

General Terms and Conditions of Ortho Caps GmbH

for Use in Business Transactions with Entrepreneurs

As of: 01/08/2023

Ortho Caps GmbH (hereinafter "orthocaps") develops and sells services, software and devices (orthocaps services) that support dentists certified for the use of orthocaps (hereinafter "practitioner" or "treating person") in the diagnosis, planning and implementation of treatments for dental and jaw misalignments.

The following General Terms and Conditions (hereinafter "GTC") apply to contracts concluded with practitioners in this regard.

1. Validity of the conditions

- 1.1 The offers, deliveries and services of orthocaps to practitioners are exclusively based on these GTC. Any counter-confirmations referring to practitioners' own terms and conditions are hereby contradicted.
- 1.2 All agreements, assurances and quality guarantees deviating from these GTC must be recorded in writing.

2. Prerequisites for the use of orthocaps services

- 2.1 orthocaps offers its services exclusively to <u>practitioners certified for the use of orthocaps</u> at the time of use.
- 2.2 Only after certification is the practitioner entitled to use orthocaps services and devices.
- 2.3 <u>Prerequisites for certification include being licensed as a dentist or orthodontist and</u> <u>successful participation in an orthocaps certification course.</u>
- 2.4 The treating person guarantees that they are licensed in accordance with the previous paragraph at the time of using orthocaps services and devices. Practitioners are prohibited from using orthocaps devices and services if the dental licence or when treating legally insured patients the contractual dental licence ends, is suspended, or revoked/withdrawn.

3. Orthocaps portal

- 3.1 The practitioner must register on the orthocaps portal <u>https://www.orthocaps.net/</u>) and obtain authorisation for the use of orthocaps.
- 3.2 Sharing log-in data is not permitted. The treating person is obliged to keep the log-in data secret and to adequately protect it from use by third parties.
- 3.3 If orthocaps services are used by unauthorised third parties using the log-in data, the treating person is liable to orthocaps for the resulting damage.



- 3.4 The storage space available in the portal may not be used to store content whose provision, publication or use violates applicable law or agreements with third parties.
- 3.5 The practitioner is obliged to adequately check files for malware/viruses or other harmful components before storing them in the portal, using state-of-the-art protection programs.
- 3.6 orthocaps is entitled to immediately block access if there is reasonable suspicion that the stored data is illegal and/or infringes third-party rights. A reasonable suspicion of illegality and/or infringement exists in particular if courts, authorities and/or other third parties inform orthocaps thereof. orthocaps must inform the practitioner of the suspension, stating the reason. The block is to be lifted as soon as the suspicion is dispelled.

4. Non-binding case assessment

- 4.1 The non-binding case assessment is a free online service for certified practitioners and serves as an aid in answering questions regarding orthocaps services.
- 4.2 In the non-binding case assessment, a brief description of the treatment goal is submitted electronically by the practitioner, and orthocaps then sends a corresponding recommendation on the possibility of using orthocaps devices.

5. Binding case submission

- 5.1 A new treatment case can be created in the portal by clicking the "Add new case" button. If the treating person clicks the "Submit" button, the exact content of the planned order is displayed on an overview page and can then be "bindingly submitted"/ordered.
- 5.2 orthocaps is entitled to make changes to the products and service regulations/-instructions even after the contract has been concluded, based on new technical developments or insights, as long as this does not significantly affect the contractual balance between the parties. The treating person is obliged to regularly check the orthocaps website for changes to product and service regulations/-instructions. However, orthocaps will also separately inform the treating person of significant changes.

6. Orthocaps software and iSetups

- 6.1 If a contract is concluded, orthocaps will create a proposal for a possible course of treatment (iSetup) using orthocaps -devices.
- 6.2 With the help of the orthocaps software ("software as a service" or "SaaS"), the practitioner then has the opportunity to further adapt the proposal to the patient's needs by using the copyright-protected orthocaps software, accessible via the internet portal, and to manage their own treatment cases. orthocaps grants the non-exclusive and non-transferable right to use the orthocaps software for this purpose until the end of the respective treatment.



- 6.3 orthocaps ensures that the stored data can be accessed via the internet and takes appropriate precautions against data loss and unauthorised access by third parties.
- 6.4 orthocaps continuously develops the orthocaps software and will improve it through ongoing updates and upgrades. Adjustments, changes and additions to the SaaS-, as well as measures that serve to identify and correct malfunctions, will be carried out as far as possible in such a way that temporary interruptions or impairments of accessibility are avoided.
- 6.5 orthocaps will promptly notify the practitioner of maintenance work.
- 6.6 orthocaps will correct software errors as far as technically possible and reasonable. The practitioner will assist orthocaps in identifying and eliminating any defects and will allow access to documents showing the detailed circumstances of the defect's occurrence.
- 6.7 The availability of the orthocaps software is 98.5% on an annual average, including maintenance work, but the availability must not be impaired or interrupted for more than two consecutive calendar days.

7. Orthocaps devices

The orthocaps devices manufactured according to the practitioner's specifications are used for the treatment of malocclusions and/or misalignments of teeth. They are orthodontic treatment devices individually manufactured by the orthocaps master laboratory in Germany. orthocaps exclusively uses materials that are approved in Germany for the manufacture of the devices.

