Product Terms and Conditions

Author: Donna Edwards

REASON FOR NEW DOCUMENT OR UP-ISSUE

Update Section 19 to include reference to EU IVDR. General legal update to terms and conditions for clarity, consistency and simplicity.

© 2022 DNA Genotek Inc., a subsidiary of OraSure Technologies, Inc., all rights reserved. This Document is the property of DNA Genotek Inc. and without its prior written consent may not be disclosed to a third Party or copied.

Product terms and conditions – FM-WI-00019_Issue 6

- 1. Controlling Provisions. These terms and conditions are the only terms that govern the provision of products this document accompanies or listed in the quotation (the "Quotation") to which these Terms are attached (the "Product(s)") by DNA Genotek Inc. ("Provider") to the customer set out in the Quotation or having possession of the Products ("Recipient", and together with the Provider, the "Parties" and each a "Party"). These terms and conditions and the Quotation, if applicable, constitute the exclusive agreement between the parties with respect to the subject matter hereof and supersede all other negotiations, communications, agreements and understandings between the Provider and the Recipient. All terms and conditions contained in any oral or written communication, including Recipient's purchase order, which are different from and/or in addition to these terms and conditions are hereby rejected and are not binding on Provider, whether or not they materially alter this document, and Provider hereby objects thereto. Recipient is deemed to have assented to all terms and conditions contained herein if any part of the Products are shipped or an invoice is presented in connection with the said Products.
- 2. **Pricing Confidentiality.** Except as otherwise provided by law, Recipient agrees to keep confidential pricing and information from Quotations and invoices. Recipient shall not use such information in furtherance of its business, or the business of anyone else, whether or not in competition with Provider.
- 3. Payment Terms/Credit. The Recipient shall pay the purchase price set forth in the Quotation in full within 30 days of the date of shipment. In the event Recipient fails to make a payment to Provider when due, all outstanding amounts owing to Provider will become immediately due and payable without notice or demand. All past due amounts owing shall accrue interest from the date due until paid in full at an annual rate equal to the lesser of (i) twelve percent (12%), or (ii) the highest rate then permitted by law, in each case compounded on a daily basis. Prices are subject to change without notice. Provider may require at any time assurances of Recipient's creditworthiness and may withdraw or limit Recipient's credit if the assurances are unsatisfactory. Recipient hereby grants Provider a purchase money security interest in the Products until the Provider is fully paid. Recipient will assist Provider in taking actions to perfect and protect Provider's security interest. Recipient may not set-off any amounts due to Provider against any amount due to Recipient by Provider.
- 4. Title/Delivery. All Products are shipped F.C.A. (Incoterms), point of shipment. Risk of loss and damage shall inure to the Recipient upon the first of transfer of goods to Recipient, Recipient's representative, or common carrier. Unless explicitly set forth in the Quotation, the cost of special packing or handling requested by Recipient shall be added to the amounts set forth in the Quotation. Recipient shall bear all costs (including storage costs) and risks resulting from (i) shipment delays it causes or requests, (ii) erroneous shipment or delivery of the Products because of inaccurate, incomplete or misleading information supplied by or on behalf of Recipient.
- 5. Taxes, Freight and Insurance. Recipient shall pay applicable taxes, which will be added to the purchase price of the Products, unless Recipient provides an exemption certificate acceptable to the taxing authorities. Any taxes Provider is required to pay or collect for the benefit of the Recipient, who shall promptly pay the amount thereof to Provider upon demand. Recipient shall reimburse Provider for any shipment, freight, insurance, customs, broker or other charges required in connection with the delivery of Products into a country, whether such charges appear separately on an invoice. The cost of any special packaging, which Recipient requests or Provider deems necessary, shall be borne by the Recipient.
- 6. **Claims, Cancellations and Returns.** Recipient must inspect Products for defects upon arrival at receiving location. Recipient must notify Provider in writing of damage, shortage or errors in shipping within five (5) days following delivery. For defects and non-conformances that are not due to

^{© 2022} DNA Genotek Inc., a subsidiary of OraSure Technologies, Inc., all rights reserved. This Document is the property of DNA Genotek Inc. and without its prior written consent may not be disclosed to a third Party or copied.

