

General Terms of Delivery of SEM-Plastomed GmbH

1. General terms, scope of application

- 1.1 These General Terms and Conditions of Delivery (GTCD) shall apply to all business relations between SEM-Plastomed GmbH (hereinafter referred to as "SEM") and its customers ("Customer"). The GTCD shall only apply if the Customer is an entrepreneur according to section 14 of the German Civil Code), a legal entity under public law or a special fund under public law.
- 1.2 These GTCD apply to all deliveries and services on our part, in particular to contracts for the sale, processing and/or delivery of movable goods, irrespective of whether we manufacture them ourselves or purchase them from suppliers (sections 433, 651 of the German Civil Code). Unless otherwise agreed, the GTCD in the version valid at the time of the order placed by the Customer shall also apply as a framework agreement for similar future contracts without our having to refer to them again in each individual case.
- 1.3 Our GTCD shall apply exclusively. Deviating, conflicting or supplementary general terms and conditions of the Customer shall only become part of the contract if and to the extent that we have expressly consented to their application. This requirement of consent shall apply in any case, for example even if we carry out the delivery to the Customer without reservation in the knowledge of the Customer's GTC.
- 1.4 Individual agreements made with the Customer in individual cases (including ancillary agreements, supplements and amendments) shall in all cases take precedence over these GTCD. A written agreement or confirmation from us in writing is binding, subject to proof of the contrary, for the content of such agreements.
- 1.5 Legally relevant declarations and notifications to be made to us by the Customer after conclusion of the contract (e.g. setting of deadlines, notifications of defects, declaration of withdrawal or reduction) must be made in writing to be effective.

2. Conclusion of contract

- 2.1 Our offers are subject to change and non-binding. This also applies if we have provided the Customer with catalogues, technical documentation (e.g. drawings, plans, calculations, calculations, references to DIN standards), other product descriptions or documents - also in electronic form. Title and copyright to such documents shall remain with SEM.
- 2.2 The Customer's order for services shall be deemed to be a binding offer to enter into a contract. Unless otherwise stated in the order, we shall be entitled to accept this offer of contract within four weeks of its receipt by us.
- 2.3 Acceptance may be declared either in writing (e.g. by order confirmation) or by performance of the services to the Customer.

3. Delivery period and delay in delivery

- 3.1 The delivery period shall be agreed individually or stated by us upon acceptance of the order. If this is not the case, the delivery period is approximately twelve weeks from the conclusion of the contract.
- 3.2 If we are unable to meet binding delivery deadlines for reasons for which we are not responsible (non-availability of performance), we shall inform the Customer of this immediately and at the same time inform him of the expected new delivery deadline. If the performance is also not available within the new delivery period, we shall be entitled to withdraw from the contract in whole or in part; we shall immediately refund any consideration already paid by the Customer. A case of non-availability of the performance in this sense shall be deemed to be in particular the failure of our supplier to deliver to us in good time if neither we nor our supplier are at fault.
- 3.3 The occurrence of our default in delivery shall be determined in accordance with the statutory provisions. In any case, however, a reminder by the Customer is required.
- 3.4 The rights of the Customer pursuant to section 12 of these GTCD and our statutory rights, in particular in the event of an exclusion of the obligation to perform (e.g. due to impossibility or unreasonableness of performance and/or subsequent performance), shall remain unaffected.

4. Performance of the services

- 4.1 In the case of project work, the Customer shall designate a contact person who can provide the necessary information and decisions at short notice or bring them about. All declarations of intent by the Customer with respect to the execution of the project or the performance of the services shall only be binding on SEM if they have been made by the designated contact person.
- 4.2 If the services of SEM consist of several parts or if the services are part of an overall project, the Customer and SEM shall define a project plan with the interdependencies of the sub-projects and their deadlines for completion.
- 4.3 SEM shall perform the services to be rendered by it in accordance with the respective state of the art in science and technology and in compliance with all relevant laws and official regulations. The same shall apply to any acts of cooperation to be performed by the Customer. The manner of performance as well as the place and time of work shall be determined by SEM.
- 4.4 The Customer shall be responsible for ensuring that the prerequisites for the use of the services provided by SEM are met. If delays or additional costs are incurred due to a lack of these prerequisites, this shall be borne by the Customer.
- 4.5 Furthermore, the Customer shall be responsible for fulfilling its obligations to cooperate, in particular in the implementation of projects, in a timely manner. If this is not the case, SEM may, after the unsuccessful expiry of a reasonable grace period, at its option withdraw from the contract and/or claim damages for non-performance.