8. Delivery, delivery time and performance time, transfer of risk

- 8.1 The orthocaps devices are delivered in accordance with the agreements made with the treating person and otherwise by using the most favourable shipping method as chosen by orthocaps. In the case of special requests, additional costs will be charged separately.
- 8.2 Delivery dates or periods are only binding if they are expressly marked as binding in text form in the order confirmation.
- 8.3 If a delivery period lasts longer than four weeks, the practitioner is entitled to withdraw from the contract with regard to the as-yet unfulfilled part after setting a reasonable grace period. If the delivery time is extended or if orthocaps is released from its obligation, no claims for damages can be derived therefrom.
- 8.4 Compliance with orthocaps' delivery and service obligations presupposes the timely and proper fulfilment of the practitioner's obligations. Incomplete submission of the required documents may therefore lead to delays.

9. Payment

9.1 orthocaps accepts bank transfers and direct debit as payment options. For first-time customers, orthocaps may restrict the accepted payment methods before accepting the order. orthocaps does not



accept payments from patients or payers, including those forwarded by the treating person or payer on behalf of a patient.

- 9.2 Payments are due immediately after the conclusion of the contract without any discounts. The practitioner will be in default at the latest 15 days after receipt of an invoice. A payment is only deemed to have been made when orthocaps can dispose of the amount.
- 9.3 If the practitioner is in default, orthocaps is entitled to demand interest at a rate of 9 percentage points above the base interest rate from that point in time. For each reminder letter sent to the practitioner after the default occurs, the expected damage in the ordinary course of events will be charged at €2.50. The practitioner is permitted to prove that no damage has occurred or that it is significantly lower.
- 9.4 Offsetting and asserting rights of retention are only permissible if the counterclaim of the treating person is undisputed or has been legally established.

10. Retention of title

- 10.1 The goods remain the property of orthocaps until full payment has been made. If the practitioner is more than ten days in arrears with the payment, orthocaps has the right to withdraw from the contract and reclaim the goods.
- 10.2 The treating person is authorised to resell the goods subject to retention of title in the ordinary course of business. In this case, upon conclusion of the contract, they hereby assign to ORTHO all claims from such resale up to the invoice value of the claim by orthocaps, regardless of whether such resale occurs before or after any possible processing of the goods supplied under retention of title. Notwithstanding orthocaps' right to collect the claim itself, the treating person remains authorised to collect the claim after the assignment. In this context, orthocaps undertakes not to collect the claim itself as long as and insofar as the practitioner fulfils their payment obligations, no application has been made for the opening of insolvency or similar proceedings, and there is no suspension of payments. If the above-mentioned securities exceed the claims to be secured by more than 10%, orthocaps is obliged to release the securities of its own choice at the treating person's request.

11. Claims for material defects

- 11.1 orthocaps guarantees that the orthocaps devices are delivered free of manufacturing defects and have the contractually agreed quality. The period for asserting claims for defects is one year from receipt of the goods.
- 11.2 Claims for material defects against orthocaps are only available to the contracting practitioner and are not assignable.
- 11.3 In all other respects, the statutory warranty rights apply.

12. Liability



- 12.1 orthocaps is liable for damages resulting from injury to life, limb and health, insofar as these are based on a culpable breach of duty by orthocaps or one of its legal representatives or vicarious agents.
- 12.2 In all other respects, orthocaps is only liable for intent and gross negligence, including that of its legal representatives and senior employees, unless a duty is breached whose observance is of particular importance for achieving the contract's purpose (cardinal duty). Cardinal duties are those contractual duties whose fulfilment enables the proper execution of a contract in the first place, the observance of which the contractual partner may regularly rely on, and the breach of which on the other hand jeopardises the achievement of the contract's purpose. orthocaps is only liable for the fault of other vicarious agents to the extent of liability for the breach of cardinal duties.
- 12.3 In the event of a breach of a cardinal duty, orthocaps is also liable for slight negligence. However, liability is limited to foreseeable damages that typically must be expected to arise within the contractual relationship.
- 12.4 Liability under the Product Liability Act remains unaffected (Section 14 ProdHG).
- 12.5 orthocaps is not liable for the loss of data and/or programs to the extent that the damage results from the customer's failure to perform data backups and thereby ensure that lost data can be restored with reasonable effort.

13. Documents

- 13.1 Files or documents/impressions sent to orthocaps become the property of orthocaps. They will not be returned to the practitioner (except for X-ray images).
- 13.2 orthocaps assumes no liability for the loss of documents and data through transmission and processing.
- 13.3 Transmitted documents directly involved in manufacturing processes, such as impressions, are checked by orthocaps and may be found unsuitable. If they are found unsuitable, the treating person must provide replacement documents insofar as required for the proper handling of the order.
- 13.4 Physical documents such as impressions and study models are kept by orthocaps only as long as necessary to properly fulfil contractual relationships. They will subsequently be destroyed or archived at orthocaps' discretion.
- 13.5 orthocaps may use documents, including but not limited to impressions, X-rays, photographs, films, study models, etc., for orthodontic/dental consultations, continuing education and research purposes, publications in professional journals or professional accompanying materials, provided there is express written consent from the patient or if the corresponding data and documents are anonymised.

