

General Terms and Conditions of Business (AGB)

1. Scope

The offers, sales and deliveries of imusyn GmbH & Co.KG ("imusyn" herein) are made exclusively based on the terms and conditions of business recited below. These terms and conditions are components of the contracts with our customers. General terms and conditions of the customer that differ from ours require our express written acknowledgment. However, overriding individual contractual covenants with our customers remain unaffected. We hereby contradict any invalidation of our terms and conditions of business.

2. Contract formation

2.1 The offers and other price quotations of imusyn are subject to change. A contract comes into being only through the written confirmation of any standing order, written order confirmation by imusyn or execution of the delivery and is governed exclusively by the content of any standing order made between the parties, the order confirmation and by these delivery terms. To be effective, oral agreements or commitments require written confirmation by imusyn.

2.2 Imusyn reserves all rights to the sales documents. They may not be made available to third parties and must be returned promptly to imusyn upon request.

3. Delivery deadlines and dates

3.1 Delivery dates and deadlines are only binding if they have been confirmed by imusyn in writing and the purchaser has communicated or provided to imusyn, in a timely fashion, all information and documents that are needed to execute the delivery and has made any stipulated advance payments as agreed. Stipulated time periods commence with the date of order confirmation. The time periods are extended accordingly in the case of supplemental or expanded orders that are placed later.

3.2 Unforeseeable, unavoidable events lying beyond the sphere of influence of imusyn for which imusyn is not accountable — e.g. force majeure, natural catastrophes or labor disputes ("disruptions") — shall, for their duration, relieve imusyn from the duty of timely delivery or performance. Stipulated time periods are extended by the length of the disruption; the purchaser shall be informed of the occurrence of the disruption in an appropriate manner. If the end of the disruption is not foreseeable or lasts longer than eight weeks, either party is entitled to rescind the agreement.

3.3 Our performance is subject to correct and timely delivery from our suppliers.

3.4 If the deliveries from imusyn are delayed, the purchaser is only entitled to rescission if the delay is attributable to imusyn and a reasonable grace period for delivery that is set by the purchaser has elapsed without success.

3.5 If the purchaser delays acceptance or breaches other duties to cooperate, imusyn is, irrespective of its other rights, entitled to warehouse the products at the purchaser's risk and expense or to rescind the contract.

3.6 Imusyn may make partial deliveries for a proper reason.

4. Shipment, passing of risk, insurance

4.1 Unless the parties have agreed otherwise, the products shall be shipped through an appropriate method of shipment in standard packaging.

4.2 Risk passes to the purchaser upon delivery of the products to the purchaser and, in the case of mail order purchases, upon delivery of the products to the person designated to execute the shipping. If there is a delay in delivering or shipping the products for reasons that are attributable to the purchaser, risk passes to the purchaser on the day of notification that the products are ready for shipment.

4.3 Insurance shall be procured only at the purchaser's request. Insurance, transport and packaging costs are charged to the recipient and shall be shown separately on the invoice.

5. Prices, payment terms

5.1 Unless otherwise agreed, the respective catalog or list prices at the time of order placement apply and the invoices are payable without deduction within 30 days of the invoice date. If the customer falls into arrears, we are entitled to charge statutory default interest from the time of default. The right to claim any greater damages for default that have been incurred remains unaffected hereby. In the event of the customer's arrearage, we also reserve the right to rescind the contract in accordance with statutory provisions. The purchaser's payments are not considered to have been made until imusyn is able to dispose over the amount paid. Imusyn shall mail the invoices no later than one day after the invoice date.

5.2 All prices of imusyn are, unless otherwise agreed, understood to be ex imusyn warehouse, exclusive of the respective statutory value-added tax and the packaging and shipping costs which are charged separately.

5.3 imusyn is entitled to make partial invoices for partial deliveries in terms of 3.6.

5.4 Drafts and checks will be accepted only by special agreement and without costs or expenses to imusyn and contingent upon final settlement.

5.5 The purchaser is only entitled to set off if the purchaser's counterclaim is undisputed or legally established.

5.6 The purchaser is only entitled to assert a right of retention to the extent that the purchaser's counterclaim is based on the same contract and is undisputed or legally established.

5.7 In the event of unusual preparatory efforts, imusyn may require a reasonable advance payment, which shall be stated on the order offer and order confirmation. In the case of an advance payment, the order is not executed until after receipt of the advance payment at imusyn. Imusyn has no liability for any delayed deliveries and liability and consequential damages resulting from an advance payment that is received late. The timeliness of the receipt of the advance payment depends on the time of receipt of the advance payment at imusyn. The customer bears the burden of proving timely receipt of the advance payment. The stated delivery time does not commence until receipt of the advance payment at imusyn.

5.8 If, after contracting, imusyn is cognizant of a lack of capacity to perform on the part of the purchaser, imusyn is entitled to execute still outstanding deliveries only in exchange for advance payment or provision of security. If the advance payments or security have not been rendered even after expiration of a reasonable grace period, imusyn may rescind individual or all of the contracts concerned, entirely or in part in each case. Imusyn remains free to assert additional rights.

