



**TERMS AND CONDITIONS
OF SALE**

1. Unless expressly provided otherwise in quotation, all quotations are subject to these general terms of ordering and supply.
2. Upon placing an order with DEXCON Pty Ltd you are accepting the above terms and conditions
3. DEXCON Pty Ltd reserves the right to make any change in the specification of the Goods and their conditions of supply and resale or re-supply that is necessary in order for them to conform with any applicable laws and conditions imposed by a relevant authority and in particular Commonwealth or State or Territorial Health Department and/or the Therapeutic Goods Administration. DEXCON Pty Ltd shall promptly inform you of any such change that it proposes to make.
4. You are responsible for ensuring the accuracy of each order you issue. Any changes and/or additions made to the order after receipt of the Invoice will incur a charge of 10% of the total affected invoice.
5. DEXCON Pty Ltd shall use its reasonable commercial endeavours to deliver the products on the estimated delivery date for each order however we shall have no liability for any delay in delivery of the product that is due to force majeure or any other factor beyond our reasonable control.
6. Shipping and Handling Charges (including requisite packaging and insurances) are only an estimate. Additional charges may be incurred AFTER the shipment has been delivered which will be reflected on your invoice.
7. DEXCON Pty Ltd acting reasonably reserves the right to increase the quoted price of the product to reflect any material increase in cost to DEXCON Pty Ltd due to manufacturing and/or importing of the product subject to giving reasonable notice to you and the prices as so altered shall apply to all product ordered after the applicable date of the increase.
8. DEXCON Pty Ltd will be accepting the following forms of payment: Credit cards (incurs 1.6% surcharge for transactions), checks and electronic transfer or deposit of cleared funds.
9. All sales are final. No Refunds will be accepted once the order is placed and paid. Notwithstanding any delays beyond the control of DEXCON (some examples of delays may be and not limited to, Manufacturer/production delay, customs clearance delays, freight congestion delays and payment of customer invoices being not being paid on time, the product will be delivered within a reasonable time frame.
10. Any QUALITY problem should be reported to DEXCON Pty Ltd within 2 weeks from the date shipment is received. 15% of invoice will be charged for restocking on all returns.
11. DEXCON Pty Ltd shall be under no liability in respect of any defect in the products arising from fair wear and tear, or any wilful damage, negligence, subsection to abnormal working conditions, failure to follow DEXCON Pty Ltd's instructions, misuse or alteration or repair of the products without DEXCON Pty Ltd's approval, or any other act or omission on the part of you, your employees or agents or any third party including any carrier or transporter of or engaged by you.
12. In the event that it is established that product supplied suffered from inherent defects in material or workmanship then DEXCON Pty Ltd's liability shall be limited to repair or (if that is not practical) replacement of the product in question; or at its discretion a credit or repayment of any part of the price for the product in question which has been paid.

13. You agree that you release and holds harmless DEXCON Pty Ltd from any consequential loss arising from an accuracy or the use of the devices supplied whether due to inherent defect in material or workmanship. DEXCON Pty Ltd shall use best endeavours in accordance with good industry practice but cannot be held liable for damages occasioned by the loss of production.
14. DEXCON Pty Ltd shall, without limiting its other obligations, use best endeavours to extend to you the benefit of any warranty given by the manufacturer in accordance with good industry practice. All other warranties or other terms, express or implied by statute or otherwise, are excluded to the fullest extent permitted by law.
15. DEXCON Pty Ltd will remain and have legal ownership, or title, to the goods listed on their invoices and will not pass to the buyer until the buyer has paid for the goods in the invoice in full. (Excludes pre-agreed payment plans whereby goods are taken prior to payment by the client on an arrangement basis at the discretion of DEXCON Pty Ltd.)
16. As a condition of acceptance of an order, DEXCON Pty Ltd requires payment in full before placing an order with the manufacturer or delivery.
17. Force Majeure

a. “Force majeure” means war, emergency, accident, fire, earthquake, flood, storm, inclement weather, industrial strike, pandemic or other impediment which the affected party proves was beyond its control and that it could not reasonably be expected to have taken the impediment into account at the time of the conclusion of this contract or to have avoided or overcome it or its consequences.

b. A party affected by force majeure shall not be deemed to be in breach of this contract, or otherwise be liable to the other, by reason of any delay in performance, or the non-performance, of any of its obligations under this contract to the extent that the delay or non-performance is due to any force majeure of which it has notified the other party in accordance with paragraph c. The time for performance of that obligation shall be extended accordingly.

c. If any force majeure occurs in relation to either party which affects or is likely to affect the performance of any of its obligations under this contract, it shall notify the other party within a reasonable time as to the nature and extent of the circumstances in question and their effect on its ability to perform.

