

# 1. General – Scope

1.1 The General Terms and Conditions of Sale and Delivery of Königsee Implantate GmbH (hereinafter referred to as "Königsee") shall apply exclusively. Any terms and conditions of Königsee's contractual partner (hereinafter referred to as "Customer") contradicting or deviating from these Terms and Conditions of Sale and Delivery are not recognised unless Königsee has expressly agreed to the application of deviating conditions in writing. These Terms and Conditions of Sale and Delivery shall also apply if Königsee performs the Customer's order without reservations in spite of being aware of terms and conditions of the Customer contradicting or deviating from the own terms and conditions of business and delivery.

1.2 The Terms and Conditions of Sale and Delivery shall also apply to all future business transactions with the Customer. These Terms and Conditions of Sale and Delivery are acknowledged by the Customer by placing the order, at the latest, however, upon acceptance of the goods.

1.3 All agreements made between Königsee and the Customer with respect to the implementation of this contract are stipulated in writing in this contract.

## 2. Offer and order confirmation

2.1 If the order is deemed to be an offer according to Section 145 BGB [Bürgerliches Gesetzbuch = German Civil Code], Königsee may accept such offer within 6 weeks but not over a turn of the year. The contract enters into effect at the latest upon dispatch of the ordered goods and upon dispatch of the first delivery in the event of partial deliveries.

2.2 As far as Königsee produces parts according to the wishes of the Customer, the drawings, illustrations, calculations and other documents prepared by Königsee and approved by the Customer are authoritative. Deviations from approved drawings, illustrations, calculations and other documents are to be agreed separately and any additional costs incurred are to be reimbursed by the buyer. Special designs requested by the Customer shall always be acquired against payment and cannot be returned. The acceptance of the produced quantity corresponds to the stipulated order quantity.

# 3. Property rights

3.1 Königsee reserves the proprietary rights and copyrights in illustrations, drawings, calculations and other documents. This shall also apply to such written documents referred to as "confidential". Before forwarding such documents to third parties, the Customer shall obtain the explicit written consent of Königsee.

3.2 If deliveries are made based on drawings, illustrations and calculations or other specifications of the Customer and if third parties assert industrial property rights in this respect, the Customer shall exempt Königsee internally from any and all claims in this respect. The copyrights in special designs remain with Königsee.

# 4. Prices

4.1 Unless provided for to the contrary in the order confirmation, the stipulated prices are net plus statutory value added tax, always "ex works" plus packaging and shipping costs.

4.2 The price and conditions of the order valid at the time of invoicing shall apply.

4.3 Any additional expenditure resulting from subsequent requests for changes can be charged to the customer by Königsee. Königsee charges a minimum quantity surcharge of €15 for orders from hospitals of less than €100, from registered doctors and medical practices of less than €50 and for veterinary orders of less than €50. For export orders we charge the following minimum quantity surcharges: 10€ minimum quantity surcharge if the total order value is less than 100€ for Austrian customers, 30€ minimum quantity surcharge if the total order value is less than 300€ for EU customers and 50€ minimum quantity surcharge if the total order value is less than 500€ for third country customers. Other agreements concerning export customers are to be made individually in writing.

4.4 If the customer wishes accelerated shipping, e.g. express or express couriers, the additional costs shall be borne by the customer; in Germany 25€, for abroad in the amount of the costs actually incurred.

4.5 Should the Customer be a member of an association which is contractually bound to Königsee, the prices, conditions and minimum order values or surcharges of the applicable agreements with the association shall apply.

4.6 If, upon conclusion of the agreement, events occur which render the prime costs of Königsee more expensive upon production or shipment of the goods, in particular due to increases of the Königsee acquisition prices for raw materials and due to wage increases, Königsee shall be entitled to increase the prices correspondingly.

# 5. Terms of payment

5.1 Invoices are due for payment within 14 days from the date of invoice without deduction. Cash discounts are only applicable if they are expressly confirmed in writing on the invoice documents by Königsee. The same shall apply to changed terms of payment. Rented sieves: inspection and sample shipments are deemed accepted and are charged when the return exceeds the stipulated period by more than 2 weeks.

5.2 Even in case of contrary terms of payment of the Customer, Königsee shall be entitled to initially set off a payment against the oldest not specifically defined debt.