6. Retention of title

6.1 The delivered products remain the property of imusyn until full payment of all receivables of imusyn that arise under the business relationship with the purchaser ("Retained Products"). If the purchaser is a customer who is not a consumer in terms of § 13 of the German Civil Code (*Bürgerliches Gesetzbuch* – BGB), the deliverable remains our property until satisfaction of all claims to which we are entitled against the purchaser under the business relationship.

6.2 In the case of an open account, the retained title is considered to be security for the outstanding balance to which imusyn is entitled.

6.3 The purchaser is permitted to sell the Retained Products only in the ordinary course of business. The purchaser is not authorized to pledge the Retained Products, to assign them as security or to make other dispositions that will jeopardize the title of imusyn. The purchaser forthwith assigns to imusyn the receivables arising from the resale of the Retained Products; imusyn forthwith accepts such assignment. If the purchaser sells the Retained Products together with other items, the assignment of receivables applies only to the portion that equals the price stipulated between imusyn and the purchaser, plus a safety margin totaling 10% of such price. The purchaser is revocably empowered to collect the receivables assigned to imusyn in its own name in trust for imusyn. Imusyn may revoke this authority and the authorization for resale if the purchaser is in default of material obligations toward imusyn (with payment, for example). In case of revocation, imusyn is entitled to collect the receivable itself.

6.4 The purchaser shall at all times provide imusyn all desired information on the Retained Products or on claims which have been assigned to imusyn hereunder. The purchaser shall immediately notify imusyn and provide the necessary information concerning third-party attachment of or claims to Retained Products. The purchaser shall at the same time notify the third party of imusyn's retention of title. The cost of defending such attachments and claims shall be borne by the purchaser.

6.5 The purchaser is obligated to treat the Retained Products with care for the duration of the retention of title.

6.6 If the realizable value of the securities exceeds the entire receivables of imusyn that are to be secured by more than 10%, the purchaser is entitled to request release to this extent.

6.7 If the purchaser is in default with material obligations toward imusyn (with payment, for example), imusyn may, notwithstanding other rights, reclaim the Retained Products and, after rescission of the contract, otherwise dispose of them for the purpose of satisfying any claims that are due against the purchaser. In such case, the purchaser shall grant imusyn or its agent immediate access to the Retained Products and surrender them. If imusyn requests surrender based on this provision, this shall not alone be considered to be rescission of the contract.

6.8 If requested by imusyn, the purchaser is obligated to adequately insure the Retained Products, to provide imusyn corresponding proof of insurance and to assign claims under the insurance policy to imusyn.

7. Qualities, purchaser's rights in the case of defects, duty to inspect

7.1 The products shall exhibit the agreed qualities upon the passing of risk; this shall be exclusively assessed according to the specific covenants made between the parties on the qualities, features and performance characteristics of the products ("Agreement on Qualities"). If the parties make no Agreement on Qualities, the rule of § 434 (1) BGB applies.

7.2 Information in catalogs, pricelists and other informational material supplied to the purchaser by imusyn as well as statements describing the product may not be understood in any way to be warranties of a particular product quality or durability; warranties of qualities or durability must be expressly agreed on in writing.

7.3 The purchaser's rights in connection with product defects require that the purchaser inspect the delivered products immediately upon delivery and notify imusyn of defects in writing immediately, but not later than ten working days after delivery; imusyn must be notified of latent defects in writing immediately upon their discovery.

7.4 With each notification of defects, imusyn shall have the right to inspect and test the products complained of. The purchaser shall allow imusyn the necessary time and opportunity for this. Imusyn may also demand that the purchaser return the products complained of to imusyn at the cost of imusyn. If a notification of defects by the purchaser proves to be unjustified and if this was perceptible to the purchaser before the defects complaint was made, the purchaser is obligated to reimburse imusyn for all expenses incurred in this connection (e.g. travel or shipping costs).

7.5 Imusyn shall cure defects by, at its option, repairing the defect without cost to the purchaser or delivering flawless replacement products (collectively: "cure").

7.6 The purchaser shall grant imusyn the reasonable time and opportunity that are needed for cure. Only in urgent cases, to prevent disproportionately greater loss or if imusyn is in default in curing the defect, shall the purchaser have the right, after advance notification to imusyn, to cure the defect personally or through third parties and to demand reimbursement from imusyn for the necessary cost of doing so.

7.7 The purchaser's rights for defects are extinguished in the case of natural wear and tear or when the expiration date of a product has passed or when defects arise for reasons that are attributable to the purchaser (e.g. due to improper handling or storage of products, due to breaches of user and operator obligations under the Medical Devices Operator Ordinance (*Medizinprodukte-Betreiberverordnung*), due to undertaking inappropriate repairs or maintenance or due to using products contrary to their intended purpose within the meaning of 9.1), unless the defects are attributable to imusyn.

