

Roche Diagnostics Limited

Standard Terms and Conditions for the Supply of Goods and Services

1. Definitions

Affiliates:

- an organisation, which directly or indirectly controls a party to the Contract;
- an organisation, which is directly or indirectly controlled by a party to the Contract;
- an organisation, which is controlled, directly or indirectly, by the ultimate parent company of a party to the Contract,

where 'Control' is defined as owning more than fifty percent of the voting stock of a company or having otherwise the power to govern the financial and the operating policies or to appoint the management of an organisation. With respect to Roche the term "Affiliate" shall not include Chugai Pharmaceutical Co. Ltd., 1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku Tokyo, 103-8324, Japan ("Chugai") and its subsidiaries, unless Roche opts for such inclusion of Chugai and its subsidiaries by giving written notice to the Customer.

Contract: the contract between Roche and the Customer for the supply of Goods and/or Services which includes these Terms, the Quotation provided by Roche and, where applicable for the provision of Services, the Roche Service Contract Document.

Customer: the person, firm, company or authority who purchases the Goods and/or Services from Roche.

Equipment: the systems specified in the Quotation.

Equipment Warranty Period: as defined in clause 7.1 of these Terms.

Force Majeure: any event or circumstance not within the reasonable control of Roche including, without limitation, industrial action, war, governmental action or regulation, act of God, epidemic or pandemic, riots or unavailability of stocks or materials.

Goods: any goods supplied by Roche to the Customer pursuant to the Contract including, but not limited to, Equipment and Reagents.

Fully Comprehensive Service Contract: a contract in relation to preventative and corrective maintenance as further detailed in the Roche Service Contract Document.

Lease Basis: Goods supplied on an operating lease or reagent rental basis.

Medical Devices Legislation: the UK Medical Devices Regulations 2002 ("UK MDR") and any UK legislation subsequently enacted which amends, substitutes or replaces the UK MDR, the EU IVDD 98/79/EC, the EU Medical Devices Regulation 2017/745 ("EU MDR"), the EU In Vitro Medical Devices Regulation 2017/746 ("EU IVDR"), and any national legislation implementing the EU IVDD and/or EU IVDR, as applicable.

Operator's Manual: the document that is supplied on the installation of the Equipment. This document outlines the technical specification, principles of operation and customer responsibilities.

Order: the Customer's return of Roche's Quotation signed by the Customer.

Price: as defined in clause 11.1 of these Terms.

Product Information: the information that is supplied with the Goods, including the product labelling, technical specifications, Instructions for Use ("IFU") and sales and packaging materials.

Quotation: the quotation or proposal provided by Roche to the Customer for the provision of Goods and/or Services and to which these Terms apply.

Reagents: the reagents specified in the Quotation.

Roche: Roche Diagnostics Limited, a company incorporated in England and Wales with registration number 00571546.

Roche Service Contract Document: the most recent published version of the document entitled the 'Roche Diagnostics Limited Service Contract'.

Services: includes, without limitation, Fully Comprehensive Service Contracts and any other services provided by Roche to the Customer as specified in the Quotation.

Terms: these Standard Terms and Conditions for the Supply of Goods and Services.

Territory: the United Kingdom ("UK") and the European Economic Area ("EEA").

Working Day: Monday to Friday excluding weekends and bank holidays.

2. General - Scope

2.1 These Terms shall apply to all Quotations and all Orders accepted by Roche including, but not limited to, the following purchase types (which shall be specified in the Quotation):

- capital purchase
- Lease Basis
- Fully Comprehensive Service Contracts

2.2 Save for as specified in clause 2.3, these Terms apply to the Contract to the exclusion of any other terms that the Customer seeks to impose or incorporate (including, without limitation, any terms which the Customer purports to apply under any purchase order), or which are implied by trade, custom, practice or course of dealing.