- 4.6 If SEM is required to provide information, instructions, manuals and the like, such information, instructions, manuals and the like shall be provided in German unless expressly agreed otherwise in an individual case or unless information in other languages is required by law or by official regulations.
- 4.7 If the Customer is a reseller of the goods purchased from SEM, he shall be obliged to comply with the dealer obligations under MDR 2017/745 as set out in section 14. The Customer shall also impose this obligation on its own customers if they are not end consumers.

5. Change Request

- 5.1 If the Customer requests in writing changes to the services to be provided by SEM, SEM shall comply with such a request for change unless this is unreasonable within the scope of its operational capacity.
- 5.2 If the request for change leads to an increased effort on the part of SEM, a mutually agreed written adjustment of the contractual provisions is required, in particular with regard to the remuneration and any agreed deadlines.

6. Delivery, transfer of risk

- 6.1 Delivery shall be made ex works of the place of business of SEM, which shall also be the place of performance for the delivery and any subsequent performance. At the request and expense of the Customer, the delivery shall be made to another destination. Unless otherwise agreed, we shall be entitled to determine the type of shipment (in particular, transport company, shipping route, packaging) ourselves.
- 6.2 If the performance of the service is delayed at the request of the Customer, the Customer shall pay the costs incurred by the storage in the amount of at least 0.5% of the total order volume per month or part thereof, beginning with the first of the month following the notification of readiness for delivery, unless the Customer proves that lower costs are incurred.
- 6.3 The risk of accidental loss and accidental deterioration of the goods shall pass to the Customer upon handover at the latest. In the event that a service is provided at a different destination at the request of the Customer in accordance with section 6.1, the risk of accidental loss and accidental deterioration of the goods as well as the risk of delay shall, however, already pass to the Customer upon delivery of the goods to the forwarding agent, the carrier or the person or institution otherwise designated to carry out the shipment.

7. Acceptance of work performance under a contract for work and services

If and to the extent that the services to be provided by SEM are of a contract for work or acceptance is expressly agreed, the following provisions shall apply:

- 7.1 Within ten calendar days after SEM has notified the Customer of the completion of the work, the Customer shall declare acceptance in writing or shall carry out an inspection together with SEM.
- 7.2 The inspection shall be deemed to have been successfully completed if the work complies in all material respects with the requirements set out in the Contract.
- 7.3 Any deviations from the contractually stipulated requirements shall be recorded in a jointly prepared protocol and remedied by SEM. Thereafter, acceptance shall be declared in writing or a further inspection shall be carried out as described above.
- 7.4 Non-substantial deviations shall not entitle the Customer to refuse acceptance. In this respect, no further inspection shall be carried out.
- 7.5 After successful completion of the inspection, the Customer shall declare acceptance in writing without delay.
- 7.6 The work to be performed by SEM shall be deemed to have been accepted if the inspection is not carried out within the aforementioned period of ten calendar days for a reason for which the Customer is responsible, if the Customer does not declare acceptance in writing without undue delay after a successful inspection, if the Customer does not sufficiently specify the reasons for refusing acceptance or if the Customer uses the work performed by SEM.
- 7.7 Individual partial work may be tested and accepted separately if this has been expressly agreed in writing.

8. Default of acceptance

- 8.1 If the Customer is in default of acceptance, fails to cooperate or delays our delivery for other reasons for which the Customer is responsible, we are entitled to demand compensation for the resulting damage including additional expenses (e.g. storage costs). For this purpose, we shall charge a lump-sum compensation in the amount of 0.5% of the total order volume per week or part thereof, starting with the delivery deadline or - in the absence of a delivery deadline - with the notification that the goods are ready for dispatch.
- 8.2 The proof of higher damages and our statutory claims (in particular reimbursement for additional expenses, reasonable compensation, termination) shall remain unaffected; however, the lump sum shall be offset against further monetary claims. The Customer shall be entitled to prove that no damage or only significantly less damage than the aforementioned lump sum has been incurred.