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If costs or interest have already occurred, Königsee shall be entitled to credit any payment initially against the cost, subsequently against the interest and finally against the main account.

5.3 The Customer shall only be entitled to set-off if and to the extent to which their counterclaims have been legally established, undisputed or acknowledged in writing by Königsee. The Customer's right of retention shall be limited to claims from the contractual relationship.

5.4 Königsee shall be entitled to charge default interest at a rate of 8% above the base rate according to Section 247 *BGB*. The right to provide evidence that a higher damage was caused by the delay is expressly reserved.

5.5 Deliveries outside of Germany are always effected against payment in advance. Amendments shall be agreed on an individual basis.

### 6. Delivery/delivery time/delay

6.1 The delivery time stated by Königsee begins when all technical issues have been clarified. Compliance with the delivery obligation by Königsee presupposes the timely and complete performance of the Customer's obligation. The right of defence by reason of non-fulfilment of contract remains reserved.

6.2 Delivery terms and delivery dates are only deemed agreed as binding if they are explicitly confirmed in writing in the offer or in the order confirmation. Delivery terms shall commence no earlier than on the day on which the contract has been concluded in writing.

6.3 The delivery term is deemed complied with if the object of delivery has left the works or Königsee has notified the Customer about the readiness for shipment until expiry of the delivery term.

6.4 Should the Customer delay acceptance or culpably infringe any other cooperation duties, Königsee shall be entitled to claim compensation for the damage incurred in this respect including any additional expenses. Further claims or rights are reserved.

6.5 As far as the requirements of para. 6.4 are given, the risk of accidental loss or accidental deterioration of the item of purchase passes to the Customer at the time in which the Customer has fallen into default of acceptance or debtor's default.

6.6 Königsee shall be liable according to the legal provisions as far as the underlying purchase contract is a fixed transaction within the meaning of Section 286, para. 2, sub-para. 4 *BGB* or Section 376 *HGB* [Handelsgesetzbuch = German Commercial Code]. Königsee shall also be liable according to the legal provisions as far as the Customer is entitled to claim that their interest in the continued fulfilment of contract no longer applies as a consequence of a delay in delivery for which Königsee is responsible.

6.7 The Customer may not assert any claims on grounds of delays in delivery which are not subject to intentional acts or gross negligence on the part of Königsee. This shall in particular apply with respect to delays in delivery on grounds of force majeure. In these cases, the stipulated date or term of delivery shall be postponed according to the duration of the obstacle to delivery.

### 7. Retention of title

7.1 Königsee retains the title in any and all supplied items until all payments from the supply relationship – also future liabilities – are received. In the event of a breach of contract, in particular delay of payment, Königsee shall be entitled to repossess the purchased item.

7.2 The Customer shall be obliged to treat the delivered objects with care and not to use them operatively before payment of the complete purchase price.

7.3 In the event of attachments or any other interventions by third parties, the Customer shall immediately notify Königsee in writing so that Königsee may lodge a thirdparty action. As far as such third party is unable to reimburse the judicial and out-of-court costs of such an action, the Customer shall be liable in this respect.

### 8. Shipment, transfer of risk

8.1. Shipment is effected at the risk of the Customer and the delivery is effected "ex works". Even if further services are rendered by Königsee, the risk always passes to the Customer no later than upon dispatch of the goods.

8.2 In the event of a delay in shipment due to circumstances for which Königsee is not responsible, the risk passes to the Customer as of the date of readiness of shipment.

8.3 Transport and all other packaging in accordance with the German Packaging Ordinance is not taken back. The Customer is obliged to provide for the disposal of the packaging at their own expense.

# 9. Liability for material defects/liability

9.1 Königsee shall not be liable for any damage incurred due to improper handling, wear and tear, storage and other acts of the Customer or third parties. The Customer undertakes to ensure that the products of Königsee are only used by such persons who are demonstrably familiar with the rules of medical practice. Furthermore, the instructions for use for implants and instruments shall be followed strictly.

9.2 The legal claims from liability for material defects shall become time-barred one year after the handover of the goods. No guarantee of durability is given in this

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respect. As regards faulty goods or goods ordered incorrectly, a notice of complaint must be filed immediately upon receipt or they must be exchanged.