2.3 If Roche and the Customer have executed a formal, bespoke written contract signed and dated by authorised signatories of both parties in relation to the provision of goods and services specified in a quotation, the terms of that contract shall apply.

2.4. Any amendments, cancellation or waiver of these Terms or the Contract must be made in writing and signed by a duly authorised representative of Roche. For the avoidance of doubt, Roche's drivers or warehouse staff are not duly authorised representatives.

2.5 Where there is a conflict between the documents which constitute the Contract, they shall take precedence in the following order:

- Quotation
- these Terms
- Roche Service Contract Document (if applicable)

3. Basis of Contract

3.1 Any Quotation provided by Roche to the Customer shall not constitute an offer and is only valid for a period of 90 days from the date of issue.

3.2 The Order constitutes an offer by the Customer to purchase goods and/or services as detailed in the Quotation subject to these Terms.

3.3 The Order shall only be deemed accepted when Roche issues written acceptance of the Order, which may include email or facsimile or, if earlier, where Roche supplies the Goods and/or Services to the Customer at which point the Contract shall come into existence (the "**Commencement Date**"). Any Order shall be accepted entirely at the discretion of Roche.

4. Goods



4.1 The Goods are as described within the Quotation and the relevant Operator's Manual and Product Information.

4.2 Roche reserves the right to amend the Operator's Manual and/or Product Information if required to do so by any applicable statutory or regulatory requirement.

5. Services

5.1 Fully Comprehensive Service Contracts and Services shall be performed in line with the Quotation, these Terms and, where applicable, the Roche Service Contract Document.

6. Delivery of the Goods and Services

6.1 Any dates quoted for delivery of Goods and Services by Roche are estimates and the time of delivery is not of the essence. Roche will not be held liable for any delay or non-delivery nor for, without limitation, any resulting loss, expense, damage or fine. Any delay in delivery will not entitle the Customer to terminate the Contract.

6.2 Unless otherwise stated in the Quotation, delivery of the Goods shall take place at the Customer's premises when unloaded from the delivery vehicle.

6.3 When signing for Goods from the carrier, the Customer agrees to check that the number of packages received is in accordance with the number on the delivery note and immediately to record any numerical discrepancy or obvious external damage on the carrier's delivery note.

6.4 Roche will consider claims for damaged Goods, shortages or incorrect deliveries if notified within 14 days of the receipt of the Goods, after which point the Goods will be deemed accepted.

6.5 Roche will not accept the return of unwanted Goods correctly delivered against an Order accepted by Roche in accordance with these Terms.

6.6 Where title to Goods has not passed to the Customer, Roche reserves the right to withhold delivery of any Goods pursuant to a Contract where the Customer goes or, in Roche's reasonable opinion, seems likely to go into liquidation, makes any composition or arrangement with its creditors or has appointed an administrator or an administrative receiver.

6.7 If the Customer fails to take delivery of the Goods and/or Services when due in accordance with the Contract then, without limitation to Roche's right to terminate under clause 15, the Customer shall indemnify Roche for all costs associated with performing the Contract up until the date of failed delivery.

6.8 Roche may deliver the Goods in instalments, which shall be invoiced and paid for separately. Each instalment shall constitute a separate Contract. Any delay or defect in an instalment shall not entitle the Customer to cancel any other instalment.

6.9 Any order received on a Friday, which requires dry ice or other form of temperature control, will be dispatched the following Monday (or in the case of an intervening bank holiday/(s)), the following Working Day). In the event that the Customer requires a weekend delivery, which Roche subsequently agrees to provide at its discretion, the Customer shall be solely responsible for any degradation of the Goods in the event the Goods cannot be delivered.

6.10 Orders below £100 or €120 shall be subject to a handling charge. Roche reserves the right to make additional charges for including, but not limited to, deliveries requiring dry ice, all special and urgent deliveries and deliveries outside the United Kingdom and the Republic of Ireland.