9. Prices and terms of payment

- 9.1 Unless otherwise agreed in an individual case, the prices quoted by SEM in the offer or elsewhere shall apply plus the respective statutory value added tax and plus packaging and freight costs as well as travel and accommodation costs, if any, in accordance with the rates of the respective valid price list and always in euros.

- 9.2 Payment is due without deductions within 14 days from the date of invoice and delivery or acceptance of the goods. However, we shall be entitled at any time, also within the framework of an ongoing business relationship, to make a delivery in whole or in part only against advance payment. We shall declare a corresponding reservation at the latest with the order confirmation.
- 9.3 Upon expiry of the aforementioned payment deadline, the Customer shall be in default without issuing a further reminder. During the period of default, interest shall be charged on the remuneration at the statutory default interest rate applicable at the time. We reserve the right to claim further damage caused by delay. Our claim for commercial maturity interest (Section [353](#) of the German Civil Code) remains unaffected.
- 9.4 The Customer shall only be entitled to rights of set-off or retention insofar as its claim has been legally established or is undisputed. In the event of defects in the delivery, the counter rights of the Customer shall remain unaffected, in particular in accordance with section 11.4 sentence 2 of these GTCD.
- 9.5 If, after conclusion of the contract, it becomes apparent (e.g. by filing for insolvency proceedings) that our claim to remuneration is jeopardised by the Customer's inability to pay, we shall be entitled to refuse performance in accordance with the statutory provisions and - if necessary after setting a deadline - to withdraw from the contract (Section 321 of the German Civil Code). In the case of contracts for the manufacture of unjustifiable items (customised products), we may declare withdrawal immediately; the statutory regulations on the dispensability of setting a deadline remain unaffected.

10. Retention of title

- 10.1 Until full payment of all our present and future claims arising from the concluded contract and an ongoing business relationship (secured claims), we retain title to the goods sold.
- 10.2 The goods subject to retention of title may neither be pledged to third parties nor assigned as security before full payment of the secured claims. The Customer must notify us immediately in writing if an application is made to open insolvency proceedings or if third parties (e.g. seizures) have access to the goods belonging to us.
- 10.3 In the event of a breach of contract by the Customer, in particular in the event of non-payment of the amount due, we shall be entitled to withdraw from the contract in accordance with the statutory provisions and/or to demand the return of the goods on the basis of the reservation of title. The demand for return does not at the same time include the declaration of withdrawal; we are rather entitled to demand only the return of the goods and to reserve the right of withdrawal. If the Customer does not pay the purchase price due, we may only assert these rights if we have previously set the Customer a reasonable deadline for payment without success or if setting such a deadline is dispensable according to the statutory provisions.
- 10.4 Until revoked in accordance with (c) below, the Customer is authorised to resell and/or process the goods subject to retention of title in the ordinary course of business. In this case, the following provisions shall apply in addition.

- (a) The retention of title extends to the products resulting from the processing, mixing or combining of our goods at their full value, whereby we are deemed to be the manufacturer. If, in the event of processing, mixing or combining with goods of third parties, their right of ownership remains, we shall acquire co-ownership in proportion to the invoice values of the processed, mixed or combined goods. Otherwise, the same shall apply to the resulting product as to the goods delivered under retention of title.
- (b) The Customer hereby assigns to us by way of security the claims against third parties arising from the resale of the goods or the product in total or in the amount of our possible co-ownership share in accordance with the above paragraph. We accept the assignment. The obligations of the Customer stated in section 10.2 shall also apply in respect of the assigned claims.
- (c) The Customer remains authorised to collect the claim in addition to us. We undertake not to collect the claim as long as the Customer meets his payment obligations towards us, there is no deficiency in his ability to pay and we do not assert the retention of title by exercising a right pursuant to section 10.3. If this is the case, however, we may demand that the Customer informs us of the assigned claims and their debtors, provides all information necessary for collection, hands over the relevant documents and informs the debtors (third parties) of the assignment. Furthermore, in this case we shall be entitled to revoke the Customer's authorisation to further sell and process the goods subject to retention of title.
- (d) If the realisable value of the securities exceeds our claims by more than 10%, we shall release securities of our choice at the request of the Customer.

