General Terms and Conditions (AGB)
Effective: 11/2025

1. Scope

1.1. These General Terms and Conditions (AGB) apply to all offers, deliveries, and services of BELUCO med GmbH (hereinafter “BELUCO med”) to entrepreneurs within the meaning of § 14 BGB, legal entities under public law, and special funds under public law.

1.2. They apply to both national and international business relationships. The contract language is German. In the event of discrepancies between language versions, the German version shall prevail.

1.3. Deviating or supplementary terms and conditions of the customer shall only apply if BELUCO med has expressly agreed to their validity in writing.

1.4. These AGB also apply to future business relationships without the need for renewed express agreement.

2. Conclusion of Contract

2.1. Offers from BELUCO med are non-binding and subject to change unless expressly designated as binding.

2.2. The contract is concluded by written or electronic order confirmation from BELUCO med. Electronic transmission methods (e.g., e-mail, e-procurement systems) are legally binding.

3. Prices and Payment Terms

3.1. All prices are ex works (EXW) plus packaging, transport costs, customs duties, charges, and the applicable statutory VAT.

3.2. For international deliveries, the agreed Incoterms® apply.

3.3. Invoices are payable within 14 days from the invoice date without deduction. In case of default, statutory interest of 9 percentage points above the base rate pursuant to § 288 (2) BGB applies.

3.4. A right of retention exists only for undisputed or legally established claims.

3.5. BELUCO med reserves the right to execute deliveries to new or international customers only against advance payment.

4. Delivery, Delivery Periods and Force Majeure

4.1. Stated delivery times are non-binding unless expressly agreed in writing as fixed dates.

4.2. Delivery delays due to force majeure, official measures, pandemics, transport disruptions, material shortages, export controls, or comparable events extend delivery periods accordingly. BELUCO med is not liable in such cases.

4.3. Partial deliveries are permissible if reasonable for the customer.

4.4. If dispatch is delayed for reasons attributable to the customer, the goods shall be deemed delivered upon notification of readiness for shipment. BELUCO med may charge storage costs from the first month.

5. Transfer of Risk

5.1. The risk of accidental loss or deterioration of the goods passes to the customer upon handover to the transport service provider.
5.2. For international deliveries, the transfer of risk is governed by the agreed Incoterm®.

6. Customer Obligations in Handling Medical Devices

6.1. The customer undertakes to store the delivered medical devices properly in accordance with the information on packaging, label, and product data sheet.
6.2. The customer shall ensure that products are checked for sterility, intact packaging, expiry dates, and batch information prior to use.
6.3. Reprocessing of single-use products ("Single Use") is strictly prohibited.
6.4. The customer undertakes to immediately report reportable incidents under EU-MDR (Regulation (EU) 2017/745) both to BELUCO med and to the competent authorities.
6.5. BELUCO med fulfills the obligations under Art. 14 EU-MDR (e.g., verification of CE marking, ensuring traceability).

7. Warranty

7.1. The warranty period is 12 months from transfer of risk.
7.2. Obvious defects must be reported in writing within 7 days of delivery; for sterile or invasive medical devices, the period is 48 hours.
7.3. In the case of justified complaints, BELUCO med forwards these directly to the respective manufacturer and, after consultation, provides either rectification or replacement delivery. If this fails, the customer may reduce the price or withdraw from the contract.
7.4. Defects resulting from improper storage, transport, use, or use contrary to product labeling are excluded.
7.5. Expiry dates do not constitute a guarantee. Replacement of expired goods does not take place.

8. Product Liability & Recall Measures

8.1. BELUCO med is not the manufacturer of the delivered products. Responsibility for product conformity, quality, safety, and regulatory requirements lies with the respective manufacturer. Liability under the Product Liability Act exists only insofar as BELUCO med is deemed a manufacturer under § 4 ProdHaftG, particularly if BELUCO med places the product on the market under its own name or brand or cannot name the manufacturer. BELUCO med fully complies with statutory distributor obligations.

8.2. In the event of recalls or Field Safety Corrective Actions (FSCA), the customer undertakes to cooperate immediately, in particular to forward information to end customers and provide traceability data.
8.3. The customer shall bear the costs of recall measures only if he is responsible for or has caused the reason for the measure.

9. Liability

9.1. BELUCO med is liable only for intent and gross negligence as well as for damages arising from the breach of essential contractual obligations. In the event of slightly negligent breach of essential obligations, liability is limited to the typical, foreseeable damage.
9.2. Liability for indirect damages or lost profits is excluded unless caused by gross negligence or intent.
9.3. Claims for damages arising from injury to life, body, or health as well as claims under the Product Liability Act remain unaffected.

10. Retention of Title

10.1. The goods remain the property of BELUCO med until full payment has been made.
10.2. In the event of resale, the customer hereby assigns the claim in the amount of the invoice value to BELUCO med.
10.3. For international customers, retention of title applies only if it can be validly agreed under the law of the destination country.

11. Export Control

11.1. The delivered products are subject to national and international export control regulations, including:
- *EU Dual-Use Regulation (Regulation 2021/821)*
- *US EAR (Export Administration Regulations)*
- *Sanctions regulations of the EU, USA, and UK*

11.2. The customer undertakes to obtain necessary permits prior to any transfer of the goods.
11.3. Upon request, the customer shall provide an End-Use Certificate (EUC).

12. Data Protection

12.1. BELUCO med processes personal data exclusively for contract performance pursuant to Art. 6 (1) lit. b GDPR and to fulfill legal obligations.

13. Compliance

13.1. The customer undertakes to comply with all anti-corruption, competition, and medical device regulations.

13.2. Benefits or advantages in the medical environment that violate § 299a/b StGB or comparable provisions are prohibited.

13.3. The customer assures compliance with the German Supply Chain Due Diligence Act (LkSG).

13.4. BELUCO med is not a manufacturer but undertakes to pass on relevant information along the supply chain in accordance with LkSG requirements.

14. Place of Performance, Jurisdiction and Applicable Law

14.1. Place of performance is Munich.

14.2. Jurisdiction for all disputes is Munich, provided the customer is a merchant or entrepreneur.

14.3. German law applies, excluding the UN Convention on Contracts for the International Sale of Goods (CISG).

14.4. For international disputes, arbitration under the DIS Arbitration Rules may be agreed.

BELUCO med GmbH