7. Quality of the Goods and Services

7.1 The warranty period for the Equipment shall be 12 months from the date of commissioning or 14 months from the date of delivery, whichever date is the sooner (the "**Equipment Warranty Period**").

7.2 Subject to clause 7.3, Roche shall, at its sole option, repair or replace the defective Equipment or refund the price of the defective Equipment in full during the Equipment Warranty Period provided Roche is notified in writing within a reasonable time of discovery that some or all of the Equipment do not comply with their published specification and that Roche is given reasonable opportunity to examine the Equipment. Should Roche elect to repair the defective Equipment, the Customer shall grant Roche a reasonable period for repairing the defects and cooperate with Roche, as appropriate. The repair or replacement of defective Equipment shall not extend the Equipment Warranty Period.

7.3 Roche shall not be liable for the failure of the Equipment to comply with its published specification where:

7.3.1 the defect has arisen due to the Customer's failure to follow Roche's oral or written instructions as to the storage, installation, commissioning, use or maintenance of the Equipment;

7.3.2 the Customer alters or repairs such Equipment without the written consent of Roche; and/or

7.3.3 the defect arises as a result of fair wear and tear, wilful damage, negligence, abnormal working conditions or any act or omission not caused by Roche; and/or

7.3.4 the Customer uses, or has used, reagents or consumables on the Equipment that are manufactured by a third party that is not Roche without the prior written authorisation of Roche.

7.4 The warranty period for the Reagents shall be the shelf-life as indicated on each relevant Reagent's packaging or package insert ("**Reagent Warranty Period**"). Subject to clause 7.5, Roche shall at its sole option, either replace or refund the price of the defective Reagents during the Reagent Warranty Period provided Roche is notified in writing within a reasonable time of discovery that some or all of the Reagents do not comply with their published specification and Roche is given reasonable opportunity to examine the Reagents.

7.5 Roche shall not be liable for the failure of the Reagents to comply with its published specification where:

7.5.1 the defect has arisen due to the Customer's failure to follow Roche's oral or written instructions as to the storage or use of the Reagents; and/or

7.5.2 the defect arises as a result of wilful damage, negligence, abnormal working conditions or any act or omission not caused by Roche.

7.6 The Customer shall inform Roche of any non-conformity where the Customer considers or has reason to believe that any Goods are not in conformity with the requirements of the Medical Devices Legislation, and shall not place such Goods on the market until they have been brought into conformity.

7.7 Roche warrants that the Services shall be performed with due care and skill.

7.8 Roche shall re-perform any Services which do not comply with clause 7.9. Except as provided within this clause 7.8, Roche shall have no liability to the Customer in respect of the failure of the Services to comply with the warranty set out in clause 7.7.

7.10 Except as provided in this clause 7, Roche shall have no liability to the Customer in respect of the failure of the Goods to comply with its published specification. Roche does not give any representation or



warranty or undertaking in relation to the Goods or Services other than those set out in these Terms and accordingly any representation, warranty or condition that might be implied or incorporated into the Contract (including the terms implied by sections 13 to 15 of the UK Sale of Goods Act 1979, by sections 3 to 5 of the Sale of Goods and Services Act 1982, and by sections 13 to 15 of the Irish Sale of Goods and Supply of Services Act 1980) are excluded to the fullest extent permitted by law.

