

General Terms and Conditions of Business Transactions, Sales, Delivery and Payment

1. Validity; Quotation and Acceptance

- (1) The following General Terms and Conditions of Sale ("GTCS") apply to all business relationships that FIOR & GENTZ Gesellschaft für Entwicklung und Vertrieb von orthopädietechnischen Systemen mbH ("Seller") concludes with customers ("Buyer"). The Buyer's deviating, conflicting or supplementary provisions shall only be valid if the Seller has accepted them in writing. These GTCS shall only apply to entrepreneurs, legal entities under public law or special funds under public law under Section 310 (1) of the German Civil Code (BGB). These GTCS shall also apply to all future transactions concluded between the Parties and also if the Seller carries out delivery of the goods in the knowledge of the Buyer's deviating, conflicting or supplementary provisions.
- (2) The Seller's quotations are subject to change, non-binding and subject to availability. This shall also apply if the Seller has provided the Buyer with catalogues, other product descriptions or documents – also in electronic form. Pursuant to Section 4 (1) of these GTCS, the prices stated in the current price list that is valid at the time the order is placed shall be decisive for the amount of the purchase price to be paid.
- (3) The Buyer's ordering of the goods shall be deemed a binding offer of contract. Unless stated otherwise in the order, the Seller shall be entitled to accept this offer of contract within four (4) weeks of receiving the same. The Seller's acceptance may be declared either in writing (e.g. by means an order confirmation) or by delivery of the goods to the Buyer.
- (4) The Buyer must take note of instructions for use enclosed with the goods on delivery or other product-related accompanying documentation enclosed with the goods. The Buyer shall relieve the Seller of every responsibility for damages caused by third parties in the aftermath of non-compliance with or complete disregard of the instructions for use.

2. Delivery; Transfer of Risk

- (1) Delivery presupposes that the Buyer's obligations have been properly met on time. The right to object due to non-performance of the contract remains reserved. Deadlines and dates for deliveries promised by the Seller are only ever approximate, unless a fixed deadline or date has been expressly promised or agreed. If a shipment has been agreed, delivery periods and delivery dates refer to the time of handover to the forwarder, carrier or other third party commissioned with transport. The assertion of claims due to non-compliance with delivery deadlines requires the Buyer to set an appropriate grace period of 21 days minimum.
- (2) Deliveries (including partial deliveries) shall be made ex Seller's warehouse. The risk of accidental loss or accidental deterioration of goods shall be deemed transferred to the Buyer on provision or dispatch of consignment. In the event of default in acceptance or other culpable breaches of duties to cooperate on the Buyer's part, the Seller shall be entitled to compensation for the resulting damage, including any additional expenses. Any further claims remain reserved. In this case, the risk of accidental loss or accidental deterioration of the goods shall pass to the Buyer at the time of default in acceptance or other breaches of duties to cooperate.
- (3) In the event of force majeure, such as strikes, shortage of raw materials, operational disruptions through no fault of the Seller, war or similar incidents, the Seller shall be entitled to postpone the execution of the orders in whole or in part until the obstacle has been remedied, without the Buyer being entitled to any claim to compensation. In this case, the Buyer shall also not be entitled to withdraw from the contract.

3. Exchange

- (1) Goods may only be exchanged in exceptional cases if all of the following conditions are met:
 - the goods in question and their packaging are undamaged;
 - the goods in question correspond to the most recent version of the product;
 - the goods in question are in their original packaging, complete, unused and in a perfect hygienic condition;
 - the goods in question are accompanied by the return form, which must be filled out in full;
 - the goods in question are returned to the Seller at the Buyer's expense;
 - the goods in question are returned in accordance with the instructions in the relevant instructions for use, particularly our transport instructions, which are supplied with the goods.

The goods shall be exchanged by shipping the goods at the Buyer's expense to the Seller's address. In the event that goods are exchanged, the goods' purchase price – less the administrative and processing costs incurred under Section 3 (2) where appropriate

– shall be credited to the Buyer's account and can be applied to the next purchase.

Goods may only be exchanged within eight months of the invoice date. The date on which the Seller receives the goods is decisive for the end of the period.

