

General Terms and Conditions of Delivery

The general terms and conditions of delivery in German shall be of significance for the contractual relationship between both parties. The English wording shall be a non-binding translation only.

I. General Conditions

1. These General Terms and Conditions of Delivery shall apply exclusively; the Supplier will not accept any conflicting business conditions or such conditions of the Purchaser that are deviating from Supplier's Conditions of Delivery, unless the Supplier has expressly agreed to those conditions in writing. Supplier's General Terms and Conditions of Delivery shall also apply in the case that the Supplier, having knowledge of conflicting business conditions or such conditions of the Purchaser that are deviating from the Supplier's Conditions of Delivery, carries out the delivery to the Purchaser without reservation.
2. These General Terms and Conditions of Delivery are only intended for use in business with entrepreneurs according to § 310 (1) BGB (German Civil Code).
3. The Supplier reserves any property rights and/or copyrights pertaining to reproductions, illustrations, drawings, calculations and/or other documents. This shall also apply to documents which are marked as "confidential". The Purchaser shall obtain Supplier's express written consent before making those documents available to third parties. In the case that no contract is awarded, the Purchaser shall immediately return all documents at Supplier's request.
4. The Supplier shall, acting reasonably, be entitled to make partial deliveries.

II. Prices and Terms of Payment

1. Prices shall be ex-works, excluding packaging, value added tax shall be added at applicable rate, unless otherwise agreed. The Supplier reserves the right to change prices if cost reductions or cost increases occur after signing of the agreement, especially through changes in material price or conclusion of a collective labour agreement. The Supplier shall substantiate these changes upon Purchaser's request.
2. If the Supplier is also responsible for assembly or erection and unless otherwise agreed, the Purchaser shall pay in addition to the agreed remuneration any incidental costs and expenses, e.g. travel costs, costs for the transport of necessary equipment and personal luggage as well as expenses and allowances remunerated by the Supplier as employer.
3. The deduction of discounts requires special written agreement.
4. Unless otherwise agreed in the confirmation of the order, the net purchase price (without deductions) is due for payment 30 days after invoice date. Statutory provisions regarding the consequences of delay or default of payment shall apply.
5. The Purchaser may set off only such claims against the claims of the Supplier that are undisputed or have been finally determined in a legally binding manner.

III. Retention of Title

1. The items of supply shall remain the property of the Supplier until each and every claim against the Purchaser to which the Supplier is entitled under their business relationship has been duly satisfied. In the case that the value of all security rights of Supplier exceeds the value of all secured claims by more than 10 %, the Supplier shall – upon Purchaser's request – release a corresponding part of the security rights until the above-mentioned 110 % limit of security rights has been reached; the Supplier is responsible for the choice of securities to be released.
2. For the duration of the retention of title, the Purchaser may not pledge or assign the retained goods as security. Resale or processing shall only be permissible in the course of ordinary business and only on condition that the Purchaser as reseller receives payment from his customer or on the precondition that claims resulting from resale shall be assigned to the Supplier in advance in the amount payable for the supply. This condition shall apply until the Purchaser has met his payment obligations or until the Supplier has revoked his consent.
3. According to paragraph 2 hereabove, the Purchaser is entitled to resale the corresponding item of supply in the course of ordinary business; however, the Purchaser hereby assigns to the Supplier all claims in the amount of the sales price including applicable VAT which the Purchaser accrues from the resale to his recipients or third parties, regardless of whether the sales item has been sold with or without processing. The Supplier accepts the assignment. The

Purchaser is entitled to collect the corresponding claims even after assignment until revoked. The Supplier's authority to disclose the assignment and to collect the corresponding claim is unhindered hereby. However, the Supplier shall commit to not collect the claims as long as the Purchaser (i) meets his payment obligations from received sales, (ii) is not in delay with his payments and (iii) as long as no application for the opening of insolvency proceedings over his estate has been submitted or a default in payments occurs.