damage, shortage or errors in shipping, Recipient must notify Provider in writing within twenty (20) days following delivery. Products must not be returned without the prior written consent of Provider. Any Products returned without the consent of the Provider shall be subject to a restocking charge of 25% of the purchase price. All Products returned with the consent of Provider must include a written notice stating the specific reason for return and must be shipped in a secure and commercially reasonable manner. Provider shall have no liability and no returns or claims for damage will be accepted in respect of Products that have been altered by or on behalf of Recipient. Recipient's exclusive remedy for defective Products is replacement pursuant to Section 14. Recipient agrees that the above (20) day period is a reasonable and sufficient to inspect the Products, and that Recipient shall be deemed to have irrevocably accepted the Products upon the expiry of such period. Recipient may not cancel or modify any signed Quotations unless it has (i) obtained Provider's written consent, (ii) paid a cancellation charge equal to 15% of the purchase price, and (iii) paid all additional charges, expenses, commissions and reasonable profits owed to or incurred by Provider in connection with such cancellation or modification. Recipient may not cancel any Quotation or order for custom Products or items, and custom Products or items may not be returned.

- 7. Use of Products and Indemnity. Recipient shall not reverse engineer, disassemble, modify, adapt or create derivative works of the Products, Product contents and/or any accompanying documentation. Products are not intended for human diagnostic or drug purposes and are provided solely for the use described on the Product or its labelling, which is for research use only unless explicitly stated otherwise. Recipient shall be responsible for obtaining applicable regulatory approvals for any uses other than the foregoing and shall indemnify and hold harmless DNA Genotek from any liability associated with such uses. Recipient's use and handling of Products shall (i) comply with good laboratory practice, (ii) comply with Section 9 (below), all applicable laws, regulations, guidelines and decisions of judicial or regulatory authorities, and (iii) shall not violate or infringe any patent or other proprietary rights of any third party. Recipient shall indemnify and hold Provider harmless from and against all losses, damages, costs and expenses relating to Recipient's non-compliance with the foregoing and any other use or misuse of the Products by Recipient.
- 8. Not For Resale or Export. Except as expressly provided herein and except in connection with Recipient's own research or as part of a service offered to Recipient's own customers, Recipient shall not lease, rent, license, sub-license, sell, re-sell, distribute, or transfer the Products to any other person or entity, including affiliates, subsidiaries, or parent companies, domestic or foreign, without Provider's prior written consent. Recipient shall not export the Products without Provider's prior written consent.
- 9. Limited Rights. The purchase of the Products conveys to Recipient the non-transferable right for use of the Products, solely by the Recipient, in compliance with the applicable intended use statement, limited use statement, or limited label license if included on or with the Products or provided separately to Recipient. No other rights are granted by this Agreement, whether expressly, by implication or by estoppels, or under any other rights owned or licensable by Provider.
- 10. **Intellectual Property.** Except as otherwise set forth in this Agreement, Provider retains all right, title and interest in and to, and possession of, all its proprietary technology, including all Intellectual Property rights associated with any ideas, concepts, methods, processes, techniques, inventions or works of authorship (including programs, improvements and documentation) developed or created by or on behalf of Provider. For the purposes of this Agreement, the term "Intellectual Property" means any and all patent rights, business processes, copyrights, data rights, trademarks, trade names, service marks, service names, trade secrets, mask works, moral rights, know-how or any other similar right arising or enforceable under the laws of any country or international treaty regime, invention or discovery of a new use, improvement or enhancement of the Products, whether patentable or not (each, an "Invention") and all intellectual property rights therein, shall be owned

^{© 2022} DNA Genotek Inc., a subsidiary of OraSure Technologies, Inc., all rights reserved. This Document is the property of DNA Genotek Inc. and without its prior written consent may not be disclosed to a third Party or copied.

by Provider. Provider may use proprietary technology in any of its Products, in whole or in part, even if the proprietary technology was developed expressly for use by Recipient. At Provider's request, Recipient will take such further actions, including the execution and delivery of instruments of conveyance, to give full and proper effect to the provisions of this Agreement.