- (2) Goods that
 - are exchanged two months after the invoice date shall be subject to 10% administrative and processing costs from the purchase price;
 - are exchanged four months after the invoice date shall be subject to 30% administrative and processing costs from the purchase price.

4. Payment

- (1) The Buyer shall pay the prices stated in the current price list that is valid at the time the order is placed, plus value-added tax at the statutory rate, post and packaging. These prices shall apply subject to any price increase that may become necessary at the time of delivery due to a substantial increase in the prices of goods from the Seller's suppliers. In this case, the prices valid at the time of shipment shall apply.
- (2) The purchase price is due from the invoice date and delivery or acceptance of the goods. Bank charges for international transfers must be borne by the Buyer. Interest shall be added to the purchase price due for payment if it is not paid within 30 days following receipt of the invoice and delivery or acceptance of the goods. Default in payment shall require no additional reminder pursuant to Section 286 (3) of the German Civil Code. The Seller reserves the right to claim further damages for default.
- (3) If payment is made within ten days of the invoice date, a 2% discount shall be granted for bank transfer and a 3% discount shall be granted for direct debit. A 2% discount is also granted if goods are delivered cash on delivery.
- (4) Any chargeback fees shall be borne by the Buyer and shall be invoiced accordingly.
- (5) If the Buyer's assets deteriorate significantly, the Seller shall be entitled to make further deliveries only against advance payment and to make all outstanding invoices due for immediate payment.
- (6) The Buyer shall only be entitled to offsetting insofar as its counterclaims are undisputed or have been legally established. The Buyer is only entitled to assert rights of retention based on counterclaims from the same contractual relationship.

5. Reservation of Title

- (1) Goods shall be delivered subject to reservation of title. They shall remain the Seller's property until all present and future receivables arising from the contractual relationship have been paid in full. The reservation of title extends to all receivables arising from the current business relationship (extended reservation of title). The goods that are subject to reservation of title may neither be pledged to third parties nor assigned as security before the secured receivables have been paid in full. The Buyer shall immediately notify the Seller in writing if an application for the institution of insolvency proceedings has been filed or if third parties have access to the goods belonging to the Seller (e.g. seizures).
- (2) The Buyer is entitled to process or combine the reserved goods with other goods or to resell them in the normal course of business. The following provisions shall additionally apply in this case.
 - a) The reservation of title extends to the products created by processing, mixing or combining the goods at their full value, whereby the Seller is deemed to be the manufacturer. If the Seller's reservation of title remains when the goods are processed, mixed or combined with third-party goods, the Seller shall acquire co-ownership of the new goods in the amount of the proportionate value of the reserved goods and the combined or newly produced goods. In all other respects, the same shall apply to the resulting product as to the goods delivered under reservation of title.
 - b) The receivables arising from resale of the goods or the product that the Buyer has against customers or cost bearers are already now assigned by the Buyer in total or proportionate to the co-ownership as security to the Seller, who accepts this assignment.
- (3) The Buyer shall continue to be authorised to collect receivables, even though this shall not affect the Seller's authority to collect receivables itself. The Seller does not invoke this right as long as the Buyer meets its contractual obligations arising from the current business relationship. If this is not the case, the Seller may demand that the Buyer informs it of the assigned receivables and its debtors, provides all the information necessary for collection, hands over the relevant documents and informs the debtors (third parties) of the assignment. If the Buyer does not meet its payment obligations vis-à-vis the Seller or if it is unable to pay in some capacity, the right to resell, process or combine the goods and the authorisation to collect the assigned receivables shall expire.
- (4) The Buyer is obligated to immediately notify the Seller of any agreements with third parties that conflict with the transfer of receivables. In the event that the goods delivered under reservation of title are resold, the Buyer is prohibited from agreeing with the third party that the purchase price receivable that the Buyer is entitled to from the resale is unassignable or can only be assigned with the third party's consent.
- (5) If the Buyer breaches the contract, including default in payment, the Seller shall be entitled to withdraw from the contract and/or to demand that the goods be returned based on the reservation of title. The Buyer shall bear all costs that the Seller incurs due to repossession of the goods. If the Seller makes use of its claim for return of the delivered goods, without prejudice to this payment obligation incumbent on the Buyer it shall be entitled to exploit the repossessed goods in the best possible way by selling them.

