the damage became known.
- 13.6 ECC is responsible for maintaining and operating the servers used for providing treatment plans and data transfer. ECC will make reasonable efforts to resolve server outages as quickly as possible and restore services to affected Customers. In the case of a server failure caused by inadequate maintenance, insufficient security measures, or gross negligence on ECC's part, ECC is liable for direct damages. However, ECC is not liable for indirect damages such as lost profits or business interruptions for the Customer.

14. Data Protection

- 14.1 The manufacturer collects, processes, and uses the Customer's personal data exclusively in accordance with applicable data protection laws.
- 14.2 The Customer agrees that the personal data collected in the course of the business relationship, as well as data provided by ECC, will be electronically stored and used exclusively for internal purposes to fulfill the contract.
- 14.3 In the case of aligner treatments, the orthodontist guarantees that patients are informed about the processing of their medical data and that they have given explicit consent.
- 14.4 ECC is entitled to hire additional service providers to ensure the proper and timely delivery of the agreed services. The Customer agrees that these service providers may also use the personal data and information from the patient record, as necessary for production.
- 14.5 Furthermore, the Customer permits the use of their personal data for information about new products, services, technical solutions, or similar offerings provided by ECC. This includes Customer analysis, statistical evaluations, offer information, direct marketing, market research and business analysis.
- 14.6 The data will be stored in accordance with the privacy policy.

The present General Terms and Conditions were last updated on August 6th 2025, and have been valid and applicable since that date.