- 11. **Changed or Discontinued Product(s).** Provider may implement Product updates, improvements and/or revisions and may discontinue or cease to make available Products in its sole discretion and without prior notice. Provider cannot guarantee Product availability indefinitely. In the event Provider cancels an order of Products, Provider may (i) refund any payment for undelivered Products, or (ii) substitute a product with equivalent functionality and performance as the Product.
- 12. Force Majeure. Provider shall have no responsibility or liability for loss or damage due to delay or inability to deliver, whether or not such loss or damage was made known to Provider, including, but not limited to, liability for Provider's non-performance caused by acts of God, war, labor difficulties, accidents, inability to obtain materials, delays of carriers, contractors or suppliers or any other causes of any kind whatever beyond the control of Provider. If any of the foregoing events occurs, Provider may at its option (i) make deliveries of the Products proportionate to production and/or postpone the shipment of the Products to a reasonable time after the event has been remedied or (ii) terminate this Agreement on 20 days notice. Under no circumstances will the Provider be liable for any special, consequential, incidental, indirect, or liquidated damages, losses, or expense (whether or not based on negligence) arising directly or indirectly from delays or failure to give notice of delay. Provider has no obligation to buy in the open market any article required by Provider to manufacture the Products when a supplier thereof has defaulted in delivery.
- 13. Warranties. Provider warrants that at the time of transfer to Recipient, Recipient's representative, or common carrier (a) it has good and marketable title to the Products, free of all encumbrances, and (b) all Products conform to the specifications listed on the Products, including information contained in any Certificate of Conformance, on the label, on the packaging, package insert, user manual, and on any other documentation accompanying the Products and/or separately provided to Recipient. The warranties provided herein are not transferable or available to any other customer or user subsequent to the Recipient. PROVIDER MAKES NO OTHER EXPRESSED OR IMPLIED WARRANTIES. PROVIDER HEREBY DISCLAIMS ALL EXPRESSED OR IMPLIED WARRANTIES, WHETHER IMPLIED BY OPERATION OF LAW OR OTHERWISE, INCLUDING, WITHOUT LIMITATION, ALL IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. EXCEPT AS EXPRESSLY SET FORTH IN THIS PARAGRAPH, ALL PRODUCTS AND/OR SERVICES PROVIDED BY PROVIDER AND ITS EMPLOYEES AND AGENTS ARE PROVIDED "AS IS" AND "WHERE IS". THE PROVIDER TAKES NO RESPONSIBILITY FOR THE RESULTS ACHIEVED BY THE RECIPIENT USING THE PRODUCT.
- 14. Remedies and Damages. Recipient's only remedy for its timely rejection of non-conforming Products or for any other failure of Provider to perform its obligations is (a) replacement of nonconforming Products by Provider at no cost to Recipient within a reasonable time after the returned Products are received by Provider in the same condition as they were received by Recipient or (b) if Provider is unable to replace non-conforming Products with conforming Products within 60 days after their return to Provider, repayment by Provider of all amounts paid by Recipient to Provider for the Products and cancellation of any balance of the purchase price owing to Provider. Provider makes no promise or representation that the Products will conform to any federal, State or local laws, ordinances, regulations, codes or standards, except as particularly specified and agreed upon in writing by an authorized representative of Provider. UNDER NO CIRCUMSTANCES, AND IN NO EVENT, WILL PROVIDER BE LIABLE FOR COSTS OF REPAIR, PERSONAL INJURY OR PROPERTY DAMAGE OR ANY INDIRECT, INCIDENTAL, PUNITIVE, SPECIAL. CONSEQUENTIAL, OR LIQUIDATED DAMAGES OF ANY KIND, WHETHER BASED UPON WARRANTY, CONTRACT, STRICT LIABILITY, NEGLIGENCE OR ANY OTHER CAUSE OF

© 2022 DNA Genotek Inc., a subsidiary of OraSure Technologies, Inc., all rights reserved. This Document is the property of DNA Genotek Inc. and without its prior written consent may not be disclosed to a third Party or copied.

ACTION ARISING IN CONNECTION WITH THE PRODUCTS. NEITHER PARTY'S LIABILITY SHALL EXCEED THE PURCHASE PRICE OF THE PRODUCT(S) HAVING GIVEN RISE TO THE LIABILITY. The foregoing limitation also applies to Provider's directors, officers, employees, agents, representatives, and licensors. Recipient acknowledges its damages are limited to those set out in this Section and expressly agrees that these damages constitute the only remedy available to Recipient, and Recipient expressly waives all other remedies and measures of damages that might otherwise be available at law or equity.