8. Customer's Obligations

8.1 The Customer shall:

- 8.1.1 ensure that the terms of the Order are complete and accurate;
- 8.1.2 comply with the Operator's Manual and Product Information;
- 8.1.3 act in full compliance with the applicable requirements of the Medical Devices Legislation if selling, distributing or otherwise making the Goods available on the market in the UK and/or the Republic of Ireland in the context of its activities;
- 8.1.4 fully cooperate and communicate with Roche and/or its Affiliates in a timely manner in all matters relating to compliance with the Medical Devices Legislation;
- 8.1.5 provide Roche, its employees, agents, consultants and subcontractors, with access to the Customer's premises, office accommodation and other facilities as reasonably required to provide the Services;
- 8.1.6 while the Goods are under its responsibility, storage or transport conditions comply with the conditions specified on the Goods or otherwise notified by Roche, and its obligations under the Medical Devices Legislation;
- 8.1.7 fully cooperate and communicate with Roche and/or its Affiliates in a timely manner in all matters relating to compliance with the Medical Devices Legislation;
- 8.1.8 notify Roche without delay of any incidents, complaints or reports concerning the Goods, and comply with any directions of Roche in any issues, proceedings or negotiations relating to such incidents, complaints and/or reports; and
- 8.1.9 comply with any reasonable instructions of Roche in relation to the Goods and/or Services.

8.2 The Customer shall, at its own cost, obtain and maintain throughout the term of the Contract any registrations, licences, authorisations and approvals necessary or required in connection with the distribution of Goods in the UK and/or the Republic of Ireland. Where any such registration, licence, authorisation or approval is required, the Customer shall provide Roche with information and/or copies of such documentation upon request.

8.3 The Customer shall permit Roche on reasonable advance written notice to inspect, during the term of this Contract, the Customer's premises and documents relevant to the distribution of Goods for the purposes of performing an audit of the Customer's conformity with this Contract.

9. Risk and Title

9.1 Risk in the Goods shall pass to the Customer at the point of delivery.

9.2 Title in the Goods shall not pass until the following:

- 9.2.1 Where Goods are Equipment provided on a **capital purchase basis**, title in Equipment shall pass at the point of full payment of the Equipment and all other sums owed by the Customer to Roche under this Contract or any other Contract between Roche and the Customer;

9.2.2 Where the Goods are Equipment provided on a **Lease Basis**, title in Equipment shall not pass and shall remain with Roche at all times;

9.2.3 Where the Goods are reagents and/or consumables, title in reagents and consumables shall pass at the point such Goods are taken into use. For the avoidance of doubt, where title passes in accordance with this clause 9.2.3 then the full Price for such Goods shall be recoverable by Roche from the Customer as a debt if there is non-payment of an invoice issued by Roche to the Customer in relation to such Goods.

9.2.4 Title in all other Goods shall pass at the point of full payment of the Goods and all other sums owed by the Customer to Roche.

9.3 Until title to the Goods has passed to the Customer, the Customer shall:

- 9.3.1 not remove, deface or obscure any identifying mark or packaging on or relating to the Goods.
- 9.3.2 maintain the Goods in satisfactory condition and keep them insured at its cost against all risks for their full Price from the date of delivery.
- 9.3.3 give Roche such information relating to the Goods as Roche may reasonably require from time to time.
- 9.3.4 allow Roche reasonable access to its premises in order to examine the Goods.
- 9.3.5 deliver the Goods up to Roche where requested by Roche to do so.

9.4 Subject to clause 9.6.1, the Customer may re-sell or use the Goods purchased on a capital purchase basis in the ordinary course of its business provided that all proceeds of sale are held on trust for Roche pending full payment to Roche in relation to the Goods. For the avoidance of doubt, Goods which are Equipment provided on a Lease Basis may not be re-sold or otherwise dealt with resulting in the Customer parting possession with the Equipment.

9.5 Any sale by the Customer permitted by clause 9.4 shall be effected by the Customer as principal and not as Roche's agent.

9.6 If, before title to the Goods passes to the Customer, the Customer becomes subject to any of the events listed in clause 15.1,

9.6.1 the Customer's right to re-sell Goods or use them in the ordinary course of its business ceases immediately;

9.6.2 Roche may at any time:

- 9.6.2 (A) require the Customer to deliver up all Goods in its possession which have not been resold; and
- 9.6.2 (B) if the Customer fails to deliver up all Goods promptly under clause 9.6.2(A), enter any premises of the Customer where the Goods are stored in order to recover them.

