



GC Tech. Europe GmbH General Terms and Conditions of Sales

1. Scope

Any sales contract entered into by GC Tech. Europe GmbH ("GC") and a buyer ("the Buyer") is exclusively governed by, in decreasing order of priority, any written agreement, the present general Terms and Conditions of sales ("T&C") and German law. These general terms and conditions shall replace all previous versions, shall be strictly interpreted, and the Buyer fully renounces the application of its own general terms and conditions.

The fact that GC does not invoke or does not try to enforce these general terms and conditions does not imply any waiver of the present terms and conditions. Any waiver or any deviations by GC will only be valid in writing.

Any agreement entered into by GC shall only be binding when executed or confirmed in writing by a competent representative of GC.

2. Offers

All orders shall be placed in writing to GC and are irrevocably binding upon the Buyer.

A binding agreement comes into force between GC and the Buyer upon signature of the order confirmation by GC, a written confirmation and acceptance of a received order, or any other clear and written agreement.

GC offers are subject to possibilities for delivery and prior sale. Thus, offers are only binding if expressly stated by GC, and remain in any case valid for one month, unless indicated otherwise.

Should GC exceptionally accept in writing to cancel an order placed by the Buyer, the Buyer shall pay to GC a lump-sum indemnity of 15% of the total price of the cancelled order, without prejudice of GC's right to claim additional damages.

The signatory who places an order in his or her own name or in the capacity of mandatary, or who fully or partially pays for the order, even on behalf of third parties, acts in the name of these third parties and commits itself jointly and indivisibly with them.

3. Price

Applicable prices are those that appear on the GC price list at date of acceptance of the purchase order. All prices are deemed plus the statutory value added tax. The prices are subject to increase at any time in the case of (i) a demonstrable increase in [raw material and component] prices and/or (ii) an increase in government levies on the ordered products. In such cases, the new price structure shall be notified to the Buyer in writing or by e-mail at least two weeks before coming into force. In all other cases of price increase, the new price structure shall be notified to the Buyer in writing or by e-mail at least three months in advance.

If the Buyer does not accept the new price, it has the option to terminate the agreement by registered letter, seven (7) days after the notification of the price increase. If GC has not received this notice of termination by the time the new price structure comes into force, the Buyer is considered to agree with the new price structure.



All taxes, duties and/or levies that concern the delivered goods or their transport, of whatever kind, including new taxes, duties and levies that might be introduced after the conclusion of the agreement, are fully for the expense of the Buyer.

For sales to distributors, no shipping costs will be charged for any orders with a value as of 500,00 EUR. For sales to any other buyers, no shipping costs will be charged for any orders with a value as of 250,00 EUR.

4. Payment

In the absence of a written agreement otherwise, the invoices of GC are payable no later than thirty (30) days after the invoice date. In the event of full or partial non-payment of an invoice by the due date, the Buyer owes default interest on the unpaid invoice amount whereas the interest rate is 9%-points above the respective base lending rate of the European Central Bank. In case GC is in the position to prove higher damages on default, for example by conducting (external) debt collection efforts, GC is entitled to assert these. Furthermore, GC retains the right to suspend further deliveries and installations and/or terminate the agreement without prior notice of default for all of the portion not yet executed, without prejudice to the damage compensation owed by the Buyer. Finally, GC retains the right to claim back the goods sold in the case of non-payment. If GC would have doubts at any time concerning the creditworthiness of the Buyer due to legal actions taken against the Buyer, due to non-payment or late payment of one or more invoices, and/or any other demonstrable event, GC explicitly retains the right to demand prior payment for deliveries yet to be made, or demand (other) guarantees, even if all or part of the goods have been sent.

The Buyer is only entitled to rights to offset if its counterclaims have been determined final and binding or have been confirmed by GC. The Buyer can only exercise a right of retention if its counterclaims are based on the same contractual relationship.

