

General Terms and Conditions of Delivery and Payment of Peter Brehm GmbH

Peter Brehm GmbH
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§ 1 Scope and Applicable Law

1. Our Terms and Conditions of Delivery and Payment apply exclusively; we do not recognise any terms and conditions of the buyer that conflict with or deviate from our Terms and Conditions of Delivery and Payment unless we have expressly consented to their applicability in text form. Our Terms and Conditions of Delivery and Payment also apply if, with knowledge of conflicting or deviating terms and conditions of the buyer, we carry out the delivery without reservation.
2. All agreements made between us and the buyer for the purpose of performing this contract are set out in writing or in text form in this contract or in the associated contractual documents.
3. Our Terms and Conditions apply only vis-à-vis traders within the meaning of § 14 BGB, legal entities under public law and special funds under public law (exclusively B2B business for endoprosthetics, implants and instruments).
4. Insofar as contractual documents are made available in several languages, the German version shall prevail in case of doubt.

§ 2 Formation of Contracts

1. All offers, prices and other statements are non-binding unless they are expressly designated as binding.
2. Orders placed by the buyer shall be deemed accepted only when they are confirmed by us in writing or in text form, by delivery of the goods or by sending an invoice.
3. The documents forming part of the offer, such as illustrations, drawings, weight and dimension information, implant specifications and instrument descriptions, are approximate unless they are expressly designated as binding.
4. In the case of products manufactured for an individual patient, custom-made products or products based on customer-specific requirements, cancellation is excluded after the start of design or manufacture unless mandatory statutory provisions provide otherwise.

§ 3 Prices

1. Unless otherwise stated in the order confirmation, our prices are in EURO "ex works Weisendorf" (EXW Incoterms 2020), excluding packaging; packaging will be invoiced separately.
2. Statutory value added tax is not included in our prices; it will be shown separately in the invoice at the statutory rate applicable on the date of invoicing.
3. Further terms and conditions arise from the delivery and shipping terms agreed in each case.
4. If more than six weeks lie between conclusion of the contract and the agreed delivery date, we are entitled to adjust the agreed price appropriately if, after conclusion of the contract, cost factors affecting pricing, in particular wages, material, energy or transport costs, import duties or excise taxes, increase or decrease and we are not responsible for the respective change in costs. Cost reductions will be taken into account in the same manner by reducing the price. An adjustment shall be made only to the extent of the actual change in costs; we will provide evidence of such changes to the buyer upon request.

§ 4 Design and Form Changes

1. Changes to the characteristics of the goods (design, material, surface treatment, packaging, instrument sets) that are immaterial to the conclusion of the contract under the principle of good faith and comply with the applicable requirements of medical device law, in particular Regulation (EU) 2017/745 (MDR), are permissible provided that they do not unreasonably prejudice the interests of the buyer.

§ 5 Delivery Time - Delay in Delivery

1. Incoterms 2020 shall apply to the interpretation of agreed trade clauses.
2. Compliance with our delivery obligation requires the timely receipt of all documents to be provided by the buyer (in particular technical specifications and approvals), the necessary approvals, and compliance with the agreed payment terms.
3. We reserve the right to make our delivery subject to correct and timely delivery to us, provided that we have concluded a congruent covering transaction and the non-delivery to us despite proper procurement is not attributable to us. In this case, we are entitled to withdraw from the contract in whole or in part. The buyer will be informed without undue delay of the non-availability; any consideration already rendered will be reimbursed without undue delay.
4. We are entitled to make partial deliveries to a reasonable extent; these shall be deemed independent deliveries.
5. In the event of force majeure or other events outside our area of responsibility and for which we are not responsible that temporarily prevent or substantially impede delivery, agreed delivery periods shall be extended by the duration of the impediment plus a reasonable start-up period. Such events may include, in particular, natural disasters, lawful industrial disputes, measures by authorities or significant supply chain disruptions that were unforeseeable at the time the contract was concluded and could not be avoided by us. If the impediment lasts longer than two months, both parties may withdraw from the contract with respect to the part not yet performed.
6. In the event of delay in delivery, our liability and any claims for damages shall be governed by the statutory provisions in conjunction with § 12 of these Terms and Conditions.
7. In the event of delay in delivery, the buyer may claim lump-sum compensation for delay in the amount of 0.5 % of the net value of the delayed delivery for each completed week of delay, but no more than 5 % in total. The buyer remains entitled to prove a higher loss, and we remain entitled to prove a lower loss or that no loss was incurred. Any lump sum paid shall be credited against further claims for damages.
8. Fulfilment of our delivery obligations is subject to the condition that no national or international provisions of foreign trade, export control or sanctions law prevent such fulfilment.

