International Terms of Sale and Delivery of Uniprox GmbH & Co. KG (General Business Terms)

Prices
are quoted net ex works in Euro currency, plus freight and taxes, if any.

Dispatch
at buyer's cost and risk even if the buyer does not bear the transportation cost. Disruptions of operations affecting us or any of our suppliers, lack of suitable personnel, strike, lockout and force majeure are causes for extending delivery and relieve us of any delivery obligation for the time of the obstruction.

Returns
outside the warranty terms are only accepted after prior advise and approval of Uniprox to the return, provided the delivery documents are submitted; it is supposed that the returned goods are in proper state. We reserve the right of rejecting the acceptance of any returned consignment. We charge an administration fee of 10 € for every consignment returned outside the warranty period. The administrational fee for goods returned 1 month or more after the date of delivery is additionally 20 % of the net order value, subject to a maximum of 25 € per article and piece; the fee is additionally 40 % of the net order value of goods returned between 6 months and 12 months after the delivery date, subject to a maximum fee of 50 € for each article and piece. Goods returned outside the warranty, especially custom made products, and 12 months or more after the date of delivery will not be accepted back.

Payment
to be made immediately after presentation of the invoice. First deliveries are only made against advance payment. If the customer is in default, any further delivery will only be made against advance payment. We charge interest on arrears at the rate of 8 % above the applicable base rate from the time at which payment is delayed. Payments by check, draft, etc. are deemed to be made when the amount has finally been credited to our account.
Uniprox GmbH & Co. KG offers its contractual partners direct debit as a secure payment method. For payments on an invoice basis, contractual partners are always requested to check the specified contract details and account information in order to detect manipulation by third parties (e.g., hackers) and avoid financial losses.
We will always communicate any changes to our bank details separately.

Retention of title
We retain the title to all goods delivered until the buyer has paid all amounts outstanding under our business relations with him. The retention of title also applies proportionately to goods, which have been processed or otherwise modified. If the goods are sold all claims on third parties are deemed

to have been assigned to us without proviso up to the total amount owing to us. Notwithstanding the assignment, the buyer is entitled to the collection of these amounts. Our right to collect the amounts is not affected by the preceding provision; however, we undertake to refrain from collection unless the buyer defaults on payment. If the buyer defaults on payment we can demand that the buyer disclose the assigned claims and the names of the debtors, provides all information required for collection of the debt, delivers all required documents and informs the debtors (third party) of the assignment. The buyer is not permitted to sell, hypothecate or assign the goods as security. Hypothecation, confiscation or any other action of constraint taken by a third party shall be communicated to us by the buyer without delay and he shall provide all information and documents to enable us to defend our rights. We undertake to release, on the buyer's demand, any security, which exceeds a secured claim that has not been satisfied by more than 20%.

Complaints

Warranty claims due to obvious defects expire unless notified to us in writing immediately within the meaning of Article 377 HGB (German Commercial Code). For the rest, the time bar for warranty claims is 1 year after delivery of the goods purchased. If the goods are defective, we makereplacement delivery or repair the goods at our choice. For reasons of hygiene, repairs can only be made to washed goods and goods, which are of good hygienic condition. If and to the extent to which we fulfil our duties of supplementary performance, in particular, the repair of defects or delivery of goods without defect, the customer cannot demand a price reduction or rescind the contract unless our attempts at supplementary performance have failed. Defects which are due to normal wear and tear, overstrain, misuse, neglect of care or non-compliance with the instructions for use are not covered by warranty.

Liability

for damage is excluded unless we or our servants are found to have acted with gross negligence or intention. This limitation of liability does not apply to damage due to injury of life, body or health or the violation of a major contractual duty.

Compliance with the requirements of the European Union Medical Device Regulation (EU) 2017/745

Preliminary Remark

From May 26, 2017, the Medical Device Regulation (MDR) (Regulation EU 2017/745) applies across Europe. The new Medical Device Regulation (MDR) replaces the directive93/42/EEC for medical devices. As a regulation, the MDR is directly applicable. It is binding for manufacturers and distributors at all stages of trade as well as the other operators; these parties are obliged to comply with the duties stipulated therein. The transitional period for the implementation of the MDR ends on May 25, 2021, which means that the regulation becomes directly applicable from that date.

The MDR imposes extensive obligations on distributors (Art. 14 MDR) and manufacturers (Art. 10 MDR) that each apply independently but must be fulfilled in combination with one another.

Implementation of manufacturer obligations

Fundamentally, Uniprox GmbH & Co. KG is a manufacturer of ready-to-sell medical devices. Accordingly, Uniprox is subject to the general obligations under Art. 10 of the MDR. In particular, these include that the medical devices produced by Uniprox must be manufactured and brought on the market according to the requirements of this regulation and that a risk management system must be established, document, applied and maintained.

Implementation of distributor obligations

'Distributor' within the meaning of the MDR (Art. 2 (34) of the MDR) *"means any natural or legal person in the supply chain, other than the manufacturer or the importer that makes a device available on the market, up until the point of putting into service."*
In this context, a distributor is also considered to be one of the economic actors listed in Article 2 (35): *"Economic operator means a manufacturer, an authorized representative, an importer, a distributor..."*.

