

# Standard Terms of Trade

An ISO 13485 company

## 1 Definitions

- 1.1 "Customer" means (a) any person that buys a Product, whether directly from Enztec or from another person and (b) any person that uses a Product.
- 1.2 "Custom Product" means (a) any Product that Enztec manufactures from information and specifications provided by a Customer and (b) any stock Product that Enztec modifies at the request of a Customer.
- 1.3 "Enztec" means Enztec Limited, a New Zealand corporation.
- 1.4 "Incoterms 2000" means an internationally accepted glossary of shipping terms published by the International Chamber of Commerce, Paris France.
- 1.5 "Information" means all information in relation to the Products that Enztec may provide, from time to time, to the Customer including, without limitation, surgical techniques, instructions for use, product labels, design history files and marketing information.
- 1.6 "Intellectual Property" means Enztec's proprietary interests in the Products and Information, whether arising under statutory or common law, including without limitation: Enztec's brands; its patents and patent applications; know-how; designs; copyrights; specifications; manufacturing methods; research and development; quality control procedures; technical and marketing documentation; and trade secrets.
- 1.7 "Products" means the full range of products that Enztec designs, manufactures and sells from time to time.

## 2 General

- 2.1 All sales by Enztec shall be subject to these Terms.
- 2.2 Any purchase order submitted by the Customer shall be subject to these Terms. Any conditions in the Customer's purchase order, or otherwise proposed by the Customer, shall not bind Enztec unless Enztec expressly accepts such conditions in writing.
- 2.3 The Customer's receipt of the Products shall constitute its acceptance of these Terms.
- 2.4 To modify these Terms, both parties must sign an agreement to that effect.
- 2.5 Sales quotations are valid for 30 days from date of issuance, after which they will lapse.

## 3 Price

- 3.1 The price does not include the following charges: (a) applicable taxes, such as goods and services tax (GST), value added tax (VAT) and sales tax and (b) the cost of freight and insurance. Enztec shall add such charges, where applicable, to the price of the Products and such charges shall appear as separate items on the invoice. Enztec may issue a supplementary invoice for any deferred or delayed charges that would otherwise be payable by the Customer but for the fact that they were not known on the date of invoice.
- 3.2 Enztec shall specify the currency in its sales quotation.

## 4 Shipping Terms

- 4.1 Enztec's standard shipping terms are *ex works* (EXW) Enztec's facility in Christchurch, New Zealand.
- 4.2 Incoterms 2000 shall govern the rights and obligations of the parties in an *ex works* shipping contract.
- 4.3 Although the shipping terms are *ex works*, Enztec shall provide a door-to-door delivery service at the Customer's risk and expense. For purposes of clarification, when Enztec provides a door-to-door delivery service, it does so purely as an accommodation to the Customer and as agent for the Customer. The provision of such service shall not alter the *ex works* shipping terms.

- 4.4 The Customer may elect to pick-up the Products and make its own shipping arrangements, provided it notes such preference when placing an order.
- 4.5 Enztec shall ship the Products as soon as they are ready for delivery. The Customer may neither delay delivery nor fail nor refuse to accept delivery.
- 4.6 Consistent with *ex works* shipping terms, risk of loss or damage to the Products shall pass from Enztec to the Customer from the moment the Products leave Enztec's premises.
- 4.7 Any delivery dates given, whether oral or in writing, shall be deemed good faith estimates only. Time is not of the essence.
- 4.8 Enztec shall use all reasonable endeavours to meet any delivery date specified in an order that it has accepted. However, Enztec shall not be responsible for late delivery due to circumstances beyond its reasonable control.
- 4.9 Enztec accepts no liability whatsoever for any loss or damage suffered by the Customer because of any delay or failure to deliver any of the Products, irrespective of the cause.
- 4.10 To assist with timely delivery, the Customer shall promptly provide all specifications and other information that Enztec requires to design and manufacture a Custom Product.

## 5 Payment

- 5.1 Payment is due by the 20<sup>th</sup> day of the month following the date of invoice unless expressly agreed in writing prior to acceptance of order. Enztec shall invoice the Customer on the date of shipment, *ex works* Enztec's facility in Christchurch.
- 5.2 The Customer shall pay the invoice price in full and shall have no right to set off against such price any claims that the Customer may have against Enztec.
- 5.3 Enztec shall provide the Customer with bank details for payments, which must be made by direct credit or wire transfer.

## 6 Inspection

- 6.1 The Customer shall visually inspect the Products, to the extent practicable, for any obvious damage, defects or other evidence that the Products do not conform to the order.
- 6.2 For any defect that the Customer could have reasonably discovered through prompt visual inspection, the Customer must give written notice to Enztec of such defect within thirty (30) days after receipt of the Products. Otherwise, the Customer shall have waived its right to make a warranty claim in respect to such defect.