§ 6 Payments

1. Invoices are due for payment net within 30 days after receipt without deduction.
2. Bills of exchange and cheques will be accepted only by express agreement and only on account of performance; any charges arising therefrom shall be borne by the buyer.
3. The buyer is entitled to set off only against counterclaims that are undisputed, have been finally established by a court or are ready for decision. This restriction does not apply to counterclaims arising from the same contractual relationship.
4. The statutory provisions apply in the event of default in payment.

§ 7 Transport and Transfer of Risk

1. Unless otherwise stated in the order confirmation, delivery shall be made "ex works Weisendorf" (EXW Incoterms 2020). The allocation of costs and transfer of risk shall be determined exclusively by this clause.
2. Insofar as a different Incoterms clause is agreed in an individual case, transport costs, obligations and transfer of risk shall be determined exclusively by the agreed Incoterms 2020 clause.
3. Obvious transport damage must be reported and documented by the buyer to the carrier without undue delay; we must also be informed without undue delay. The statutory rights of the buyer remain unaffected.

§ 8 Retention of Title and Security Rights

1. Delivered implants and instruments shall remain our property until full payment of all present and future claims arising from the ongoing business relationship.

2. The buyer is entitled to resell the goods subject to retention of title in the ordinary course of business. The buyer hereby assigns to us the claims arising from the resale in the amount of the invoice value of the goods subject to retention of title; we accept the assignment.
3. In the event of processing, combining or mixing of the goods subject to retention of title, we shall acquire co-ownership in the ratio of the value of the goods subject to retention of title to the value of the new item. The buyer shall, at its own expense, adequately insure the goods subject to retention of title against fire and theft damage.
4. In the event of attachments or other interventions by third parties, the buyer must inform us without undue delay and provide us with the documents required to safeguard our rights. Insofar as the third party is unable to reimburse the judicial or extrajudicial costs of an intervention, the buyer shall be liable for the shortfall incurred by us.
5. If the realisable value of the securities to which we are entitled exceeds the claims to be secured by more than 10 %, we will, at the buyer's request, release securities of our choice.
6. The buyer will take all measures and make all declarations necessary to render our retention of title or comparable security rights effective in the respective country of destination and to maintain them.

§ 9 Compatibility

1. Compatibility between implant components (in particular body, stem, head and inlay) is warranted only for original products of Peter Brehm GmbH or for combinations expressly approved by us.
2. If products are combined with third-party products without our express approval, there shall be no claims for defects or damages against us insofar as the alleged defect or damage is based on this combination. Mandatory statutory grounds of liability and § 12 remain unaffected.

§ 10 Liability for Defects

1. The commercial duty to inspect and notify defects is governed by § 377 HGB. Obvious defects must be notified in text form without undue delay, but no later than within 10 working days after delivery. Hidden defects must be notified in text form without undue delay after their discovery.
2. The buyer must give us the opportunity to inspect the defect complained of and, upon request, make the goods complained of available at its own expense. Until completion of the inspection, the goods complained of may not be altered, further processed or disposed of without our consent.
3. The buyer may not remedy defects itself or have them remedied by third parties without our prior consent. This does not apply insofar as immediate measures are required for compelling medical, safety-related or statutory reasons.
4. Claims for defects shall not exist insofar as the alleged defect is based on improper storage or transport after transfer of risk, incorrect handling, use not in accordance with the intended purpose, failure to observe instructions for use or other product information, repairs or modifications by third parties that have not been approved by us, or other circumstances within the buyer's sphere of risk.
5. In the event of justified defects, we shall, at our option, rectify the defect or provide a replacement delivery. If subsequent performance fails or is unreasonable for the buyer, the buyer shall be entitled to the statutory rights of withdrawal or price reduction. Claims for damages shall be governed by § 12.
6. The limitation period for claims for defects is one year from delivery. This does not apply insofar as longer periods are mandatory by law, in particular in the event of fraudulent concealment of a defect, in the event of a guarantee assumed by us, in the cases of § 438 para. 1 nos. 1 and 2 BGB and for recourse claims insofar as the statutory provisions, in particular §§ 445a, 445b BGB, preclude a shortening. The statutory limitation provisions apply to claims for damages.
7. Insofar as this is necessary to fulfil statutory obligations in the area of market surveillance, vigilance or product safety, the buyer will provide us with all information and documents necessary to investigate a reported incident or defect. These include, in particular, batch numbers, product references, implant cards,