11. Warranty claims

- 11.1 The statutory provisions shall apply to the rights of the Customer in the event of material defects and defects of title (including wrong delivery and short delivery), unless otherwise stipulated below.
- 11.2 The Customer's claims for defects are subject to the condition that he has fulfilled his statutory obligations to inspect and give notice of defects (sections [377](#), [381](#) of the German Commercial Code). If a defect becomes apparent during the inspection or at a later date, we must be notified thereof in writing without delay. The notification shall be deemed to have been made without delay if it is made within two weeks, whereby timely dispatch of the notification shall suffice to meet the deadline. Irrespective of this obligation to inspect and give notice of defects, the Customer shall notify us in writing of obvious defects (including incorrect and short deliveries) within two weeks of delivery, whereby timely dispatch of the notification shall also suffice to meet the deadline. If the Customer fails to carry out the proper inspection and/or give notice of defects, our liability for the non-notified defect shall be excluded.
- 11.3 If the performance rendered by SEM is defective, we may first choose whether to provide subsequent performance by remedying the defect (subsequent improvement) or by delivering a defect-free item (replacement delivery). Our right to refuse subsequent performance in accordance with the statutory and other applicable provisions shall remain unaffected.

- 11.4 We are entitled to make the supplementary owed performance dependent on the Customer paying the amount due. However, the Customer shall be entitled to retain a part of the amount which is reasonable in relation to the defect.
- 11.5 The Customer shall give us the time and opportunity required for the subsequent performance owed, in particular to hand over the item complained about for inspection purposes. In the event of a replacement delivery, the Customer shall return the defective item to us in accordance with the statutory and other applicable provisions. Subsequent performance shall neither include the removal of the defective item nor its re-installation if we were not originally obliged to install it.
- 11.6 We shall bear the expenses necessary for the purpose of inspection and subsequent performance, in particular transport, travel, labour and material costs, if there is actually a defect. Otherwise, we may demand reimbursement from the Customer of the costs incurred as a result of the unjustified request for rectification of the defect (in particular inspection and transport costs), unless the lack of defectiveness was not recognisable to the Customer.
- 11.7 In urgent cases, e.g. if operational safety is endangered or to prevent disproportionate damage, the Customer has the right to remedy the defect himself and to demand compensation from us for the expenses objectively necessary for this. We must be informed immediately of any such self-execution, if possible in advance. The right of self-performance shall not apply if we would be entitled to refuse a corresponding subsequent performance in accordance with the statutory and other applicable provisions.
- 11.8 If the supplementary performance has failed or if a reasonable deadline to be set by the Customer for the supplementary performance has expired unsuccessfully or is dispensable in accordance with the statutory and other applicable provisions, the Customer may withdraw from the contract or reduce the remuneration. In the case of an insignificant defect, however, there shall be no right of withdrawal.

12. Other liability

- 12.1 Insofar as nothing to the contrary arises from these GTCD including the following provisions, we shall be liable in accordance with the statutory provisions in the event of a breach of contractual and non-contractual obligations.
- 12.2 We shall be liable for damages - irrespective of the legal grounds - in the event of wilful intent and gross negligence. In the event of simple negligence, we shall be liable, subject to a milder standard of liability, in accordance with statutory provisions (e.g. for care in own affairs) only
- a) for damages resulting from injury to life, body or health,
 - b) for damages arising from a not insignificant breach of a material contractual obligation (obligation the fulfilment of which is a prerequisite for the proper performance of the contract and on the observance of which the contractual partner regularly relies and may rely); in this case our liability shall be limited to the reimbursement of the foreseeable, typically occurring damage.

- 12.3 The limitations of liability resulting from section 12.2 shall also apply in the event of violations of duties or in favour of persons, whose fault we are responsible for according to legal provisions. They do not apply if we have fraudulently concealed a defect or have given a guarantee for the quality of the goods and for claims of the Customer under the German Product Liability Act.
- 12.4 Claims for damages due to defective performance shall require that the damages have been caused by negligent or wilful behaviour of XY according to the aforementioned clauses. A claim for damages in lieu of performance shall require the prior setting of a reasonable deadline by the Customer.
- 12.5 The Customer may only withdraw from or terminate the contract due to a breach of duty which does not consist of a defect if we are responsible for the breach of duty. A free right of termination on the part of the Customer (in particular in accordance with sections [651](#) and [649](#) of the German Civil Code) is excluded. In all other respects, the statutory requirements and legal consequences shall apply.
- 12.6 The limitation period for claims arising from material defects and defects of title is one year from delivery. If acceptance has been agreed, the limitation period shall commence upon acceptance. However, claims for damages by the Customer pursuant to section 12.2 sentence 1 and sentence 2 a) as well as pursuant to the German Product Liability Act shall become time-barred exclusively in accordance with the statutory limitation periods.