## 7 Indemnity and Disclaimer

- 7.1 The Customer defends, indemnifies and holds Enztec harmless from and against all causes of action, claims, suits, proceedings, damages and judgments by third parties (collectively "Claims"). The foregoing indemnity shall not apply to Claims based solely on an alleged manufacturing defect in the Products.
- 7.2 The Customer acknowledges that the Products are capable of being used in many different surgical procedures. Enztec provides general guidelines concerning the suitability of its Products. It is not always possible for Enztec to provide specific guidelines for all surgical procedures. Proper selection of a specific Product for a specific surgical procedure will always be the Customer's responsibility. The Customer must assume the ultimate responsibility for the selection and use of the Products. Enztec does not

warrant the performance of its Products or their suitability for any specific purpose.

## **8 Information**

8.1 Enztec does not warrant that the Information is timely, complete or accurate. Enztec accepts no liability for any errors or omissions in the Information. Any Information provided shall not be deemed a warranty, representation or guarantee concerning a Product's suitability or fitness for a Customer's specific purpose. The Information shall not expand Enztec's obligations under its standard Product warranty. The Information shall not constitute a warranty that the Customer will derive any particular benefits from the Products. It is the Customer's responsibility to determine the suitability of the Products for its own use. The Customer must use its own independent judgment and assessment and should not rely on any opinions, interpretations, statements, assurances or representations in the Information or otherwise.

8.2 Although the Information may include surgical techniques and Product usage guidelines, Enztec cannot know the actual condition of a given patient nor the countless other variables that relate to the proper diagnosis and treatment of such patient. For that reason, the Customer shall not rely upon any Information provided by Enztec but shall rely, instead, on its own professional judgment.

8.3 The Customer shall keep any non-public Information (e.g. design history files) strictly confidential.

## **9 Product Changes**

9.1 Because Enztec is continually improving and upgrading its Products, the specifications, dimensions and Information are subject to change without notice. The foregoing shall not apply in circumstances where the Customer has (a) furnished its own specifications and information pursuant to clause 4.10 and (b) it is an express condition of sale that Enztec manufacture the Custom Product to conform to the Customer's specifications and information.

## **10 Professional Advice**

10.1 For the reasons mentioned in clause 8.2, Enztec does not provide professional advice concerning the Products or their use.

10.2 The Customer accepts responsibility for ensuring that its employees, agents and customers are appropriately trained and experienced in the use of the Products and have read any relevant Information provided by Enztec.

10.3 The Customer accepts responsibility for ensuring that surgeons and other end users know how to use the Products. The Customer shall discharge this responsibility through training sessions, hands-on demonstrations and technical support.

## **11 Traceability and Product Recall**

11.1 Enztec has adopted Product traceability procedures conforming to relevant law. The Customer shall adopt its own Product traceability procedures conforming to the relevant law in the Customer's jurisdiction. The Customer shall procure its agents, dealers, distributors and any other persons to whom the Customer sells or transfers the Product, to adopt Product traceability procedures conforming to relevant law.

11.2 In the event that Enztec initiates a Product recall, the Customer shall provide reasonable and timely assistance to Enztec to enable Enztec to comply with its regulatory obligations with respect to the Products. Without limiting the generality of the foregoing, the Customer shall provide Enztec with contact details for customers and other persons further down the distribution chain, including the end user.

## **12 Limitation of Liability**

12.1 The Customer shall strictly comply with any instructions for use, care and maintenance, trouble shooting, warnings and safety procedures provided by Enztec. Where appropriate, the Customer shall pass any such instructions to its customers and end users and the Customer shall use its best endeavours to ensure that they comply with such instructions. Enztec shall not be

liable for any costs or damages incurred by any person because of such person's failure to comply with such instructions.

12.2 To the maximum extent allowed by law, Enztec disclaims liability for direct, indirect, incidental, special or consequential costs or damages of any kind. Without limiting the generality of the foregoing, Enztec disclaims liability for: (a) Damages to person or property caused by a Product; or (b) Damages resulting from the inability to use the Product, including loss of profits, loss of operations whether incurred by the Customer, its employees or a third party.

12.3 The liability of Enztec under any circumstance shall not exceed the original purchase price paid by the Customer for the Product giving rise to such liability.

## **13 Warranty**

13.1 All Products sold are subject to Enztec's standard warranty, which covers defects in materials and workmanship. The term of such warranty is 12 months from date of shipment *ex works* Christchurch. However, if the Instructions for Use in respect to the Product specify a different term, the Instructions for Use shall govern.

13.2 Enztec's warranty contains important exclusions, disclaimers and limitations of liability. Enztec has posted a copy of its warranty on its website. The Customer may also obtain a copy directly from Enztec.

## **14 Custom Products**

14.1 In relation to a Custom Product, the Customer acknowledges that: (a) Enztec is not responsible for developing the information and specifications furnished by the Customer; (b) Enztec does not possess the clinical skills to determine the completeness and accuracy of such information and specifications; (c) Enztec is not in a position to know all relevant details, applications and circumstances relating to a Custom Product; and (d) Enztec may not know whether a Custom Product is suitable for all purposes intended by the Customer.