9.3 Königsee may choose between repair and new delivery.

9.4 The expenses necessary for the purpose of subsequent performance shall not be borne by Königsee to the extent to which the expenses increase because the goods have been relocated after delivery to any place other than the Customer's commercial establishment. This shall not apply if the relocation corresponds to the designated use of the item.

9.5 The liability for damages of Königsee according to statutory provisions is unlimited if any breach of duty attributable to Königsee is subject to an intentional act or gross negligence. As far as the breach of duty attributable to Königsee is based on simple negligence and a material contractual duty has been culpably infringed, the liability for damages shall be restricted to the foreseeable damage which typically occurs in similar cases. Any further liability is excluded.

9.6 The liability according to the provisions of the German Product Liability Act shall remain unaffected. This shall also apply to the liability for injury of life, body and health.

### 10. Return conditions:

10.1 The legal claims from liability for material defects shall become time-barred one year after the handover of the goods. No guarantee of durability is given in this respect.

10.2 Returns are carried out by contacting a service employee at Königsee who will assign a return number by telephone, which are to be assigned to the return shipment.

10.3 Königsee has the right to choose between rectification of defects and new delivery.

10.4 The return of not originally packed goods (due to defects) will only be accepted with a filled out sterilization certificate, prior notification of complaint to the safety officer of Königsee and a return authorization number from Königsee Implantate.

10.5 Custom-made products are excluded from the right of return.

10.6 Damaged implants and instruments are returned to the consignor without crediting. Special and custom-made products will not be credited and are excluded from return.

10.7 Königsee is free to take back the finished product.

#### 11. Joint and several liability

11.1 Any liability for damages exceeding the liability according to Section 6 is excluded independent from the legal nature of the asserted claim. This shall in particular apply to claims for damages on grounds of negligence upon conclusion of the contract, for any other breaches of duty or on grounds of tortious claims for compensation for damages according to Section 823 *BGB*.

11.2 The limitation according to Section 10.1 shall also apply to the extent to which the Customer instead of a claim for damages demands reimbursement of useless expenditure instead of performance.

11.3 To the extent to which liability for damages vis-à-vis Königsee is excluded or limited, this shall also apply in view of the personal liability for damages of Königsee's employees, staff members, representatives and vicarious agents.

## 12. Securing of the retention of title

12.1 Königsee retains the title in the purchased item until receipt of all payments from the delivery contract. In the event of a breach of contract by the Customer, in particular delay of payment, Königsee shall be entitled to repossess the purchased item. If Königsee takes the purchased item back, this constitutes a withdrawal from the contract. Upon repossession of the purchased item, Königsee shall be entitled to offset the utilisation proceeds against the liabilities of the Customer – less reasonable utilisation costs.

12.2 The Customer is obliged to treat the purchased item with care; they are in particular obliged to insure the item against fire and water damage and theft at their own expense, with the insured sum being adequate to cover the replacement value. As far as maintenance and inspection work is required, such work has to be performed by the Customer in due time and at the Customer's own expense.

12.3 In the event of attachments or any other interventions by third parties, the Customer shall immediately notify us in writing so that Königsee may lodge an action according to Section 771 *ZPO* [Zivilprozessordnung = German code of civil procedure]. As far as the third party is unable to compensate Königsee for the judicial and outof-court costs of such an action, the Customer shall be liable vis-à-vis Königsee for the loss incurred.

12.4 The Customer may only resell the purchased item in the ordinary course of business upon valid written agreement; however, the Customer already now assigns to Königsee any and all claims in the amount of the final invoice amount (including VAT) of Königsee's claim incurring to them from reselling towards their customers or third parties, independent from whether the goods were resold without or after processing. After the assignment, the Customer is still entitled to collect this claim. Königsee's

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right to collect the claim themselves shall remain unaffected. Königsee, however, undertakes not to collect the claim as long as the Customer complies with their payment obligations arising out of the proceeds collected, is not in default of payment and in particular has not filed a request for the opening of insolvency proceedings and payments have not been suspended. If this, however, is the case, Königsee may demand that the Customer informs Königsee of the assigned claims and the debtors, provides all information required for collection, provides the relevant documents and informs the debtors (third parties) about the assignment.