6. Statutory Warranty

- (1) If the goods delivered by the Seller show material defects, the Seller shall assume the warranty in accordance with the statutory provisions, unless stipulated otherwise below.
- (2) However, any warranty is excluded if
 - a) after handover to the Buyer, the Buyer or a third party makes changes to the goods that extend beyond installation in accordance with the state of the art and the Seller's instructions for use or do not comply with the same; or

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- b) the goods are combined with other manufacturers' brands that are in violation of the state of the art, the installation method or the Seller's instructions for use and have not been approved by the Seller, unless this change to the goods or combination with other manufacturers' brands is not the cause of the defect; or
- c) the goods are used repeatedly, unless this repeated use is not the cause of the defect. Repeated use means that
 - the goods are used in another custom-made product; or
 - the goods are reused beyond the original indication-based selection.

Accordingly, such damages that are attributable to improper use, careless maintenance and failure to observe the instructions for use shall be excluded from the warranty.

- (3) Only the product description and manufacturer's specifications that are the subject matter of the purchase contract in question shall be decisive for determining the quality of the goods. The suitability of the goods for the intended purposes, particularly with respect to patient care, is not covered by the quality of the goods. Customary or minor, technically unavoidable deviations shall not constitute defects.
- (4) The Seller's warranty obligation shall only apply if obvious defects are reported in writing without delay, no later than eight days following receipt of the goods, and if defects that are not recognisable on inspection are reported in writing within the same period following discovery, by returning the goods and the necessary accompanying documents. Uncertainties shall be borne by the Buyer.
- (5) Notwithstanding Section 438 (1) (3) of the German Civil Code, the limitation period for warranty claims is set at one year from delivery. This shall also apply to contractual and non-contractual claims for compensation asserted by the Buyer based on defective goods, unless the application of the regular statutory limitation period (Sections 195 and 199 of the German Civil Code) would lead to a shorter limitation period on a case-by-case basis. However, claims for compensation asserted by the Buyer under Section 7 (1) and (2) (a) of these GTCs and pursuant to the German Product Liability Act shall become time-barred exclusively in accordance with the statutory limitation periods.

7. Disclaimer

- (1) Liability for damages exists – irrespective of the legal grounds – in the context of fault-based liability in the case of intent and gross negligence.
- (2) In the event of simple negligence, the Seller shall only be liable, subject to statutory limitations of liability (e.g. personal due diligence, insignificant breach of duty), for
 - a) damages resulting from injury to life and limb or harm to health;
 - b) damages resulting from the breach of a material contractual obligation (an obligation, the fulfilment of which makes proper performance of the contract possible in the first place and on the observance of which the Party regularly relies and may rely); in this case, however, our liability is limited to compensation for the foreseeable, typically occurring damage.
- (3) The limitations of liability in Section 7 (2) shall not apply if the Seller has fraudulently concealed a defect or has given a guarantee for the quality of the goods and for the Buyer's claims under the German Product Liability Act.