- 15. Arbitration. The Provider and Recipient will attempt in good faith to resolve through negotiation any dispute, claim or controversy arising out of or relating to these terms and conditions, the breach hereof or the Products. Either the Provider or Recipient may initiate negotiations by providing written notice to the other Party, setting forth the subject of the dispute and the relief requested. The Party receiving such notice will respond in writing within five days with a statement of its position on and recommended solution to the dispute. If the dispute is not resolved by this exchange of correspondence or the Party receiving such notice fails to timely respond, then representatives of each Party with full settlement authority will meet at a mutually agreeable time and place within twenty days of the date of the initial notice in order to exchange relevant information and perspectives, and to attempt to resolve the dispute. If the dispute is not resolved by these negotiations, the Parties will submit to arbitration before a single arbitrator agreeable to the Parties. If the Parties cannot agree on an arbitrator within 10 days after arbitration has been requested in writing, the arbitration will proceed in Ottawa, Ontario, before a single arbitrator knowledgeable with the biotechnology industry but not associated with a biotechnology company, appointed by Provider pursuant to the rules of the International Commercial Arbitration Act (Ontario). The award is to be rendered in such form that judgment may be entered thereon in the highest court of any forum having jurisdiction. The arbitration will take place under the rules then used by the International Commercial Arbitration Act (Ontario). The cost of any such arbitration will be borne equally by all parties thereto.
- 16. Governing Law. This contract is construed according to and governed by the laws of Ontario and the laws of Canada applicable therein, without giving effect to: (i) the principles of conflicts of law and that body of law applicable to choice of law; (ii) the United Nations Convention on Contracts for the International Sale of Goods, and/or its implementing and/or successor legislation and/or regulations; and/or (iii) the Uniform Commercial Code and/or its implementing and/or successor legislation and/or successor legislation and/or regulations, as applicable respectively. Except to the extent required by law, the Parties waive trial by jury.
- 17. **Affiliate(s).** For the purpose of this Agreement, the term "Affiliate" shall mean any corporation or other business entity controlling, controlled by or under common control with a party; and for such purpose, "control" shall mean direct or indirect ownership of: i) fifty percent (50%) or more of the voting interest in such corporation or other entity; ii) fifty percent (50%) or more of the interest in the profit or income in the case of an entity other than a corporation; or iii) in the case of a partnership, control of the general partner. The name of each party appearing herein shall be deemed to be the name of each such Affiliate of that party to the extent necessary to carry out the intent of this Agreement, and provided further that the performance of the obligations of any such Affiliate shall be deemed by the Party to this Agreement.
- 18. General. This contract will not be assigned by the Recipient to any other party without the written consent of the Provider. These terms and conditions of sale are not construed against the Party preparing them, but shall be construed as if all Parties jointly prepared these terms and conditions of sale and any uncertainty or ambiguity will not be interpreted against any one party. Provider's failure to insist upon the strict performance of any term or condition herein is not deemed a waiver of any of Provider's rights or remedies hereunder, nor of its right to insist upon the strict performance of the same or any other term herein in the future. If any provision hereof is held to be illegal, invalid or unenforceable under any present or future laws, such provision is fully severable and the terms

^{© 2022} DNA Genotek Inc., a subsidiary of OraSure Technologies, Inc., all rights reserved. This Document is the property of DNA Genotek Inc. and without its prior written consent may not be disclosed to a third Party or copied.

and conditions herein will be construed and enforced as if such illegal, invalid or unenforceable provision had never been made a part hereof. The remaining provisions herein will remain in full force and effect and will not be affected by such illegal, invalid or unenforceable provisions or by their severance from this Agreement.

