

General Terms and Conditions of Primed Halberstadt Medizintechnik GmbH

I. Scope of application

1. Sale and delivery of all products distributed by **Primed Halberstadt Medizintechnik GmbH** (hereinafter referred to as „**Primed**“) in Germany and abroad shall be exclusively made on the basis of these General Terms and Conditions. They shall be deemed to have been recognized when an order is issued or a delivery is accepted by the ordering party or their agents.
2. This also holds true for future business transactions or deliveries between the same parties, without the requirement of an express reference.
3. Our Terms and Conditions shall also apply if there are indications to the contrary in the terms and conditions of the ordering party or the supplier. We hereby expressly object to these Terms and Conditions, unless **Primed** has agreed to such deviating Terms and Conditions in writing.
4. Individual agreements reached between the parties shall remain unaffected by these Terms and Conditions.
5. Should individual terms be or become inoperative, the remaining terms will not be affected.

II. Orders and Acknowledgement of orders

1. Our offers are non-binding. Orders shall only be binding for us if we acknowledge them in writing or by fax/email or by sending the goods to you. Any verbal collateral agreements, modifications or assurances regarding offers or written agreements shall have no effect until confirmed by us in writing.
2. We expressly reserve the right to modify the items ordered and delivered, particularly with regard to material and workmanship, in the interest of technical development.
3. For transactions comprising several individual deliveries, each delivery shall be regarded as a different transaction.

III. Prices

1. Our prices are quoted ex works without packaging
2. If the price has been agreed to be related to the weight of parts, the final price will be calculated on the basis of the weight of the approved type samples.

IV. Terms of delivery, transfer of risk, packaging, dispatch

1. Delivery deadlines or periods shall only be binding if expressly agreed in writing. **Primed's** compliance with the obligation to supply goods is dependent upon the prompt and proper fulfilment of the ordering party's obligations. We reserve the right to defend against non-fulfilment.
2. In case of delays in delivery due to force majeure or other events which make it increasingly difficult or even impossible for **Primed** to meet delivery commitments in time, **Primed** shall not be answerable for the non-performance of any binding delivery dates.
3. The risk of damage, deterioration, destruction or loss of the goods shall be transferred to the party ordering as soon as the consignment has been handed over to the person executing the transport or has left **Primed's** warehouse or factory for the purpose of dispatch. If dispatch is delayed at the request of the ordering party or through the fault of the ordering party, the risk shall pass to the ordering party after the notification of readiness for dispatch.
4. Upon written request of the ordering party, the goods will be insured against storage damage, breakage, transportation damage and fire damage at the latter's cost.
5. Unless otherwise agreed, **Primed** will choose packaging and dispatch at their own discretion.
6. Special packaging material (also pallets) that have not been invoiced, shall remain the property of the supplier. The ordering party shall be obliged to store the packaging material with due care and make sure that the packaging is returned free of charge.
7. **Primed** reserves the right to charge the shipping costs incurred for order-related short quantities.

V. Terms of payment

1. All payments shall be made in Euros to **Primed** only.
2. Unless otherwise agreed, the purchasing price:
 - a) for moulds and tools is to be paid 50% when the order is acknowledged, the other 50% of the order price are to be paid within 30 days after submitting the type samples specified in the contract. Once the ordering party has confirmed their change requests before the moulds are produced, all costs incurred up to that time will be charged insofar as they exceed the down-payment.
 - b) must be paid net (without any deductions) within 30 days after date of invoice.
3. In case any agreed payment dates are exceeded, interest amounting to 4% above the respective discount rate of the Federal Bank of Germany will be charged, unless **Primed** can provide evidence of higher debit interest.
4. Cheques and rediscountable bills of exchange will only be accepted by way of fulfilment; all associated costs will be payable by the purchaser. The ordering party shall not be entitled to set off and enforce retaining liens for any adverse claims not recognised by **Primed**.
5. If the terms of payment are not observed or circumstances become known justifying serious doubts about the credit standing of the ordering party, all the claims held by **Primed** will become payable immediately. In addition, **Primed** has the right to require advanced payments for orders still outstanding and to rescind the contract after granting a reasonable period of extension or to require compensation for non-performance; moreover, **Primed** can prohibit the purchaser from reselling goods and repossess at the expense of the ordering party any goods which have not been paid for.

