

Elos Medtech Pinol A/S - GENERAL TERMS

1. Scope and Applicability

Elos Medtech Pinol A/S (Danish Reg. No. 13746184; "Elos") is engaged in the development and manufacture of medical technology products and components (jointly referred to as "Products").

Products are intended only for use by professionals. Any liability for use by non-professionals is disclaimed.

These General Terms shall apply between Elos and you as a customer ("Customer"). Any other terms inconsistent with these General Terms shall only apply to the extent they have been expressly accepted in writing by Elos.

Products include components manufactured in accordance with Customers' specifications and Elos' own products.

Quotes are valid for 5 days, unless otherwise specified by Elos.

Information posted on websites do not constitute a binding offer, but only an invitation to Customer to submit a purchase order. Only purchase orders expressly confirmed by Elos are binding for Elos.

2. Consulting

If Elos undertakes to design, manufacture and/or market new Products for Customer or provide other advisory services, the work to be performed by Elos ("Consulting") shall be specified in writing.

Unless otherwise agreed, Consulting will be performed on a time and material basis.

If it becomes apparent that a deadline will be exceeded to any significant extent, Elos shall inform Customer so reasonable measures may be decided. Elos shall not be liable in the event of delays, nor if the objective of the Consulting is not obtained.

3. Manufacturing – Limited Warranty

Elos warrants that Products are manufactured in accordance with ISO 13485 and specifications agreed in writing and that Products will be free from defects in workmanship for a period of 2 years for instruments, model analogues and scanning abutments, 10 years for Elos Accurate prosthetic products and 1 year for all other Products, all from the date of Elos' delivery.

Unless otherwise explicitly agreed, Elos' visual standards for Products apply and Elos only performs control during production with sampling according to DS/EN 2859, level II-S3, AQL: 1.5.

This limited warranty does not apply to, and Elos makes no representations or warranties whatsoever with respect to: (i) materials supplied by Customer or Customer's suppliers; (ii) Products that have been abused, damaged, altered or misused after delivery; (iii) prototypes, pre-production units, test units and other similar Products; (iv) defects resulting from tooling, designs or instructions provided by Customer; and (v) Customer's non-compliance with Elos' design instructions and instructions for use.

Upon failure of a Product to comply with this limited warranty, Elos' sole obligation, and Customer's sole remedy, is for Elos, at its option, to repair or replace such Product and return it to Customer freight prepaid or issue a credit note reflecting any reduced value of the Product. Customer shall return Products covered by this limited warranty freight prepaid after submitting a failure report to Elos and receiving a return material authorization ("RMA") from Elos. Any return of Products will be subject to certain conditions and Elos' approval.

Customer shall bear all risk, costs and expenses associated with Products returned to Elos for which no defect is found.

Customer will provide its own warranties directly to any of its end users and other third parties. Customer shall expressly indicate that end users and third parties must turn solely to Customer in connection with any problems, warranty claims or other matters concerning Products.

Elos specifically disclaims any implied warranty, condition of merchantability, fitness for a particular purpose and non-infringement of third party rights.

4. Product Changes

Any changes to Products shall be subject to the parties reaching agreement upon new specifications as well as payment for obsolete materials and Products, work-in-progress, revalidation of processes and equipment, and revised delivery schedules and prices, in the absence of which Elos shall be entitled to reasonable payment or compensation as applicable.

5. Forecasts and Invoicing of Materials and Products

To secure a stable workflow for Products manufactured in volume Customer may provide Elos with a rolling forecast on monthly basis showing Customer's Product requirements for the applicable lead time of the Products plus at least 3 months.

Unless otherwise agreed Elos shall be authorized to procure materials to cover the forecasted requirement for the applicable lead time of the Products plus 3 months and to manufacture Products to cover the applicable lead time of the Products plus 1 month of the forecast.

If materials so procured are not used or Products so manufactured are not ordered within 3 months after the applicable time period, Elos shall be entitled to invoice such materials and Products to Customer.

6. Shipment

Shipments are made EXW (Ex Works, Incoterms 2010) Elos' facility. All freight, insurance and other shipping expenses, as well as any special packaging expenses, shall be paid or reimbursed by Customer.

If a shipment will be delayed, Customer shall be notified as soon as Elos is aware that the Products will not meet its scheduled shipment date. Customer may as its sole remedy cancel a delayed order with no charge for the cancellation, but only if the shipment is late by more than 30 days due and only if the delay is due to reasons within the reasonable control of Elos.

Customer shall inspect deliveries for correct quantity and transport damages within 3 days of receipt. Deliveries not rejected during said period shall be deemed accepted.

7. Regulatory Compliance

Compliance with applicable laws and regulations, including obtaining any required approvals, maintenance of technical files and instructions for use, CE marking and post market surveillance, are the responsibility of Customer for all Products specified by Customer.

Customer is obliged to report any occurrences of influence to the safety of Products to Elos in writing immediately.

8. Prices and Payment

All prices are including standard packaging but exclusive of shipping expenses, insurance, taxes, duties, VAT and similar expenses, which shall be paid by Customer.

Fees and prices may be increased if e.g. the market price of energy, materials, labour and other production costs increase beyond normal variations as demonstrated by Elos.

If credit terms have been agreed Customer shall pay invoices in the quoted currency in accordance therewith. Elos is entitled to demand security for due payment. A monthly interest of 1.5% per commenced month shall accrue on any late payments.

In case of any delay in paying any amount by its due date, Elos is entitled to cancel or hold up execution of pending orders.

9. Tools and Calibration

Unless otherwise explicitly agreed and paid for by Customer, any special tooling or equipment developed in connection with manufacturing of Products shall belong to Elos.