Distributors have the following general obligations in accordance with Art. 14 MDR:

- Formal obligations to inspect and inform in the event of non-conformity before making products available on the market (section 2);
- The distributor must ensure the storage and transport of products according to the conditions set by the manufacturer (section 3) as well as
- Obligations concerning information, cooperation and documentation as part of market monitoring after making the products available on the market (section 4-6).

In addition, **specific obligations** apply in the respective context, particularly if these are generally directed at economic actors (which include distributors along with manufacturers, authorized representatives and importers). These include the following:

- Ensuring an appropriate level of traceability for products within the supply chain (Art. 25, Art. 27 (8) MDR);
- Implementing corrective actions within the framework of market monitoring carried out by the authorities (Art. 95 (1) and 3 MDR);
- Where relevant, the registration of distributors in accordance with the respective national provisions (Art. 30 (2) MDR);

- The obligation of on-going product observation after bringing medical devices on the market (see Art. 25 (1) MDR concerning traceability in conjunction with the post-market surveillance obligation in accordance with Art. 2 (60) MDR).

Traceability

In order to ensure traceability, the distributor and its customers must establish in principle the following:

- An agreement concerning their collaboration;
- The distributor's obligation to keep information available for the authorities, including the establishment of an appropriate method and documentation, e.g. in accordance with ISO 13485 as well as
- a regulation for cases involving the cessation of business or insolvency on the part of the distributor.

In line with the provisions regarding traceability, the distributor assures Uniprox GmbH & Co. KG that it is possible to individually contact all recipients of medical devices from Uniprox GmbH & Co. KG in order to hand over specific safety-relevant information and instructions to them or to consult these recipients appropriately in this regard.

Acceptance and documentation of experiences, findings and other information about the products

In addition, distributors are obliged:

- To document, retain and continuously update the experiences, findings and other information about the products;
- To implement suitable procedures for acceptance and retention, and
- To establish a regulation for cases involving the cessation of business or insolvency on the part of the distributor.

The distributors will provide Uniprox GmbH & Co. KG with their findings and experiences and other information concerning the products and practical experiences at the request of Uniprox GmbH & Co. KG, or as warranted without being requested to do so.

Support with customer surveys

Distributors are also obliged:

- To support the manufacturer by forwarding experiences, findings and other information about the products/goods, and
- To forward all experiences, findings and other information to the manufacturer, particularly where there is suspicion of serious incidents or serious danger to public health.

Advertising
The distributors have a general obligation only to use advertising materials that have been approved by the manufacturer.

Distinction of product ranges

General
Generally, Uniprox medical devices feature a CE marking. In this way, Uniprox GmbH & Co. KG ensures that the medical device in question complies with the MDR.

However, mass-produced devices, which need to be adapted to meet the specific requirements of any professional user (e.g. orthopedic technician) and devices, which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of any authorized person, shall not be considered custom-made devices.

Prosthetic components
The prosthetic components supplied by Uniprox GmbH & Co. KG bear a CE mark in accordance with Regulation (EU) 2017/745 (MDR), even though they are not marketed as independent medical devices within the meaning of Art. 2 MDR. The fittings are intended exclusively for further processing and, in combination with other components, are incorporated into a custom-made device in accordance with Art. 2 No. 3 MDR.

Orthoses
All orthoses from Uniprox GmbH & Co. KG are issued with a CE marking.

Supplementary notes regarding inspection obligations

Formal inspection obligations
You can find the CE marking on the product packaging, the instructions for use and directly on the product.
The UDI (Unique Device Identification) marking is provided by means of a data matrix code on each packaging label.
Instructions for use are enclosed in the packaging for each medical device.
You can download the IFU for medical devices manufactured by Uniprox as well as the CE declaration of conformity for our medical devices from our website.

Transport and storage
You can find information about the transport and storage conditions on the product packaging and in the instructions for use.

Market monitoring
If you have reason to suspect that a product does not comply with the regulations of the MDR, please contact one of the contacts below immediately.

Traceability
Traceability is ensured by means of the UDI marking. Information about the material number, production date, date of manufacture and expiration date is stored in the data matrix code and also indicated in plain text on the label.

Contact for notifications and queries:

Sales

Mail	info@uniprox.de
Phone	+49 36628 66 33 00
Fax	+49 36628 66-33 55

Person responsible for regulatory compliance (Art. 15, MDR)

Mail	vigilance-md@uniprox.de
Phone	+49 36628 66 33 00
Fax	+49 36628 66-33 55
Contact:	Steffen Lasch

Legal venue
The place of performance is the business seat of this company. The legal venue for all controversies from the business relations is Gera.

Partial invalidity
If any provision in these Terms of Sale and Delivery should be or become invalid or unenforceable, the other provisions will not be affected by this. The ineffective or unenforceable provision will be substituted by a valid and enforceable provision, which reflects the original intention of the parties as closely as possible.

Valid
December 2025