- 19. European Union Terms and Conditions. To the extent Products will be put on the market or into service (which terms include, without limitation, the supply for distribution, consumption or use, and the making available to a user as being ready for use) by or on behalf of the Recipient in any European Union territory or market, whether in return for payment or free of charge, Recipient shall comply with the MDR and/or IVDR (as defined below) and the terms and conditions set forth in in this Section 19 and shall require users (as defined in the MDR and IVDR) to agree to obligations sufficient to enable Recipient to comply with these terms and conditions. For the purpose of this Section 19, the term "Recipient" is deemed to refer to anyone who will put the Products on the market or into service in any European Union territory or market. The following terms and conditions are intended to ensure conformity with Regulations (EU) 2017/745 and 2017/746 of the European Parliament and of the Council of 5 April 2017 (the "MDR" and "IVDR" respectively). Terms used herein, which are not defined, shall have the meanings set forth in the MDR and IVDR; whichever is applicable accordingly to the product.
 - a. In the event Recipient or user has reason to believe that a Product that has been placed on the market is not in conformity with the MDR and/or IVDR or any applicable laws and regulations, is defective, or falsified, then Recipient shall inform Provider as soon as possible, and in no event later than two business days after having become aware.
 - b. Recipient shall cooperate with Provider and its authorized representative and the competent authorities to ensure that the necessary corrective action(s) are taken to bring that Product into conformity, withdraw it, or recall it. Where such Product presents a serious risk or is falsified, Recipient shall also immediately inform the competent authorities of the member states in which they made the Product available and, if applicable, the notified body that issued a CE certificate for such Product.
 - c. Recipient shall report to Provider, as soon as possible, and in no event later than two business days after having become aware all matters of vigilance, including complaints or reports of suspected incidents related to Products that Recipient has placed on the market.
 - d. Recipient shall keep a register of complaints, non-conforming devices, and recalls and withdrawals, and provide Provider with a copy of that register annually or when requested by Provider together with any information requested in order to allow an investigation to take place.
 - e. Recipient's reporting shall be compliant with all current requirements under MDR and/or IVDR and all applicable laws and regulations.
 - f. Recipient shall maintain proper traceability records of Products, including information regarding (i) to whom they have directly supplied the Product; (ii) who has directly supplied them with such Product; and (iii) any health institution or healthcare professional to which they have directly supplied Products. Recipient shall provide such traceability records to Provider annually or when requested by Provider.
 - g. Recipient shall cooperate with Provider and its authorized representatives in matters of vigilance and compliance with MDR and/or IVDR and applicable laws and regulations.
 - h. Recipient, if acting also as importer, shall verify that (i) EU declaration of conformity of the Product has been drawn up, (ii) a manufacturer is identified and that an authorized

^{© 2022} DNA Genotek Inc., a subsidiary of OraSure Technologies, Inc., all rights reserved. This Document is the property of DNA Genotek Inc. and without its prior written consent may not be disclosed to a third Party or copied.

representative in accordance with Article 11 of the MDR and/or IVDR has been designated, (iii) the device is labeled in accordance with the MDR and/or IVDR and accompanied by the required instructions for use, (iv) where applicable, a UDI has been assigned, (v) Product is registered in the European Database on Medical Devices (EUDAMED), (vi) the registered name and address of Recipient at which they can be contacted shall be indicated on the Product or on its packaging or in a document accompanying the Product (in case of additional label it shall not obscure any information on the Product label).

- i. Recipient shall ensure that conditions of storage or transport do not jeopardize its compliance with the general safety and performance requirements set out in Annex I of the MDR and/or IVDR and shall comply with any conditions set by Provider.
- j. Recipients who are not importers, shall verify (i) EU declaration of conformity of the device has been drawn up, (ii) the device is accompanied by the information to be supplied by Provider in accordance with Article 10(11) of the MDR and/or Article 10(10) of the IVDR, (iii) the device includes the Importer on the label or on its packaging or in a document accompanying the Product, (iv) UDI has been assigned if applicable, importer shall verify device is registered in EUDAMED.
- k. Recipient shall ensure that conditions or storage or transport comply with any conditions set by Provider.
- Recipient shall defend, hold harmless and indemnify Provider for any losses, damages, liabilities, claims, actions, judgments, penalties, fines, costs, or expenses incurred by Provider to the extent caused by Recipient's failure to comply with the MDR and/or IVDR or this Section 19
- m. Recipient acknowledges that, pursuant to Section 7, any modification, adaptation or creation of a derivative of the Products is a breach of this Agreement. Without limiting the foregoing, Recipient acknowledges that the foregoing actions by the Recipient would require it to assume the obligations incumbent on the manufacturer pursuant to Article 16 of the MDR and IVDR.