



# General Terms and Conditions of Sale International June 2021

## 1. General

The following conditions apply to all offers, deliveries and services and are agreed part of all contracts concluded with VBM, whether through written, verbal or telephone orders. Conflicting conditions of customers are excluded. Following general terms and conditions apply exclusively, as well as the "Regulations for distribution partners to implement the Medical Device Regulation (EU) 2017/745" of VBM where applicable.

## 2. Offers

Offers of VBM are non-binding if nothing else has been explicitly agreed upon.

## 3. Purchase Orders

Purchase orders and corresponding terms are accepted by the order acknowledgement of VBM. Products, quantities, prices, and terms mentioned in the order acknowledgement are binding. Amendments are only accepted after written confirmation by VBM.

Order quantities must be in complete packing units.

Cancellation of confirmed orders by the purchaser requires written approval of VBM. Compensation charges might arise from such cancellation.

## 4. Prices

The current price list of VBM applies. All prices are in EURO (€), net (excluding value added tax), ex works, plus packing costs and insurance.

## 5. Delivery

Delivery is FCA Sulz a.N. (Incoterms 2020). The delivery times stated by VBM are non-binding and determine the time by when the goods will be ready for dispatch. Part deliveries are permitted. No claims can be asserted against VBM for the consequences of delayed or missing deliveries.

## 6. Payment Terms

Invoices of VBM are payable without any deduction and within the agreed payment period. Any discounts are only admissible if mentioned in the invoice. VBM reserves the right to demand advance payment.

VBM also reserves the right to add interest and dunning fees on payment delays.

## 7. Traceability / Vigilance

The distributor and its representatives are obliged to establish a system for full product surveillance and traceability of medical devices to users respectively customers. The customer shall inform VBM immediately of any complaints, incidents or other events and market observations regarding the products of VBM.

## 8. Warranty

Insofar as nothing to the contrary arises from these GTC including the following provisions, VBM is liable for a breach of contractual or non-contractual obligations in accordance with the statutory provisions.

VBM is liable for damages – regardless of the legal grounds – in the event of intent and gross negligence. In the case of simple negligence VBM is only liable for

- damages resulting from injury to life, body, or health
- damages from the violation of an essential contractual obligation (an obligation whose fulfilment makes the proper execution of the contract possible in the first place and on whose compliance the buyer regularly relies and may rely); in this case, however, VBM's liability is limited to the typically occurring damage.

VBM is not liable for the consequences of improper handling or modification of the products, inadequate maintenance on the part of the buyer or third parties, or for defects based on normal wear and tear or caused by transport.

## 9. Liability

The buyer must check the delivery immediately and must report all defects and missing goods within one week after receipt in written form. Hidden defects must be notified immediately after detection.

VBM provides a warranty for a period of 12 months from the date of delivery for the proper functioning of the products supplied by VBM and for their durability when handled properly. For energetically operated devices like Tourniquet Devices and Pressure Infusers, Manujet, Cuff Controller as well as for Cuff Manometers, a warranty period of 24 months from the date of delivery applies.

## 10. Return of goods / Goods for trial

The goods supplied by VBM can be returned after consultation and permission within 30 days from invoice date. Excluded are special procurements, customized products, and sterile products according to MDD/MDR. The goods must be returned unopened in their undamaged original packaging. VBM reserves the right to charge a handling fee. For more information, please refer to the terms of service conditions on the VBM homepage [www.vbm-medical.de](http://www.vbm-medical.de).

After the agreed trial period of loaned goods, these must be returned to VBM cleaned or sterilized. VBM will charge for any damage caused by testing. Please note that loaned goods must be returned to VBM. In case of an order, new goods will be supplied.

## 11. Retention of title

VBM retains title to all goods supplied by VBM until full payment of the purchase price.



## 12. Place of fulfilment and jurisdiction

Sulz a.N., Germany is the place of fulfilment for all deliveries and services of the contracting parties (national and international). Any controversy, claim, or dispute not settled by arbitration shall be litigated before the competent courts at the place of business of VBM. VBM is instead also entitled to assert its claims at the general place of jurisdiction of the buyer.

Our GTC and all contracts concluded under these GTC shall be governed by the laws of the Federal Republic of Germany to the exclusion of UN Convention on Contracts for the International Sale of Goods (CISG).

## Regulations for distributors to implement the Medical Device Regulation (EU) 2017/745 June 2021

The following Regulation for distributors to implement the Medical Device Regulation (EU) 2017/745 ("MDR") applies for all legal relations between the company VBM Medizintechnik GmbH ("VBM") and the purchasers of its products wherever the purchaser acts as a distributor ("distributor") according to Regulation (EU) 2017/745 for medical devices. Further the requirements of the General Terms and Conditions of Sale of VBM apply in addition. This Regulation will apply in priority in case of conflicts or contradictions compared to the General Terms and Conditions of Sale. If there is a specific Supply - / Quality – or Distribution Agreement with the distributor, this shall take precedence.

1. The distributors are obliged to meet the requirements and duties of MDR article 14. To make a product available on the market, the distributors shall carefully consider the applicable requirements as part of their activities.
2. The distributors ensure traceability of the products to the customer at any time (REF and serial or LOT number). Where applicable, the distributors verify whether a UDI has been assigned.
3. The distributors ascertain CE marking and the EU Declaration of Conformity of the products.
4. The distributors must adhere to the storage and transport conditions of the products set by VBM to ascertain their integrity.
5. The distributors may not make any modifications to the products of VBM, the associated packaging and labeling (i.a. instructions for use).
6. The distributors shall keep a register of and shall adequately treat non-conforming devices (which may be observed by the distributors e.g. during incoming inspection). The distributors immediately provide detailed information on the non-conformities to VBM.

7. The distributors shall immediately forward all kinds of complaints on the products (received by customers in writing, electronically or verbally) to VBM immediately and in writing via [service@vbm-medical.de](mailto:service@vbm-medical.de). The distributors are not entitled to perform any repairs or service procedures. This is the sole responsibility of VBM and authorized VBM service partners.

8. The distributors who have received information about incidents related to a device where patients, users or third parties have been harmed or may have been harmed, shall immediately forward this information by e-mail to [fieldsafetynotice@vbm-medical.de](mailto:fieldsafetynotice@vbm-medical.de). The distributors will support VBM in evaluation and assessment of the incident. VBM decides whether an incident is reported to the competent authority.

9. The distributors will send all kinds of customer feedback regarding the devices to [service@vbm-medical.de](mailto:service@vbm-medical.de).

10. If VBM decides on a product recall, Field Safety Corrective Action (FSCA) or Field Safety Notice (FSN), the distributors will support VBM with their resources.

11. All relevant documentation and records related to the sale of the devices (e.g. for traceability, quality management, etc.) shall be kept by the distributors for at least 10 years from the shipping date or for the lifetime of the corresponding product.