Should one of the reasons stated in the preceding sentence apply, the Purchaser is obliged to inform his clients or third parties of the assignment immediately, to disclose the assignment and to instruct third parties immediately to make payments with redeeming effect to the Supplier only. Furthermore, the Purchaser has to notify the Supplier of all claims as well as of all information and data on third debtors, to hand over all pertinent information and documents and to communicate all necessary data for debt collection against third parties. In the case that the value of all security rights of the Supplier exceeds the value of all secured claims by more than 10 %, the Supplier shall – upon Purchaser's request – release a corresponding part of the security rights until the above-mentioned 110 % limit has been reached; the Supplier is responsible for the choice of securities to be released.

4. The Purchaser is obliged to immediately inform the Supplier of all pledges, confiscations, acts of disposal, other encumbrances caused by third parties or any act of enforcement by third parties. If and insofar as the Purchaser stores items supplied by the Supplier, he is obliged to keep those apart and away from his other goods, articles and items and to mark them as under retention of title in favour of the Supplier.
5. In case of Purchaser's negligent violation of fundamental contractual obligations, especially default of payment, the Supplier is entitled to call back the supplied items after issuing a reminder; the Purchaser is obliged to release all relevant items. Taking back items by the Supplier implies the withdrawal of the contract. The Supplier's right to lodge further claims remains unaffected. After withdrawal of the items, the Supplier is entitled to their liquidation; all liquidation results shall be offset against the Purchaser's obligations under deduction of adequate liquidation costs.
6. The Purchaser is obliged to treat all items carefully; he is especially obliged to insure those – at his own expense – against damages resulting out of fire, water and burglary at original value. By signing the aforementioned insurances for the supplied items, the Purchaser shall – as far as possible – name the Supplier as beneficiary. In the case that the Supplier shall receive payments or merits from the aforementioned insurances which exceed the sales price or his other claims against the Purchaser, the Supplier is obliged to give back this excessive amount to the Purchaser. In the case that maintenance and inspection works to the supplied items are necessary according to the handbook and/or maintenance book, the Purchaser shall perform these in time at his own costs and expenses. The performance of the aforementioned works shall be substantiated to the Supplier immediately after the performance thereof.

IV. Time for Delivery and Delay

1. The observance of the stipulated time for delivery is conditional upon the timely receipt of all documents, necessary permits and releases, especially of plans, to be provided by the Purchaser, as well as fulfilment of the agreed terms of payment and other obligations by the Purchaser. If these conditions are not fulfilled in time, the time for delivery will be extended accordingly; this does not apply if and to the extent that the delay is caused by negligence of the Supplier.
2. If the non-observance of the time for delivery is due to force majeure such as mobilization, war, riot, strike, lock-out or similar events such time shall be extended accordingly.
3. If the Purchaser culpably delays acceptance or if he culpably violates any other duties to cooperate, the Supplier is entitled to claim further damages, including possible increase in expenditure. The Supplier's right of lodge further claims remain unaffected.
4. If the Supplier is in delay, he is liable in cases of wilful acting or of gross negligence of the Supplier or of any representative of Supplier according to legal regulations. In case of simple negligence, Supplier's liability is limited to damages inherent to this type of contract or foreseeable damages. Apart from the cases in sentence 1 hereabove, Supplier's liability for delay in (partial) performance for damages for breach of duty (§ 280 BGB) shall be limited to a total of 5 % and for damages in lieu of performance (§§ 281 ff. BGB) and/or reimbursement of futile expenses (§ 284 BGB) shall be limited to a total of 10 % of the value of the belated (partial) delivery; further claims of the Purchaser are excluded, even after any possible deadline

which has been set to the Supplier for performance has expired. The aforementioned limitations shall not apply in cases of harm to life, body or health.

5. Insofar as the delivery of the contractual good shall be impossible to the Supplier in whole or in part, Section IV. Paragraph 4 of these General Terms and Conditions shall apply mutatis mutandis regarding the liability of the Supplier.
6. If the Supplier is in delay with his obligation to perform and if he is only able to execute the agreed performance later than originally stipulated, the Supplier may – with reasonable fixing of a date – call on the Purchaser to bindingly declare whether the Purchaser will accept the contracted performance even belatedly or whether the Purchaser withdraws from the contract. In the request with the appointment of a date, the Supplier has to state whether the contract will be terminated or continued if the Purchaser does not declare himself within the set time period. The Purchaser's further claims and rights remain unaffected.