12.5 The processing or reshaping of the purchased item by the Customer is always effected on behalf of Königsee. If the purchased item is processed with other objects not belonging to Königsee, Königsee shall acquire co-ownership in the new product in the ration of the value of the purchased item (final invoice amount plus VAT) to the other processed products at the time of processing. Furthermore, what applies to the purchased item delivered subject to retention of title shall also apply to the object generated by processing.

12.6 If the purchased item is inseparably mixed with other objects not belonging to Königsee, Königsee shall acquire co-ownership in the new product in the ration of the value of the purchased item (final invoice amount plus VAT) to the other mixed products at the time of mixture. If the mixing is effected in such a way that the product of the Customer is deemed the main product, it is agreed that the Customer grants us the pro-rata co-ownership. The Customer shall retain the resulting sole or co-ownership on behalf of Königsee.

12.7 The Customer shall also assign all claims for securing claims of Königsee against them which result against any third party due to the connection of the purchased item with a property.

12.8 Königsee undertakes, upon request of the Customer, to release the securities accruing to Königsee to the extent to which the realisable value of the securities of Königsee exceeds the claims secured by more than 10 %; the selection of the securities to be released is incumbent upon Königsee.

# 13. Loaned goods

Loaned goods are made available for the agreed loan period.

For products delivered non-sterile, the conditions of forms F-239 "Conditions and Prices for Loaned Sets (non-sterile)" and F-241 "Proportionate reprocessing fee for the provision of loaned and consignment Sets (non-sterile)" shall apply.

For sterile products, the contractual conditions Loan OP sterile from D-00032.03 and contractual agreements Loan OP sterile from D-00032.06 shall apply.

### 14. Rented goods

Rented goods are made available for the agreed rental period.

For products delivered non-sterile, the conditions of forms F-239 "Conditions and Prices for Loaned Sets (non-sterile)" and F-241 "Proportionate reprocessing fee for the provision of loaned and consignment Sets (non-sterile)" shall apply.

For sterile products, the contractual terms Rent short sterile from D-00032.02 and contractual agreements Rent short sterile from D-00032.05 apply.

### 15. Commissioned goods

Commission goods will be made available over the defined contract period.

For products delivered non-sterile, the conditions of forms F-239 "Conditions and Prices for Loan Sets (non-sterile)" and F-241 "Proportionate reprocessing fee for the provision of loan and consignment Sets (non-sterile)" apply.

For sterile products, the contractual conditions of the Contract Agreement on Long Term Rental sterile from D-00032.01 and Contract Agreement KONSI on Instruments in connection with the use of sterile implants from D-00032.04 apply.

### 16. Ban on assignment

Any and all claims of the purchaser from the contractual relationship with Königsee cannot be assigned.

### 17. Product liability

17.1 The Customer may only use the goods according to their intended use and shall ensure that these goods are only resold to persons familiar with the dangers and risks involved with the products. Explicit reference is made to Section 9.1 hereof.

17.2 The Customer shall be obliged to ensure that the products delivered by Königsee are not altered manually. This shall in particular apply to the extent to which the implants are made of titanium since alterations in this respect may provoke breakage of the products or superficial damage of the products which may cause damage to health. The Customer shall bear the sole liability for such damages and exempts Königsee internally from all claims in this respect. The prescribed instructions for use in the IFU implants and IFU instruments apply.

17.3 Distributors and importers shall be obligated within the meaning of Article 25 (1) of Regulation (EU) 2017/745 on medical devices (MDR) to achieve an appropriate level of traceability of devices in co-operation with the manufacturer.



### 18. Miscellaneous

18.1 Aschau district – Am Sand 4, 07426 Allendorf is the place of performance.

18.2 The Local Court of Erfurt shall be the place of jurisdiction for any and all disputes arising out of the contract. Königsee, however, shall also be entitled to assert claims against the Customer before a court in the Customer's general jurisdiction or where the Customer has a branch.

18.3 EURO is the exclusive trading currency.

18.4 Orders and other contractual agreements shall be made out in German or English. German and English are contractual languages.

18.5 This contract is exclusively governed by German law. The United Nations Convention on Contracts for the International Sale of Goods (CISG) shall not apply.

18.6 Should individual provisions of this contractual relationship be or become invalid, this shall not affect the validity of the remaining provisions. The parties shall take reasonable efforts to replace the invalid provision by a valid provision coming as close as possible to the economic purpose of the contract.