14.2 Enztec undertakes to use its skill and experience to manufacture Custom Products to meet the Customer's requirements. However, in recognition of clause 14.1, Enztec expressly disclaims any liability of any kind, nature or description resulting from the use of a Custom Product.

14.3 Enztec shall provide development and manufacturing services on a best endeavours basis only, and entirely at the Customer's risk. The Customer agrees that Enztec shall not be liable for any errors or omissions in rendering such development and manufacturing services.

## **15 Intellectual Property**

15.1 The Customer hereby acknowledges Enztec's ownership of the Intellectual Property. The Customer disclaims any interest in the Intellectual Property. The Customer shall not challenge the validity of the Intellectual Property. The Customer shall not take or support any action prejudicial to the Intellectual Property or Enztec's interests therein.

## **16 No Sale by Description or Sample**

16.1 Subject to clause 16.2, Enztec does not warrant that the Products conform to any specific design or sample. Enztec reserves the right to alter its Product dimensions, drawings, specifications, designs, materials components and construction methods. Enztec may do so without notice. Any such alterations shall not impose on Enztec an obligation to alter Products that Enztec has already delivered to the Customer.

16.2 Clause 16.1 shall not apply in circumstances where the Customer has (a) furnished its own specifications and information pursuant to clause 4.10 and (b) it is an express condition of sale that Enztec manufacture the Custom Product to conform to the Customer's specifications and information.

## **17 Changes**

17.1 The Customer may request in writing any change to an order. Enztec shall not withhold, unreasonably, its

consent. However, the Customer shall bear any additional costs incurred by Enztec because of such change.

**18 Cancellation**

18.1 Once Enztec has confirmed, in writing, a Customer's order, such order is not cancellable except with Enztec's express written agreement and upon such terms as Enztec specifies.

**19 Verbal Instructions and Orders**

19.1 The Customer shall immediately confirm, in writing, all verbal instructions and orders. Enztec may wait until the Customer does so before executing the Customer's verbal instructions and orders. If Enztec does not wait, Enztec shall execute the Customer's verbal instructions and orders entirely at the Customer's risk. In that case, Enztec accepts no responsibility for errors and omissions.

**20 Purchase Money Security Interest**

20.1 The Products shall remain personal property and shall retain their character as such even when the Customer incorporates, affixes, attaches or assembles the Products to an instrument, instrument sets, implants or the like.

20.2 Enztec retains a purchase money security interest in the Products sold and delivered to the Customer. Enztec may perfect its security interest by registering one or more Financing Statements pursuant to the Personal Property Securities Act 1999. The Customer waives any right to receive verification of financing statements so registered.

20.3 If the Customer fails to comply with the terms of payment of Enztec, then Enztec, in addition to its rights and remedies under the Personal Property Securities Act 1999, shall be entitled to such other rights and remedies as may be available to it under either statutory or common law.

**21 Representations**

21.1 Enztec's staff, agents and representatives have no authority to make any representations, statements, warranties, conditions or agreements that conflict with these Terms, unless made in writing and signed by a duly authorized officer of Enztec. Any such unauthorized representations, statements, warranties, conditions or agreements shall not bind Enztec nor form part of any contract between the Customer and Enztec.

**22 Other Clauses**

22.1 Returns. Returns (other than for warranty purposes or damage claims) shall be in Enztec's sole and absolute discretion. Products returned must be in the same condition as received.

22.2 Governing Law. New Zealand law shall govern these Terms. The Customer submits to the non-exclusive jurisdiction of New Zealand courts.

22.3 Invalidity. If any clause in these Terms is determined to be illegal or unenforceable for any reason, the parties shall modify such clause, but only to the extent necessary to make it legal and enforceable. If modification is not possible without materially altering the intent of the clause, the parties shall sever such clause from these Terms and, if possible, renegotiate in good faith such other means to reflect the intent of such severed clause. Notwithstanding such severance, the parties shall enforce the other clauses in these Terms as if such severed clause was never a part thereof.

22.4 Compliance with Law. The Customer shall comply with all applicable laws within its jurisdiction.

22.5 Conflicts. The specific terms of any sales confirmation, sales quotations or invoice to which these Terms are attached, or incorporated by reference, shall prevail in the event of a conflict.

22.6 Force Majeure. Enztec shall not be liable for any failure or delay in delivering the Products resulting from circumstances beyond its reasonable control, including, without limitation: Unavoidable delays in production; delays in the delivery of raw materials; default by subcontractors; default by component suppliers; strikes and labour unrest; shipping delays; shortages; war; acts of terrorism; government or regulatory intervention; fire; flood; accident; natural disaster; or any other event interpreted under New Zealand law as an "act of God". If Enztec invokes force majeure, it shall do all reasonable things within its power to end the circumstances causing the force majeure and to mitigate any losses that the Customer may suffer as a consequence thereof. However, Enztec shall not be liable for any such losses.

22.7 Non-waiver. No failure by Enztec to insist upon strict performance of any of these Terms, or delay in exercising any of its rights or remedies, shall constitute a waiver or variation of these Terms or a waiver of any such right or remedy.