5. Delivery

The communicated delivery times are purely indicative. GC is not responsible for indirect damage resulting from late delivery or lack of delivery. If the delay in delivery lasts more than thirty (30) days, the Buyer has the right to cancel the purchase by registered letter without judicial intervention. Any advance payment made by it will be refunded. The Buyer explicitly renounces any other possible means of redress, in particular the awarding of any form of damage compensation. Compliance with GC's delivery obligation presumes the timely and proper satisfaction of the Buyer's obligations.

GC retains the right to make partial deliveries. The partial delivery of an order may never serve as justification for the refusal to pay for the goods delivered.

The goods sold shall be delivered in accordance with the Incoterms 2020 CIP, unless expressly agreed otherwise. The Buyer is obliged to receive the goods delivered by a carrier on behalf of GC at the agreed date, and to foresee the required space so that the goods can be delivered. The carrier shall deliver the goods to the ground floor of the registered office of the Buyer, unless agreed otherwise. Upon delivery, the Buyer shall sign the delivery note in acknowledgement of receipt. However, the risk shall transfer from GC to the Buyer at the point where the goods are taken in charge by the carrier.



Title to the goods shall only pass to the Buyer when full payment (including accessories) of the invoice for the aforementioned goods has been made. The Buyer has to notify GC immediately in writing in case of attachments or other interventions of third parties so that GC is able to file an action according to § 771 ZPO (German Code of Civil Procedure). For the duration of the retention of title, the goods are to be insured by the Buyer against fire, water, theft and burglary theft; the rights from these insurances will be assigned to GC which accepts these assignments. In case the Buyer resells the goods, the Buyer will grant an extended retention of title to GC. The Buyer shall however be entitled to collect this claim towards the Sub-Buyer while GC retains the right to collect the claim itself.

6. Returned goods

In the event that the Buyer wishes to return goods to GC, the following rules apply:

- No returned shipment of goods shall be accepted without prior written notice (return request) and respective prior approval by GC Sales Department;
- The returned goods shall only include goods directly purchased by the returning party from GC;
- The return shall be requested at the latest one month after receipt of the goods by the Buyer;
- In the event of a complaint request, any used implant and abutments has to be sterilized by the Buyer, for example in an autoclave; the complaint request must be accompanied with a completed Aadvia™ Implant Complaint Questionnaire (if the product is an implant);
- Any return request must be accompanied with an excel listing of the goods mentioning the following:
 1. Article No
 2. Description
 3. Quantity
 4. LOT No.
 5. Expiry date
 6. Reason for complaint
 7. Information about desired replacement (with Article No. and Quantity)
- All returned goods shall have a remaining shelf life of minimum 14 months from the receipt of the returned goods at GC;
- The goods must be in a resalable condition, which includes but is not limited to the following:
 1. No dealer stickers
 2. Undamaged, clean original packaging
 3. Closed & sealed packages
- In the event that the return of the good is justified, i.e. approved by GC Sales Department due to e.g. upselling, product switch with upselling, product exchange with upselling or the like, the returned good is subject to a 15% return fee of the original price.
- In the event that the return of the good is unjustified, i.e. none of the aforementioned reasons are given, but the return is approved by GC Sales Department though, the returned good is subject to a 30% return fee of the original price.
- In case of an unannounced return (= no approval by GC Sales Department), no credit note will be issued. In this case, the Buyer has the choice of either getting the returned goods back at his expense or leaving it up to GC to dispose about the returned goods without any credit and at his expense.



7. Compliance with the Laws applying to Medical Devices

In the event that the sold products are medical devices, the Buyer shall observe all applicable legal provisions (laws, rules, regulations or applicable orders), particularly the requirements of the medical device legislation, with regard to the storage and distribution of the products. Especially the compliance with the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices is to be highlighted in this context.