VI. Moulds and tools

1. The mould and tool price also includes the sampling costs but not the costs for testing and processing equipment and modifications requested by the ordering party.
2. Unless otherwise agreed, **Primed** is and remains the owner of the moulds and tools produced for the ordering party by **Primed** themselves or by a third party assigned by **Primed**. These moulds and tools shall be exclusively used for the orders of the ordering party, as long as the ordering party honours their payment and purchasing obligations. **Primed's** obligation to store the moulds will expire two years after the last delivery of parts.
3. If in accordance with the terms of this agreement the ordering party is to become the owner of the moulds and tools, the ownership shall be transferred to the ordering party after paying the purchasing price for the moulds and tools. The handing over of the moulds and tools to the ordering party shall be replaced by **Primed's** obligation to store them. Regardless of the ordering party's legal claim for restitution of property and the service life of the moulds, **Primed** shall be entitled to be the exclusive owner of the moulds, until a minimum quantity to be agreed upon has been purchased and/or until a certain period of time has elapsed.
4. For moulds and tools owned by the ordering party pursuant to item 3 and/or moulds and tools loaned out by the ordering party, **Primed's** liability regarding storage and maintenance is restricted to the care expended on their own property. Maintenance and insurance costs shall be borne by the ordering party. **Primed's** obligations shall expire if the ordering party- on completion of the order and after respective demand- fails to collect the moulds within the adequate period. As long as the ordering party has not fulfilled their contractual obligations in full, **Primed** has a right of retention to the moulds.

VII. Material provision

1. Whenever materials are provided by the ordering party, these materials shall be supplied in due time and perfect condition at the cost and risk of the ordering party and must include reasonable excess quantities of no less than 5%.
2. If these requirements are not met, the supply period will be extended by a reasonable period of time. Except in cases of force majeure, the ordering party shall pay the additional costs thus incurred, including those of interruption of production.

VIII. Reservation of title

1. The goods supplied will remain **Primed's** property until all claims held by **Primed** against the ordering party have been settled. The ordering party is not authorised to dispose of the conditional goods in other ways, in particular by pledging or assignment as security. In cases of breach of contract on the part of the ordering party, especially default of payment, **Primed** shall be entitled to reclaim and take back the goods.

2. The ordering party shall be entitled to resell the goods as part of ordinary business transactions. The ordering party assigns to us claims to the goods held against a third party in the course of resale, up to the corresponding invoiced amount. We accept this assignment. Following the transfer, the customer shall be authorized to collect the amounts receivable. However, we undertake not to collect said amount receivable for as long as the customer meets their financial obligations out of the proceeds collected, does not default on payment and has not applied for composition or bankruptcy proceedings or has suspended payments. But should such situation arise, we may demand that the customer disclose the claims assigned and the related debtors, that they provide all information necessary for collection, that they hand over all pertinent documentation and that they inform the debtor of the assignment.
3. Processing or compounding by the ordering party shall exclude the acquisition of owner-ship; **Primed** shall remain the owner of the new product. In case of processing, connecting or mixing according to the intended use, the assignment shall correspond to the invoiced amount of the goods used.
4. If **Primed** exercises their reservation of ownership in compliance with the above provisions by repossessing conditional goods, they shall be entitled to sell the goods on the open market or have them auctioned. The goods will be repossessed at the amount of the proceeds obtained but at no more than the agreed supply prices. The right to make further claims for damages, in particular loss of profits, is reserved.