7.8 Imusyn shall assume the costs of transportation, tolls, labor and materials that are incurred for the purpose of cure.

7.9 Should the cure fail, be unreasonable for the purchaser or should imusyn refuse it under § 439 (3) BGB, the purchaser may, at the purchaser's option, (8.1 a) rescind the contract in accordance with the statutory provisions or reduce the purchase price and (8.1 b) request damages under subparagraph 8 or request reimbursement of the expenses which the customer has incurred in vain.

7.10 The limitation period for the purchaser's rights due to defects is twelve months from delivery of the products to the purchaser. The limitations provisions of § 479 BGB remain unaffected. Damages claims by the purchaser for reasons other than defective products and with respect to the purchaser's rights for fraudulently concealed or intentionally caused defects are subject to statutory limitation periods.

8. Limitation of liability and damages

8.1 Subject to the provision in 8.2, imusyn's legal liability for damages is limited as follows:

(a) The amount of imusyn's liability for the slightly negligent breach of material contractual obligations is limited to damages that are typically foreseeable upon execution of the contract;

(b) Imusyn is not liable for the slightly negligent breach of minor contractual obligations. Imusyn has no liability for damages when and to the extent such damages arise because the customer is guilty of using the products in a manner contrary to their intended purpose under 9.1 and/or culpably breaches user and operator obligations under the Medical Devices Operator Ordinance.

8.2 The above limitation of liability does not apply in cases of compulsory legal liability — particularly under the Product Liability Act (*Produkthaftungsgesetz*) — as well as in the case of the assumption of a guarantee or culpably caused physical injuries.

8.3 The purchaser is obligated to take reasonable measures to prevent and mitigate loss.

9. Use in accordance with intended purpose, indemnification of imusyn

9.1 The intended purpose of the products is equivalent to the use that is expressly defined by imusyn in the labeling, the instructions for use, the safety data sheet or the promotional materials for the products. The intended purpose also refers in particular to the modification of products as well as the combination of products with other medical devices or other products which are not expressly approved by imusyn as well as any defined restrictions on use of the products (e.g. as general laboratory supplies, research-only product or single-use product); a validation of products by the purchaser has no influence on the intended purpose in terms of this subparagraph.

9.2 With respect to each other, the purchaser shall indemnify imusyn for all claims that are asserted against imusyn by third parties with regard to those products which the purchaser has culpably used contrary to their intended use and/or, in the course of using them, the purchaser has culpably breached user or operator obligations under the Medical Devices Operator Ordinance, if and to the extent that such conduct has become the cause of the accrual of the claim. This shall also apply to all court and out-of-court costs which arise in the exercise of the rights of imusyn. This indemnification obligation does not exist when and to the extent that the claim is based on a culpable breach of contractual or legal obligations by imusyn which causes the claim to accrue.

10. Reporting of incidents

10.1 If in relation to products the purchaser becomes aware of an incident within the meaning of the Medical Devices Operator Ordinance (as defined in 10.2 below), the purchaser shall comply with the reporting obligations that are incumbent on the purchaser under such ordinance. Notwithstanding the foregoing, the purchaser is obligated to report an incident to imusyn without delay, but not later than 24 hours after becoming aware of it, while safeguarding data protection regulations. Oral or telephonic reports must be followed by a written report to imusyn not later than within an additional 24 hours.

10.2 An incident is a malfunction, a failure or a change in the characteristics or performance or an inadequacy in the labeling or the instructions for use of a medical device which has led, might have led or might lead to the death of a patient, a user or another person or to a serious deterioration in his state of health.

11. General provisions

11.1 Amendments and supplements to the agreement and/or these delivery terms and to side agreements must be in written form. This also applies to an amendment of this written form requirement.

11.2 The parties are cognizant of the risk that, contrary to their present beliefs, individual or multiple terms of the agreement and/or these delivery terms might prove to be ineffective or void. In such a case as well, the parties desire to exclude any doubt concerning the validity of the agreement and/or the delivery terms. Even in the event of the ineffectiveness or invalidity of individual or multiple terms of this agreement and/or these delivery terms, the agreement and/or these delivery terms are therefore not intended to remain only in doubt, but always effective. The parties undertake in such case to replace the ineffective terms with those effective terms that come closest to the commercial purpose of the ineffective terms.

11.3 The exclusive judicial venue for all disputes arising from the contractual relationship is the competent court in each case for the registered office of imusyn GmbH & Co.KG. Imusyn is, however, entitled to commence legal action against the purchaser at any other legal judicial venue.

11.4 The law of the Federal Republic of Germany shall apply with exclusion of the UN Convention on Contracts for the International Sale of Goods (CISG).

11.5 The company imusyn GmbH & Co.KG is authorized pursuant to § 27 et seq. of the Federal Data Protection Act (*Bundesdatenschutzgesetz* — BDSG) to store, transmit within and outside of Germany, use, modify and delete the customer's personal data in the course of business.