surgical reports, sterilisation records and other information required for fault analysis, insofar as such information is available.

8. The buyer will inform us without undue delay of any suspicion of a serious incident within the meaning of the applicable medical device law provisions, a field safety corrective action or any other safety-related event in connection with our products.

9. The buyer must fulfil the traceability obligations incumbent upon it under the applicable medical device law provisions and properly retain the data and documents required for this purpose. These include, in particular, UDI data, batch numbers, product references, implant documentation and other information required for identification, risk assessment or implementation of safety measures.

§ 11 Single-Use Devices

1. Products and instruments marked by the manufacturer as single-use devices shall be used only once in accordance with their intended purpose.
2. We do not intend the reprocessing and reuse of single-use devices to constitute use in accordance with the intended purpose. Insofar as reprocessing or further use is legally permissible, it shall be governed exclusively by the applicable medical device law provisions. There shall be no claims for defects or damages against us insofar as a defect or damage is based on reprocessing or reuse for which we are not responsible. Mandatory statutory grounds of liability remain unaffected.
3. If the buyer culpably breaches the above obligations, it shall indemnify us against justified claims by third parties, including the necessary costs of legal enforcement, insofar as the claims are based on the breach of duty for which it is responsible.

§ 12 Liability

1. We shall be liable without limitation for damage resulting from an intentional or grossly negligent breach of duty, in the event of culpable injury to life, body or health, in the event of fraudulent concealment of a defect, where a guarantee has been assumed, and under the Product Liability Act and other mandatory statutory liability provisions.
2. In the event of a slightly negligent breach of an essential contractual obligation, the fulfilment of which is a prerequisite for the proper performance of the contract and on compliance with which the buyer may regularly rely, our liability shall be limited to the damage foreseeable at the time the contract was concluded and typical for the contract. In all other respects, liability for damage caused by slight negligence is excluded.
3. To the extent permitted by law, in cases of slightly negligent breach of duty we shall not be liable for indirect damage, consequential damage, business interruptions, production losses, lost profits, lost savings, loss of use, administrative expenses, personnel costs or other pure financial losses.
4. Claims for reimbursement of recall costs, field safety measures, field corrective measures, market surveillance measures or comparable expenses shall exist only in accordance with mandatory statutory provisions.
5. The above limitations of liability shall apply accordingly for the benefit of our legal representatives, employees, persons employed in performing our obligations and vicarious agents.
6. In all other respects, liability for damage caused by slight negligence is excluded.

§ 13 Goods Sent for Inspection and Consignment Goods

1. Goods sent for inspection must be returned within six weeks after receipt unless otherwise agreed. If they are not returned within the prescribed period, we are entitled to invoice the goods at the agreed prices or, in the absence of an agreement, at the prices applicable upon expiry of the period.

2. For consignment goods, an inventory reconciliation shall be carried out at least once a year; further contractual provisions remain unaffected.

§ 14 Place of Performance and Jurisdiction

1. If the buyer is a merchant within the meaning of the German Commercial Code, a legal entity under public law or a special fund under public law, Weisendorf shall be the place of jurisdiction for all disputes arising from or in connection with the business relationship. We are also entitled to sue the buyer at its general place of jurisdiction.
2. The law of the Federal Republic of Germany shall apply to the exclusion of the UN Convention on Contracts for the International Sale of Goods (CISG).
3. The place of performance shall be Weisendorf unless expressly agreed otherwise.

§ 15 Severability Clause

1. Should individual provisions of these Terms and Conditions be or become invalid or unenforceable in whole or in part, the validity of the remaining provisions shall remain unaffected. The statutory provisions shall take the place of the invalid or unenforceable provision.