8. Seller's Warranty

- (1) In addition to the statutory warranty entitlement, the Seller shall grant the Buyer a ten-year warranty from the invoice date for upper and lower parts of joints in accordance with the conditions set out below. Only the original buyer is entitled to make warranty claims. Warranty claims are not transferable to third parties.
- (2) If an upper or lower part of a joint breaks, the Seller shall provide the Buyer with an equivalent product free of charge within the warranty period, provided that the prerequisites set out in Section 8 (3) are met and the warranty is not excluded under Section 8 (4).
- (3) The warranty shall only be granted to the Buyer if the Buyer has made the joint using the Orthosis Configurator on our website www.orthosis-configurator.com when ordering the goods. This configuration must be sent to the Seller together with specific reference to making a claim under the warranty. Furthermore, a digital photo of the entire custom-made product (viewed from the side) must be sent to the Seller. Additionally, whether the warranty is granted depends on the Buyer's compliance with and complete documentation of the necessary conditions contained in the respective instructions for use to guarantee a fundamentally unrestricted period of use.
- (4) The warranty is excluded in the following cases:
 - if the Buyer failed to report the defect to the Seller in writing within 30 days of becoming aware of the same; or
 - if the Buyer did not provide the Seller with any written description of the defect when reporting the same; or
 - if the Buyer was using the goods repeatedly in another custom-made product; or
 - if the Buyer has failed to comply with the instructions for use, particularly in the event of non-compliance with the state of the art, as well as in the event of negligent or intentional damage or improper use, particularly the use of force when handling or processing the goods; or
 - in the event of damage to the goods caused by processing that was carried out contrary to the instructions in the documentation accompanying the goods, particularly the Seller's instructions for use; or
 - if the Seller's goods are combined with other manufacturer's goods.

- (5) The scope of the warranty only covers the goods delivered by the Seller, but not the time that the Buyer spends working on manufacturing the custom-made product.

9. Regulations with Regard to Regulation (EU) 2017/745 for Medical Devices

- (1) Within the scope of application of these GTCs, the following regulations shall additionally apply if and to the extent to which the deliveries from the Seller to the Buyer are medical devices as well as their components according to Regulation (EU) 2017/745 (hereinafter summarised: medical devices) and the Buyer will make the medical devices available on the market as distributor according to Art. 2 (34) Regulation (EU) 2017/745. The Seller is the manufacturer of the medical devices according to Art. 2 (30) Regulation (EU) 2017/745.
- (2) The Buyer shall comply with the obligations of distributors that it has to take on as distributor according to Art. 14 Regulation (EU) 2017/745.
- (3) The Buyer and the Seller shall cooperate to ensure full traceability of the medical devices, especially for the case of field safety corrective actions. According to Art. 25 (2) Regulation (EU) 2017/745, the Buyer shall ensure that, for a period of at least ten (10) years after having placed the last medical device on the market, it is able to identify at any time to the competent authority from whom it has obtained the medical devices and to whom it has supplied the medical devices. The Buyer shall establish a procedure suitable for giving this information and document its compliance. In order to ensure full traceability of the medical devices, the Buyer shall document in particular from whom it has obtained the medical devices and to whom it has supplied the medical devices. The Buyer shall have this documentation ready and keep it for the above-mentioned period for inspection by the competent authorities. The Buyer shall make appropriate arrangements so that the documentation can also be made available for the above-mentioned period in the event of termination of business operations.
- (4) The Buyer shall inform the Seller without delay about a suspected non-compliance of the medical devices with Regulation (EU) 2017/745 and about any notifications from the market, especially received complaints, claims or reports of suspected incidents or a serious risk in connection with the medical devices. The Buyer shall document the aforementioned information and keep this documentation for at least ten (10) years after having placed the last medical device on the market. The Buyer shall make appropriate arrangements so that the documentation can also be made available for the above-mentioned period in the event of termination of business operations.
- (5) The Buyer shall comply with the storage and transport conditions for the medical devices in accordance with the Seller's specifications, taking into account the instructions for use and/or the labelling and document the compliance. The Buyer shall make this documentation available to the Seller upon request.
- (6) If the Seller provides the Buyer with materials for advertising the medical devices (e.g. texts, designations, trademarks, illustrations or other signs), the Buyer shall exclusively use these advertising materials regarding the medical devices. Should this not be the case and the Buyer intends to use its own materials for advertising the goods, the Buyer is obliged to submit these materials to the Seller for inspection before using them and to use them only if the Seller gave its written approval.

10. Applicable Law; Place of Performance and Jurisdiction

- (1) These GTCs and the contractual relationship between the Seller and the Buyer are governed by the laws of the Federal Republic of Germany, to the exclusion of the provisions set out in the UN Convention on Contracts for the International Sale of Goods (CISG).
- (2) The place of performance and exclusive place of jurisdiction for all disputes arising from or in connection with the contractual relationship shall be the Seller's or its legal successor's registered office.