10. Roche's Obligations

10.1 Roche shall:

- 10.1.1 provide the Customer with all information, data and documentation required for the safe handling and use of the Goods, and to secure any registrations, licences, authorisations or approvals that the Customer may be required to obtain and/or retain by law;
- 10.1.2 provide the Customer with any updated versions of the Product Information and other relevant documentation when available; and
- 10.1.3 notify the Customer of any safety alerts, notices or other communications issued by the relevant regulatory authorities or any similar communications issued by Roche relating to the Goods.



11. Price and Payment

11.1 The price shall be as set out in the Quotation (the "Price").

11.2 The Price is subject to variation without notice prior to delivery of the relevant Goods or Services.

11.3 The Price shall be exclusive of value added tax (VAT) which the Customer shall additionally be liable to pay to Roche at the prevailing rate, subject to the receipt of a valid VAT invoice.

11.4 Unless otherwise stated in the Quotation, Roche shall invoice:

11.4.1 for Goods supplied on a capital purchase basis, at the point of despatch of the Goods;

11.4.2 for Goods supplied on a Lease Basis, following supply;

11.4.3 for Fully Comprehensive Service Contracts, annually in advance; and

11.4.4 for reagents and consumables and for all other Goods, at the point of despatch of the Goods.

11.5 The Price shall be payable by the Customer within thirty (30) days of the date of invoice in full and in cleared funds payable to the account notified by Roche to the Customer in writing. Roche reserves the right to withdraw these credit terms at any time without notice.

11.6 The Customer shall notify Roche of any invoice discrepancy within 14 days of the date of invoice after which time, the invoice shall be deemed accepted.

11.7 Time for payment by the Customer shall be of the essence.

11.8 Without limitation to Roche's remedies under clauses 11.9, 12 and 15, where the Customer is late paying any Roche invoice by a period greater than or equal to 14 days from the point it was due, Roche reserves the right, however is not obliged, to withhold a subsequent supply of Goods and/or Services.

11.9 Without limitation to Roche's remedies under clauses 11.8, 12 and 15, where the Customer fails to make payment due to Roche by the due date, the Customer shall pay interest on the overdue sum from the due date until payment of the overdue sum. Interest under this clause 11.9 shall accrue each day at 8% a year above the Bank of England base rate from time to time.

11.10 Roche reserves the right to increase the Price of the Goods and/or Services, by giving notice to the Customer at any time before delivery, to reflect any increase in the cost of the Goods to Roche which is due to:

11.10.1 any factor beyond the control of Roche (including foreign exchange fluctuation, increases in taxes and duties, increases in labour, materials and other manufacturing costs);

11.10.2 any request by the Customer to change the delivery date(s), quantities or type of Goods ordered or inaccurate information in respect of the delivery of the Goods.

11.11 Roche shall be entitled to increase the Price of any Fully Comprehensive Service Contract on an annual basis in line with the Retail Price Index.

11.12 Roche reserves the right to review the pricing for reagents and/or consumables on an annual basis.

11.13 All amounts due under the Contract shall be paid in full without any set-off, counterclaim, deduction or withholding (except for any deduction of tax as required by law).

11.14 If, in the reasonable opinion of Roche, the credit-worthiness of the Customer deteriorates before delivery of the Goods or Services, Roche

may in its sole discretion require full or partial payment prior to the delivery of the Goods or Services. Roche will notify the Customer of this requirement where applicable.

12. Safety and Recall

12.1 The Customer should satisfy itself that the persons responsible for the shipping, storage, handling and/or use of any Goods supplied by Roche have all the information required on health and safety requirements (as required by applicable law) and conditions of storage and any health and material safety data sheets and/or Product Information.

12.2 Roche shall not be liable to the Customer in any civil proceedings brought by the Customer against Roche in respect of a breach of the applicable law, shipping, storage, handling or use instructions or any other applicable health and safety legislation or any regulations, orders or directions made pursuant to such health and safety legislation in force from time to time or under any directive, regulation, order or other instrument relating to health and safety, where such exclusion of liability is permitted by law.