V. Transfer of Risk

1. Unless otherwise stipulated in the order confirmation, "delivery ex works" is agreed.
2. As far as the parties have agreed upon "freight paid" the risk shall pass to the Purchaser as follows
 - a) if the supply does not include assembly or erection, when goods have been separated in order to be shipped or when those goods have been picked up. At the Purchaser's request and expense, supplies shall be insured by the Supplier against the ordinary risks of transport, if the Purchaser has indicated a signing of such an insurance agreement in written form before completion of the contractual items in Supplier's works, or
 - b) if the supply includes assembly or erection, on the day on which the goods are taken over into the Purchaser's own place of business.
3. If the shipping, the delivery, the beginning or completion of assembly or erection or the taking over into Purchaser's own place of business is delayed for reasons caused by negligence of the Purchaser, or if the Purchaser has failed to accept delivery for any other reasons, the risk shall pass to the Purchaser.

VI. Warranty

1. Damage claims by the Purchaser require Purchaser's fulfilment of his obligations to scrutinise and – if there is a reason to do so – to reject the goods according to § 377 HGB (German Commercial Code).
2. In the case that the supplied items are defect; the Supplier is entitled – at his own choice – to remedy the defect in the form of removal of defects or in form of subsequent delivery of new items free of defects. Increased costs and expenses for such remedies which ensue from the fact that the supplied items have been transferred to a place other than the place of performance shall be borne by the Purchaser.
3. In the case that the Supplier fails to remedy the defect, the Purchaser is entitled to withdrawal or diminution at his own choice.
4. The warranty does not cover natural wear and tear or damages arising, after the transfer of risk, from faulty or negligent handling, excessive strain, unsuitable equipment or from particular external influences, which are not assumed under the contract, or from non-reproducible software errors. The warranty does not cover modifications or repairs carried out improperly by the Purchaser or by third parties.
5. Insignificant deviations from the contracted specifications or marginal limitations in serviceability do not constitute a defect or damage of the supplied items.
6. The Supplier is liable according to statutory provisions, if the Purchaser claims for damages as a result of malicious intent or gross negligence. In case of simple negligence, the Supplier's liability is limited to damages inherent to this type of contract or foreseeable damages. Apart from the cases set out in Sentence 1 hereabove, the Supplier is liable according to statutory provisions insofar as the Supplier culpably violates fundamental contractual duties; even in this case, the Supplier's liability is limited to damages inherent to this type of contract. The aforementioned limitations shall not apply in cases of harm to life, body or health; the same also applies to coercive liability according to Product Liability Act (*Produkthaftungsgesetz*). Liability for Supplier's delay is ruled by Section IV. Paragraph 4 exclusively.
7. The period of limitations for defect or damage claims is 24 months starting with the date of risk transfer.

VII. Further Liability

1. Further liability by the Purchaser other than stated in Section IV. Paragraph 4 and Section VI. hereabove is excluded regardless the legal nature of the claim. This applies especially to claims arising out of default on completion of the contract, for other breaches of contractual duties or for tortious claims to remedy of property damage according to § 823 BGB (German Civil Code).
2. The limitations in para 1 shall also apply in the case that the Purchaser claims for reimbursement of futile expenses (§ 284 BGB) instead of claims for compensatory damage in lieu of performance (§§ 281 ff. BGB).
3. In the case that the Supplier delivers items according to a statement of requirement provided by the Purchaser or according to other provisions, the Purchaser by negligence is liable for the non-violation of third parties' industrial property rights or any other rights of third parties due to the manufacturing and delivery of items. If and insofar as claims are raised against the Supplier due to the violation of third parties' rights as set out in the sentence hereabove, the Purchaser shall indemnify and hold harmless the Supplier of all costs and expenses which are claimed against the Supplier from and in connection with claims and demands from the third parties. The Purchaser is obliged to provide security to the Supplier, at the Supplier's demand, in the amount of expected indemnities.