13. Intellectual property

- 13.1 Insofar as we also transfer industrial property rights, know-how or other intellectual property to the Customer, the Customer shall be granted a non-exclusive right in this respect to use these rights itself within the scope of the contractual purpose or to grant its customers rights of use in connection with the associated delivery item. Any use beyond this is prohibited.
- 13.2 Reproduction, revision, translation may only take place within the legally permissible framework sections 69a et seq of the German Copyright Act).
- 13.3 The Customer is not permitted to remove or change manufacturer's details and trademarks.
- 13.4 The Customer shall impose all the aforementioned obligations on its customers in the same manner.

14. Trader obligations under the MDR 2017/745

- 14.1 Within the scope of these GTCD, SEM shall assume the position of a manufacturer for the medical devices pursuant to Article 2 No. 30 of Regulation (EU) 2017/745 and the Customer as the contractpartner shall assume the position of a distributor pursuant to Article 2 No. 34 of Regulation (EU) 2017/745.
- 14.2 The Customer undertakes to comply with the obligations of a trader under Article 14 of Regulation (EU) 2017/745.

- 14.3 The Customer and SEM shall cooperate to ensure the traceability of the goods.

Pursuant to Art. 25 (2) of Regulation (EU) 2017/745, the Customer undertakes to ensure that for a period of ten years after he has delivered the last goods he will be able to provide the competent authority at any time with information on who he has received the goods from or to whom he has delivered the goods. In this respect, the Customer undertakes to set up and document a suitable procedure for the provision of this information.

The Customer undertakes to hand over the documentation suitable for providing information to SEM after the expiry of the aforementioned ten years or to dispose of it properly upon written request by SEM. The Customer undertakes to comply with the obligations set out in section 14.3 even if it has ceased operations before the expiry of the aforementioned ten years or if insolvency proceedings are opened against it.

- 14.4 The Customer undertakes to document all experience and knowledge of the goods, including trends to be observed, and all complaints or reports of suspected incidents in connection with the goods which it receives, and to retain this documentation for a period of ten years. In this respect, the Customer undertakes to establish and document a suitable procedure for the receipt of such experiences, findings, complaints or reports about the goods and for the documentation thereof and to keep this documentation up to date.

The Customer undertakes to comply with the obligations set out in section 14.4 even if it has ceased operations or insolvency proceedings have been opened against it before the expiry of the aforementioned ten years.

- 14.5 The Customer undertakes to pass on to SEM without delay all experience and findings about the goods, including any trends to be observed, and all complaints or reports of suspected incidents in connection with the goods which it receives.

In the event of suspected serious incidents pursuant to Art. 2 No. 64 Regulation (EU) 2017/745, the forwarding shall be made in advance by telephone (+49 (0) 2681/ 950 78-0), fax (+49 (0) 2681/ 950 78-18) or by email to quality@plastomed.de.

- 14.6 Before using its own advertising materials and in the event of subsequent changes of advertising materials, the Customer undertakes to obtain prior written approval from SEM.

15. Choice of law and place of jurisdiction

- 15.1 The laws of the Federal Republic of Germany shall apply to these GTCD and the contractual relationship between us and the Customer.

- 15.2 If the Customer is a merchant within the meaning of the German Commercial Code, a legal entity under public law or a special fund under public law, the exclusive place of jurisdiction for all disputes arising directly or indirectly from the contractual relationship shall be at the registered office of SEM. The same shall apply if the Customer is an entrepreneur pursuant to section 14 of the German Civil

Code (BGB). However, we shall also be entitled in all cases to bring an action at the place of performance of the delivery obligation pursuant to these GTCD or a prior individual agreement or at the general place of jurisdiction of the Customer. Overriding statutory provisions, in particular on exclusive jurisdiction, shall remain unaffected.