IX. Liability for defects

1. The ordering party shall be obliged to inspect the goods received from **Primed** immediately after delivery and to report any defects or delivery errors immediately, at the latest within one week after receipt of the goods. Any defects that cannot be detected even by careful scrutiny of the goods within one week after receipt of the goods shall be notified in writing immediately after discovery, but at the latest six months after receipt of the goods enclosing certificate of the consignment in question.
2. Failure to comply with the instructions for use or the indications on the packaging of the goods, or to use or store the goods according to the intended use, will result in the lapse of all warranties, unless it conflicts with any legal requirements.
3. If **Primed** has provided advice to the ordering party, **Primed** shall be liable for functionality and suitability of the consignment only upon prior express written approval.
4. In case of a justified notice of defects- for which quality and workmanship of the samples approved by the ordering party in writing shall prevail- **Primed** shall be entitled at its own discretion to either remedy the situation or substitute the product free of charge. Replaced goods are to be returned to **Primed** at their request.
5. Unauthorised re-working and improper handling shall result in the loss of any right to claim compensation due to defective parts. After giving **Primed** prior notification, the ordering party is authorised to rework items and to require compensation for reasonable costs only if this is being done to avert unreasonable losses or if **Primed** is in default with the remedying of defects.
6. In particular, our liability for all breaches of obligations relating to the implementation of a contract, irrespective of the legal reason, shall be limited to the compensation for the direct damage which is reasonably foreseeable for us, but no more than 7.5% of the net value of the goods ordered. Under no circumstances we will accept liability for damage arising from business interruption or loss of production, in particular loss of profit and increased production costs.
7. The aforementioned limitation of liability shall not apply if the damage is attribute to a wilful or grossly negligent breach of duty. Liability in accordance with the German Product Liability Act shall not be affected.

X. Return of goods

1. **Primed** will accept the return of goods only in justified exceptional cases. The goods can only be returned with express written approval; without this approval no credit note will be issued for the returned goods.
2. The amount to be refunded for the returned goods depends on their age and their suitability for resale. Non-re-saleable goods and individually manufactured products are excluded from return.
3. The customer shall bear the risk for the transport of returned goods.

XI. Intellectual and industrial property rights

1. We reserve the ownership rights and copyrights to illustrations, plans, drawings, drafts, design proposals, calculations and any other documents enclosed with **Primed's** offers or which have been disclosed to the ordering party within the framework of the cooperation. The ordering party shall require **Primed's** written approval for their distribution to third parties.
2. Whenever **Primed** supplies drawings, models or samples to the ordering party, the latter warrants that no property rights of third parties are breached thereby. The ordering party shall hold **Primed** harmless in relation to claims from third parties and reimburse any damages incurred. If a third party forbids production or supply by invoking a property right which they hold, **Primed** is entitled to discontinue work without reviewing the legal situation.

XII. Export and Domestic Distribution

1. Prior written consent is required for the sale, shipment, and export of our goods to Canada, the USA, Japan, Brazil, and China. We reserve the right to assess a contractual penalty in the event that goods are traded on these markets without our written consent.
2. Each reseller shall be obliged to guarantee traceability of their final customers, so that in case of a recall according to MDR 2017/745, their final customers can be reached and the medical device can be withdrawn from the market. This obligation also applies for the period after the business relations have ended.
3. Deliveries and services are subject to the condition that performance is not opposed by national or international regulations, in particular, but not limited to, export control regulations, embargos, or other sanctions. The contracting parties covenant to provide any and all information and documentation required for the export/shipment/import. Delays resulting from export assessments or approval procedures render deadlines and delivery periods ineffective. If the required permits are not issued, the contract shall be deemed as not concluded with regard to the ordered goods; damage compensation claims related to these delays and overruns of the aforementioned deadlines are precluded.

XIII. General Obligations of the Dealer and the Customer (Art. 14 MDR 2017/745)

All dealers and customers who procure products from **Primed** and in turn offer these products on the market or distribute them commercially are subject to the general obligations of Art. 14 MDR 2017/745.

XIV. Place of fulfilment, place of jurisdiction and applicable law

1. The place of fulfilment for any obligations arising from the contractual relations between **Primed** and the ordering party is the head office of our company.
2. The place of jurisdiction is- at **Primed's** discretion- **Primed's** head office or the head office of the ordering party. This shall also apply to documentary, bills of exchange and cheque proceedings.
3. These Terms and Conditions and all contractual relations between the parties shall be governed by the law of the Federal Republic of Germany. Applicability of the UN Convention on Contracts for the International Sale of Goods shall be expressly excluded.