Particular provisions related to COVID-19 test kits

18. Purchases related to COVID-19 are subject to prepayment, any cancellation of pre-paid orders once your order has been placed with our manufacturer will incur a 100% administration fee and charge on any refundable request for cancellation of your order unless your order can be re-sold or a negotiated rate at the discretion of DEXCON Pty Ltd.

19. You acknowledge that most COVID-19 products are Class III and IV medical devices subject to strict conditions imposed by the Therapeutic Goods Administration (“TGA”). We refer to all requires of the TGA and relevant legislation as TGA Law.

<https://www.tga.gov.au/>

20. As an essential condition of ordering and supply, the use and operation of the devices must be supervised by a medical practitioner (who must be registered as such with the Medical Board of Australia or successor body).

21. As an essential condition of ordering and supply You and your medical practitioner must sign and return to us an acknowledgement in the form below or as updated and provided by DEXCON Pty Ltd from time to time. The TGA commonly amend or vary their conditions in respect of medical devices and in particular Class III devices from time to time.

22. The TGA has strict requirements as to post market (after sales) vigilance and monitoring and strict requirements in regard to product recalls. As an essential condition of supply you agree to promptly provide all required assistance and co-operation to allow us to comply with TGA requirements. <https://www.tga.gov.au/book-page/step-9-ongoing-responsibilities>

23. The requirements can as at 3 April 2020 extend for up to 10 years from the supply of the device and importantly include requirements as to access to site and to records; reporting of incidents and performance issues relating to the devices; assisting in investigations; and, maintain detailed records as to the particular products supplied and the testing performed by them. The chain of evidence must be maintained between batch number and point of care test.

GENERAL CONDITIONS OF ACKNOWLEDGEMENT

COVID-19 MEDICAL DEVICES (POCT TESTS)

1. The Parties acknowledge and confirm that this acknowledgement and confirmation of acceptance is in furtherance to compliance the TGA Health Safety Regulation and in particular the Therapeutic Goods Act 1989 and Therapeutic Goods (Medical Devices) Regulations 2002 (“TGA Law”).
2. The Supplier supplies medical testing kits (the “Devices”) for administration by qualified clients under the supervision and control of licensed health care professional in accordance with TGA Law.
3. The parties acknowledge that:
 - (a) COVID-19 is an emerging infectious disease resulting in serious illness and death in Australia and worldwide; A recognized vaccine or therapy to treat or prevent this disease has not yet been developed; The SARS-CoV-2 virus has demonstrated the ability to spread rapidly and presents grave risk to public health and potentially will have significant impact on the Australian healthcare system.
 - (b) The correct interpretation of test results in conjunction with the clinical presentation of a patient is critical to informing patient management and minimisation of further transmission of the virus; Accurate identification of a COVID-19 infection based on serology results, particularly those obtained from rapid tests used at the point of care, requires an understanding of the antibody response profile; There is a window period between virus infection and the production of IgM and IgG antibodies, and the sensitivity and specificity of IgM/IgG antibody tests early in SARS-CoV-2 infection, is as yet, not well characterized; The misinterpretation of serology results in the point-of-care setting if testing is not performed by suitably qualified persons with appropriate skills and knowledge presents grave risk to public

health, which could result in serious illness and death of the patient and other persons that the patient comes into contact with.

(c) Transmission-based precautions must also be used when collecting specimens from patients with a communicable disease; Blood specimens collected for point-of-care testing should be regarded as potentially infectious not just for SARS-CoV-2, but also for other blood-borne infectious diseases; Staff must be trained in appropriate specimen collection and infection control procedure.

(d) The condition requiring administration by qualified clients is necessary to prevent imminent risk of death or serious illness from COVID-19 that may be caused by inappropriate use of the Device or misinterpretation of results where the test is not performed by suitably qualified persons with appropriate skills and knowledge.