In particular, the Buyer shall ensure the traceability of the products according to Article 25 of Regulation (EU) 2017/745 so as to enable products to be recalled if necessary. The Buyer shall document any data necessary to trace the medical device products, like for example UDI number as well as date, place and person of delivery or application (dentist, distributor or patient), and shall hand out or inform the dentist to hand out this relevant information to the patient who has received or has been treated with the medical device as far as it is an implantable medical device. The Buyer shall pass on this obligation to further distributors in the case that the Products are being sold from a distributor to another distributor.

If the Buyer is distributor of the products, it shall undertake to further abide by the general obligations set out for distributors in Articles 14 and 16 of the Regulation (EU) 2017/745. In particular, a distributor shall ensure that, while a medical device is under its responsibility, storage or transport conditions comply with the conditions set by GC. Furthermore, if a distributor considers or has reason to believe that a device which it has made available on the market is not in conformity with this Regulation due to any risks/problems/malfunctions, it shall immediately (within 1 working day) inform GC in writing. The distributor shall cooperate with GC and with competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or to recall it, as appropriate, is taken. Where a distributor considers or has reason to believe that the device presents a serious risk, it shall also immediately inform the competent authorities of the Member States in which it made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.

Buyer's complaints that are received will be processed to GC, any distributor involved shall provide assistance if required. Any distributor shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and keep GC informed of such monitoring and provide them with any information upon their request.

A distributor shall, upon request by a competent authority, provide it with all the information and documentation that is at its disposal and is necessary to demonstrate the conformity of a medical device.

8. Force majeure

In the case of force majeure, the obligations of the affected party with respect to the other party are suspended. By force majeure is understood the situation in which the execution of the agreement by one of the parties is fully or partially prevented, whether temporarily or not, due to circumstances outside the will of this party, even if this situation was already foreseen at the time of the formation of the agreement. This includes but is not limited to war, mobilization, strikes, lock-outs, official decrees. In this case, the parties will take all reasonable efforts to limit the effects of the situation of force majeure. If the situation of force majeure should last more than two months,



the other party is entitled to cancel the agreement without the intervention of a court, without the party appealing to force majeure being obliged to pay any compensation to the other party.

Inasmuch as the obligation of the Buyer with respect to GC is in essence a payment obligation, force majeure on the part of the Buyer is hereby excluded.

9. Complaints

Possible visible defects and non-conformities in the delivery (e.g. missing goods or deviating deliveries) must be mentioned on the delivery note without delay. They shall be deemed accepted provided they have not been reported within three (3) working days following the delivery. The Buyer must describe the defects and non-conformities in detail and include clear photos.

Other defects that remain hidden, despite proper inspection of the goods at the time of the delivery, must be reported immediately by registered letter and no later than five (5) working days after their discovery, on pain of lapse of right of recourse. This notification must contain a detailed description of the defect and clear photos must be included.

10. Warranty

The following warranty clause covers clinical components and instruments that are part of the Aadva™ system, i.e. implants, cover screws, abutments, bridge cylinders, abutment screws, bridge screws, clinical instruments and other prosthetic accessories ("Products"), manufactured and distributed by GC. The warranty outlined in these T&C is exclusively for the benefit of the eligible treating dentist ("Dentist") and is not for the benefit of any other person or entity, including patients, laboratories and other intermediate suppliers.

The warranty for the Products is granted for the following periods, subject to the limitations and exceptions of these T&C:

- ten (10) years warranty from the date of shipment to the end customer (Dentist) for Aadva™ implants;
- ten (10) years warranty from the date of shipment to the end customer (Dentist) for Aadva™ abutments and prosthetic accessories.

GC guarantees for ten (10) years from the date of shipment to the end customer (Dentist), to replace any Aadva™ implant that fails to remain in the bone in which it is implanted. GC will in such case replace free of charge the implant and Aadva™ restorative components placed on the implant at the time of failure with the same Aadva™ implant and restorative components (Aadva™ abutments and prosthetic accessories) as installed on the implant at the time of failure (the only possible changes are related to diameter and/or length).