VIII. Data Protection; Data Storage; Traceability of Products pursuant to DIN EN ISO 13485

1. The Supplier shall be entitled to process and store the data relating to the contract between the Supplier and the Purchaser and the data which refers to this Agreement to the extent necessary for execution and performance of the Agreement and as long as the Supplier is obliged by law to store such data. The Purchaser explicitly accepts that the Supplier shall capture, process and store the data of the Purchaser to enable full and continuous traceability of the supplied products pursuant to DIN EN ISO 13485.
2. Pursuant to DIN EN ISO 13485, full and continuous traceability of all supplied medical devices (IVD) must be guaranteed. The Purchaser acknowledges that both the Purchaser and also the Supplier are obliged to ensure the traceability of the supplied medical products and they both shall comply with the corresponding regulation.
3. The Purchaser agrees that the data which is relevant for performance of the Agreement shall be stored by the Supplier, and both the Purchaser and the Supplier agree that the data which is relevant for performance of the Agreement and for the traceability of the products pursuant to DIN EN ISO 13485 shall be stored not only by the Supplier, but if necessary also by the Manufacturer as defined in the German law concerning medical products (Medical Products Act – "MPG").
4. The Purchaser shall disclose his full name and address to the Supplier and shall notify the Supplier promptly of any change whatsoever in his name, company name and/or address.
5. In the case of a resale or any other transfer of the supplied product, regardless of the type of legal transaction and no matter whether inside or outside an EU/EEA Member State, the Purchaser shall ensure full and continuous traceability of the product pursuant to DIN EN ISO 13485. For each sale of a supplied product, the Purchaser is obliged to record the serial number or batch number of the product sold as well as the full name, company name and address of his customer and to store that data for a minimum period which is equivalent to the shelf life of the medical product as stated by the Supplier or the Manufacturer. The Purchaser shall be obliged to store the aforesaid data for a minimum period of 10 years as from product release. The records must be produced and managed so that they are legible, easily identifiable and retrievable. The records produced by the Purchaser must be disclosed to the Supplier or the Manufacturer as defined within the legal regulations at any time on demand.
6. In the case of resale or any other transfer of the supplied product, regardless of the type of legal transaction and no matter whether inside or outside an EU/EEA Member State, the Purchaser shall ensure that his customers also comply with DIN EN ISO 13485 and the obligations related thereto and that his customers comply with the statutory provisions of the traceability of the products and that the Purchaser in turn shall enter into identical contractual obligations with his customers to pass these obligations on to his customers. The Purchaser shall also procure and take contractual precautions to ensure that in case of any further transfer of the product, the customers of the Purchaser in turn impose an obligation on their customers to ensure full and continuous traceability of the product pursuant to DIN EN ISO 13485.
7. If the Purchaser fails to comply with his obligations pursuant to DIN EN ISO 13485, Article 7.5.3 and pursuant to this provision and the Supplier consequently sustains any disadvantages, in particular in case of any recall of the supplied product, the Purchaser shall bear all costs and/or

expenses which have been sustained or are sustained in future by the Supplier provided that these are caused by the non-compliance with the obligation on the part of the Purchaser. If, in case of a recall of the supplied product, the Supplier sustains any costs and/or expenses caused by non-compliance with the provisions of DIN EN ISO 13485 on the part of a customer of the Purchaser, the Purchaser shall reimburse the Supplier for all costs and/or expenses which have been sustained or are sustained in future by the Supplier caused by the non-compliance with the provisions on the part of the Purchaser or his customers. The Purchaser reserves the right to claim compensation from his customer if and insofar as the customer is responsible for the damage.

IX. Final Provisions

1. If the Purchaser is a businessman, the sole place of jurisdiction for all disputes arising directly or indirectly out of the contract shall be Osterode am Harz (Germany). However, the Supplier shall also be entitled to take legal actions against the Purchaser in a court at his business seat or residence. Furthermore, statutory provisions shall apply.
2. All relations between the parties shall be governed by German law excluding the United Nations Convention on Contracts for the International Sale of Goods (*UN-Kaufrecht*).
3. Place of Performance is Osterode am Harz (Germany) unless otherwise stipulated in the order confirmation.
4. The German wording of the general terms and conditions of delivery shall prevail only. The English wording shall be a non-binding translation thereof.