4. For the purposes of this agreement the following are qualified clients: laboratories that are accredited pathology laboratories; medical practitioners who are registered under a law of a State or Territory; health care professionals in residential and aged care facilities; Commonwealth, State or Territory department of health; and/or an agency of the Commonwealth, State or Territory acting on behalf of Commonwealth, State or Territory department of health.

5. The Client noted on page one hereof acknowledges and undertakes that it is and will remain a qualified client and hereby indemnifies the Supplier from a breach of this undertaking and immediately upon losing qualifying status is shall take all steps necessary to maintain compliance or to cease a default including to suspend operations, to regain qualification and/or return or secure the Devices pending return to the Supplier or to an alternate qualified person or entity.

6. The Client acknowledges and undertakes that it will not forward or on supply the Devices to any person or entity who is not or would be considered to be a qualified client.

7. The Client agrees to store and handle the Devices in accordance with good industry practice and any guidelines provided by the Supplier or directions of a competent authority.

8. The Client shall use the Devices at its own risk, shall be responsible for supervising its operation and shall indemnify the Supplier from claims arising from its use or operation. The Client will ensure that all of its employees, servants, contractors and agents administering or using the Devices are adequately informed and aware of and comply with their responsibilities under TGA Law.

9. In respect of any compliance issue either party may and must take direction from the Therapeutic Goods Administration or the Minister for Health of the relevant jurisdiction whether State, Territorial or Commonwealth.

10. In accordance with the requirements of TGA Law and competent authorities as directed from time to time the Client agrees it shall provide all reasonable assistance required to allow the Supplier to do the following for the TGA regulator and relevant authorities:

- (a) Provide a report of any adverse events, corrective and preventative actions, and customer complaints provided in the context of the number of devices supplied since the introduction of the Device(s) to market in Australia and Worldwide;
- (b) Information regarding any refusals by Regulatory Authorities for the supply of the Device(s) in any other regulatory jurisdictions.
- (c) Further analytical and clinical evidence to support: (i) Analytical and clinical performance of the device; (ii) Device stability (e.g, shelf-life stability, transport stability)
- (d) Instructions for use that provide updated information on the analytical and clinical performance characteristics of the Device.
- (e) Evidence of how the user may verify, at the time of use that the Device will perform as intended by the manufacturer through the use of controls and/or calibrators.
- (f) Participate in any recall or audit of the Devices required by the TGA regulator or other relevant authority.

11. Further to the acknowledgements above and to the emergency nature of the circumstances of supply, the Parties agree that the Devices are first line Point of Care Test measure to assist in the screening of persons for COVID-19. The Parties acknowledge that the Supplier cannot give a 100% guarantee as to the reliability or accuracy as to any test results, whether positive or negative and cannot and will not be held responsible for consequential loss – in particular damage associated with the loss of production of a minesite.

12. If any term, provision, covenant or restriction of this agreement is held by a court of competent jurisdiction or other competent authority to be invalid, void or unenforceable, the remainder of the terms, provisions, agreements, covenants and restrictions of this agreement shall remain in full force and effect and shall in no way be affected, impaired or invalidated so long as the economic or legal substance of the transactions contemplated hereby is not affected in any manner materially adverse to any party hereto. Upon such a determination, the Parties shall negotiate in good faith to modify this agreement so as to effect the original intent of the Parties as closely as possible in a reasonably acceptable manner in order that the matters contemplated hereby may be consummated as originally contemplated to the fullest extent possible.

13. These conditions come into force as each party accepts the terms of agreement by signature or course of conduct and shall continue until termination by reasonable notice. These conditions are subject to such amendment and alteration from time to time as required to ensure compliance with TGA Law. The Supplier shall endeavour to promptly notify the Client of any such changed conditions.

14. The Client shall use the Devices at its own risk, shall be responsible for supervising its operation and shall indemnify the Supplier from claims arising from its use or operation.

15. This agreement may consist of a number of copies (including facsimile or electronic copies), each signed by one or more parties to the agreement. A copy of a counterpart sent by facsimile or by electronic mail: must be treated as an original counterpart; is sufficient

evidence of the execution of the original; and, may be produced in evidence for all purposes in place of the original.

16. All purchases made through DEXCON Pty Ltd are governed under Australian Law and any disputes will be determined within the courts of New South Wales, Australia.