GC guarantees for ten (10) years from the date of shipment to the end customer (Dentist), to replace free of charge any non-temporary and non-provisional Aadva™ restorative component (Aadva™ abutments and prosthetic accessories) that fails with the same restorative component.

To receive benefits under these T&C, the Dentist must comply with all of the following:



- Warranty claims must, to remain eligible, be reported to GC within fifteen (15) days from the date on which the claimed defect was discovered. Reporting shall fully comply with the procedure set out herein. Dentist shall contact the GC Sales Representative or GC Customer Service to request a complaint record form and receive instructions for Product return; and
- The completed complaint record form, documenting the cause of the claimed failure, must be returned to GC accompanied by the Product in question within the time stated above. Any product must be decontaminated prior to return to GC; and
- Dentists submitting a complaint record form for surgical benefits, must provide documentation of the case and demonstration that implants were indicated and that no contra-indicated conditions existed for that particular patient; and
- All procedures using the Products – before, during and after implantation – must be performed in accordance with GC protocols, guidelines and instructions, as well as generally accepted dental practices.

The warranty granted in these T&C shall not apply in the following situations:

- The failure is caused by a trauma, an accident, or by any other damage caused by the patient or a third party; or
- The failure is caused by a clinical component placed in patients with accepted contra-indicated conditions to successful implant integration, including but not limited to diseases related to alcoholism, uncontrolled diabetes, and habitual drug dependency; or
- The failure is due to normal wear and tear; or
- The Product subject to warranty claims is a single-use instrument; or
- The Product subject to warranty claims has been used in direct or indirect combination with a clinical component or instrument originating from another manufacturer than GC.

Transport costs and transport risk shall be borne by the Dentist. The cost of return shipment shall be borne by GC in cases covered by the warranty under these T&C.

Except for the warranty specified in these T&C, GC does not make any representation, warranty, covenant or other undertaking, expressed or implied, written or oral, with respect to the Products, including (without limitation) any implied warranties of merchantability, durability or fitness for a particular use or purpose.

11. Liability

The Buyer may claim damage compensation only in the case of serious or intentional error on the part of GC.

To the maximum extent permitted by the applicable law, GC excludes liability for immaterial, indirect or consequential loss, including but not limited to loss of profit, production restrictions, lost savings, damages, personnel costs, administrative costs, claims by third parties.

Insofar as GC depends on the cooperation, services and supplies of third parties in the execution of its obligations, it cannot be held liable for any damage resulting from their error, including serious or intentional error.

In the event that the goods sold by GC would exhibit defects, the Buyer may only claim repair or replacement of the delivered goods, without the Buyer being entitled to claim any form of damage compensation.



The Products, its labels, instructions for use and warnings will be designed, translated, tested and approbated for use in the countries of the EMEA (Europe, Middle East and Africa) (hereinafter "Territory") only. The Buyer understands and accepts that the Products are not designed for use outside the Territory. To the extent permissible by law, GC accepts no responsibility or liability for any damage or loss caused by the Buyer's sale of the Products outside the Territory. GC can further claim direct and indirect damages of any kind arising from or in any way connected to the sale of its products outside the Territory.

All clauses which restrict the free movement of goods within the European Economic Area or subject it to special conditions are void.

Except as otherwise limited under the present conditions, GC's liability in respect of any failure to perform any provision of any contract and/or of the present conditions, shall be limited, per event, to the turnover realized by GC with the sale of goods to the Buyers during the twelve (12) months preceding the date of failure or, if the contractual relation has lasted for less than twelve (12) months, to the projected yearly turnover based on the turnover realized until the date of failure.

12. Applicable laws and jurisdiction

All agreements to which these general terms and conditions apply, as well as all other agreements resulting thereof, are governed exclusively by German law. Application of the Vienna Sales Convention of 11 April 1980 is explicitly excluded.

All disputes between parties concerning agreements subject to these general terms and conditions belong exclusively to the competence of the courts of Hagen, Germany.