Elos shall be entitled to charge Customer fees in accordance with Elos' current price list for required calibration of Customer specific tools applied during manufacture. Tools are usually calibrated at least once every year.

10. Confidentiality – Use as Reference

Each party undertakes to treat and maintain non-public information received or otherwise obtained from the other party as confidential and not to use such confidential information for any purpose other than performing in accordance with applicable contractual obligations. These duties are without limitation in time.

Elos is entitled to state Customer's name in Elos' list of references, unless Customer requires otherwise.

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11. Intellectual Property Rights (IPR)

Customer retains title to designs and specifications provided by Customer.

Elos retains title to all its IPR, including drawings and designs made by Elos. Customer may only use such drawings or designs in accordance with written agreement with Elos.

Title to any improvements to Customer's Products made by either party or the parties jointly shall vest in Customer. Notwithstanding this, Elos shall have a perpetual, irrevocable, worldwide, royalty-free, fully paid up, assignable license to use or have used and license IPR generated by itself or jointly with Customer for applications other than the Products manufactured by Elos for Customer.

12. Infringement of Third Party Rights – Mutual Indemnification

Elos warrants that to the best of its knowledge the production processes applied for manufacturing Products will not infringe any third party's copyrights, patents, trade secrets, or other proprietary rights.

Subject to the limitations of liability set out in these General Terms Elos, at its expense, will defend Customer against claims based on an allegation of such infringement, and pay any resulting costs and damages awarded against the Customer and the part of any settlement that is attributable to such infringement, provided that (1) Customer notified Elos promptly in writing of the claim; (2) Elos was permitted full control of the defence or settlement of the claim; and (3) Customer cooperated reasonably in such defence or settlement at Elos' expense.

In its defence or settlement of any such claim, Elos may at its discretion: (A) procure for Customer a right to continue using or selling Products; (B) modify the manufacturing process so that the use or selling of the Products becomes non-infringing but still retains the same level of functionality and performance; (C) replace the Products with equivalent products not subject to such claim; or (D) issue a credit note reflecting any reduced value of the Product.

Customer shall offer an infringement warranty similar to the above concerning Products designed or specified by Customer, and Customer shall pay any resulting costs and damages awarded against Elos that are attributable to such infringement and will pay the part of any settlement that is attributable to such infringement subject to the same provisions that are applicable to Elos' warranty (1-3 and A-D).

Elos's duty of indemnification is in lieu of any and all other remedies of Customer with respect to infringement and shall only be valid in countries designated by Customer when purchasing Products.

Elos does not warrant that the results of Consulting do not infringe any third party's copyrights, patents, trade secrets, or other proprietary rights.

13. General Limitations of Liability

Elos shall in no event be liable for any loss or damage arising, directly or indirectly, from the use of the Products or for any direct, indirect, special, incidental, punitive, exemplary or consequential losses or damages, including but not limited to loss of opportunity, use, data, income or profit, or interrupted operation, nor shall Elos be liable for any post-processing or misappropriate use, handling or exposure of Products.

Elos' aggregated liability shall in no event exceed the lesser of sums paid by Customer to Elos during the 6 months prior to Customer raising the claim towards Elos for the relevant Products, or EUR 50,000.

Any claim for liability shall be received by Elos in writing no later than 6 months after delivery of the relevant Product, or the claim will become void.

14. Product Liability – Indemnification

Elos shall only be liable for defects caused by defective Products pursuant to the mandatory provisions of the Danish Product Liability Act (Produktansvarsloven). In no event shall Elos be liable for damage or injury caused by a defective product on any other basis.

Elos shall maintain a product liability insurance in an appropriate amount. Elos is only liable towards Customer to the extent that the claims are covered by Elos' product liability insurance.

Customer shall indemnify Elos for any product liability caused by Products in excess thereof.

15. Force Majeure

Elos shall not be liable for any failure to meet its obligations as the result of any cause beyond its reasonable control, including, without limitation, labour disruption, acts of terror, fire, floods, accidents to machinery, material shortages, failure by any supplier, extreme weather or any other cause generally referred to as a force majeure. Elos shall be entitled to postpone delivery, until such circumstances has ceased or, alternatively, terminate the specific deliveries with immediate effect in whole or in part without being liable for losses or damages. Either party shall be entitled to cancel orders delayed for more than 3 months owing to force majeure without incurring any liability to the other party.

16. Termination

Contracts may be terminated by either party (a) for convenience upon 6 months written notice to the other party, or (b) if the other party defaults in any payment to the terminating party and such default is not remedied within 7 days after the delivery of written notice thereof by the terminating party to the other party, (c) if the other party defaults in the performance of any other material term or condition of a contract and such default continues unremedied for a period of 30 days after the delivery of written notice thereof by the terminating party to the other party, or (d) pursuant to section 15 (Force Majeure).

Expiration or termination of a contract shall not affect the amounts due under such contract by either party that exist as of the date of expiration or termination.

All obligations, liabilities and limitations that, by their nature, are intended to survive expiration or termination shall remain in effect beyond any expiration or termination.

17. Disputes

Unless the parties agree otherwise, any dispute arising out of or in connection with these General Terms shall be finally settled in Copenhagen, Denmark, in accordance with the Rules of Procedure of the Danish Institute of Arbitration (Danish Arbitration).

Danish law, except its choice of law rules, shall apply. The United Nations Convention on Contracts for the International Sale of Goods shall not apply.

Notwithstanding the above, Elos shall at its discretion be entitled to subject a dispute to settlement under the law and by the appropriate courts of the country in which Customer is domiciled.