14. Final provisions

14.1 <u>Annex 1 is an integral part of these GTC.</u>



- 14.2 The law of the Federal Republic of Germany governs these Terms and Conditions and the entire legal relationship between orthocaps and the practitioner. The contract language is German. The provisions of the UN Sales Law do not apply. orthocaps may also make the GTC available in other languages. The German version is decisive for interpretation.
- 14.3 Changes to these GTC will be communicated by email. If the customer does not object to a change within four weeks of receiving the notification, the changes are deemed accepted by them. The right to object and the legal consequences of remaining silent will be pointed out separately in each case in the event of a change.



Annex 1

I. Obligations of the treating person

- (1) Decisions regarding assessment, diagnostics, planning and treatment of patients must be made by the treating person under their own sole responsibility, and based on a comprehensive and complete explanation to the patient.
- (2) The responsibility of the treating person for orthodontic treatment expressly also extends to the revision, evaluation, modification and confirmation of the orthocaps proposal as part of treatment planning.
- (3) The treating person is obliged to keep copies of the documents available in accordance with their professional and if applicable contractual dental documentation obligations and to keep them for the legally prescribed periods. orthocaps assumes no liability for the loss of documents and data through transmission and processing.
- (4) It is solely the responsibility of the treating person to implement recommendations from orthocaps or to decide whether orthocaps devices and services are suitable for use on a specific patient, for a specific use, or to achieve a specific result.
- (5) The treating person must ensure that the use of orthocaps devices and -services complies with the current state of dental knowledge and the generally accepted industry standard, and make sure to follow the orthocaps product and service regulations/instructions.
- (6) The treating person must inform patients that additional costs may arise if the orthocaps devices are not worn according to the instructions.
- (7) The treating person must indemnify orthocaps from any liability resulting from improper use of orthocaps devices and -services or incomplete or erroneous information.
- (8) When treating patients insured under statutory health insurance, the treating person must also ensure to be personally approved to participate in the contractual dental care. The treating person must observe the professional and contractual regulations, especially those relevant to their chamber law, the Fifth Social Code, the Federal Dental Fee Schedule, and the Orthodontic Guideline of the Federal Joint Committee.
- (9) Insofar as the transmission, collection, processing and use of personal (health) data to or by orthocaps require the consent of the patients concerned under data protection law, this must be duly obtained by the practitioner before transmitting the data and this due obtention must be proven on request.

II. Duty to inform about treatment risks

(1) orthocaps generally recommends orthodontic treatment only for periodontally and dentally stable patients. Nevertheless, the use of orthocaps devices and -services can entail risks. The practitioner is obliged to inform their patients about all risks that may arise in each individual case.

- orthocops[®]
- (2) This may include, in particular, the following risks.
 - Poor compliance or anatomical peculiarities, such as unusually shaped teeth, can extend the treatment duration and impair the quality of the final result or the ability to achieve the desired result.
 - The practitioner must inform the patients that additional costs may arise if the orthocaps devices are not worn according to the instructions.
 - Some sensitivity of the teeth is to be expected after the insertion of orthodontic devices.
 - Gums, cheeks and lips may become abraded or irritated.
 - Teeth may shift after treatment. This tendency can be reduced by regularly wearing retention devices after completing orthodontic treatment.
 - Caries, periodontal diseases, gum inflammations or visibly remaining spots (e.g. decalcification) on the teeth may occur if orthodontic patients consume sugary foods and do not clean their teeth thoroughly or lack sufficient oral hygiene.
 - The devices can temporarily affect the ability to speak while being worn.
 - The use of the devices can temporarily result in increased saliva flow or dry mouth. Certain medications can enhance this effect.
 - Enamel reduction may be necessary on some teeth to make room for tooth movement.
 - General medical conditions and medications can also affect orthodontic treatment.
 - The health of the bones and gums that support the teeth may be impaired.
 - Oral surgical interventions may be necessary to correct crowding or serious jaw disorders. If such surgical interventions are necessary, the risks associated with anaesthesia and healing must be taken into account.
 - A previously traumatised or significantly restored tooth can be damaged by orthodontic treatment. In rare cases, further dental treatment may then be necessary (e.g. endodontic or further restorative measures).
 - Existing dental reconstructions (e.g. crowns) may become loose and need to be recemented or in some cases even replaced.
 - Short clinical crowns can lead to retention problems and hinder tooth movement with the orthodontic device.
 - In some patients, the length of the tooth root may be shortened by orthodontic treatment. This may affect the lifespan of the teeth.
 - Orthodontic devices may break.
 - Orthodontic devices or their parts may accidentally be swallowed or inhaled. This risk is increased if the devices are shortened or modified by the treating person.
 - In rare cases, problems may also occur in the jaw joint, which can cause joint pain, headaches or ear complaints.
 - Allergic reactions may occur.
 - To prevent supraeruption, all teeth should be at least partially covered.