12.3 Should the Customer re-sell any Goods in accordance with these Terms:

12.3.1 the Customer shall at its own expense establish a system that enables it to track which Goods are delivered to which customer and as such undertakes to maintain appropriate, up-to-date and accurate records to enable the immediate recall of any individual or batches of Goods for at least 10 years after the last Good covered by the declaration of conformity has been placed on the market. These records shall include (but are not limited to) records of deliveries to customers (including identity of the product, UDI, batch/lot numbers, serial numbers, quantity, delivery date, name and address of customer, telephone number, fax number and e-mail address);

12.3.2 if there is a risk that serious deterioration in the state of the health of a patient or user may occur in connection with any Goods, Roche may require that the re-sale of the Goods be stopped immediately upon the Customer receiving notification thereof in writing or by e-mail; and

12.3.3 the Customer shall take such action and give such information and assistance that Roche shall reasonably require to recall Goods or investigate a potential issue relating to the Goods including, but not limited to, acknowledging receipt of any safety, recall or other notification sent by Roche and reporting requested information and/or confirmations back to Roche without delay. Roche shall inform the Customer promptly about its intent to or the necessity of withdrawal of all or a part of Goods from trading.

12.4 The Customer shall without delay take such action and give such information and assistance that Roche shall reasonably require to investigate any potential issue relating to the Goods.

12.5 The Customer shall provide such assistance and provide such information as Roche may reasonably require to enable Roche to comply with its obligation in relation to complaints, reports and product recalls in accordance with the Medical Devices Legislation.

13. Indemnity

13.1 The Customer agrees to indemnify and hold Roche harmless from and against any losses, claims, costs, expenses, penalties, legal costs and damage (whether direct, indirect or consequential) including, without limitation, third party claims arising out of: (i) the abnormal or improper use, misuse or neglect of the Goods; (ii) any act or omission in breach or negligent performance of the Contract including, without limitation, any breach of warranty.

14. Limitation of Liability

14.1 Nothing in these terms shall limit or exclude Roche's liability for:

- 14.1.1 death or personal injury caused by its negligence.
- 14.1.2 fraud or fraudulent misrepresentation.
- 14.1.3 breach of the terms implied by section 2 of the UK Supply of Goods and Services Act 1982.
- 14.1.4 breach of the terms implied by section 12 of the UK Sale of Goods Act 1979 or section 12 of the Irish Sale of Goods and Supply of Services Act 1980.
- 14.1.5 defective products under the Consumer Protection Act 1987 or the Irish Liability for Defective Products Act 1991.
- 14.1.6 any other liability of Roche which may not be lawfully excluded or limited.

14.2 Subject to clause 14.1, Roche shall not be liable to the Customer, whether in contract, tort (including negligence), for breach of statutory duty, or otherwise, arising under or in connection with the Contract for:

- 14.2.1 loss of profit, business, revenue, anticipated savings or goodwill, in each case whether direct or indirect or
- 14.2.2 any type of special, indirect or consequential loss.

14.3 Subject to clause 14.1, Roche's total liability to the Customer whether arising in contract, tort (including negligence), breach of statutory duty or otherwise under or in connection with the Contract shall be limited to the Price.

14.4 The provisions of this clause 14 shall survive expiry or termination of the Contract.

15. Termination

15.1 Without affecting any other right of remedy available to it, Roche may immediately suspend performance of the Contract or terminate the Contract without liability to the Customer if:

- 15.1.1 the Customer fails to make payment in accordance with clause 11.
- 15.1.2 the Customer fails to pay any other debt due and payable to Roche by the relevant date.
- 15.1.3 the Customer commits a material breach of the Contract (and for the avoidance of doubt and without limitation, any breach of clauses 11, 16, 17, 18, 20 and 23.1 will be considered a material breach).
- 15.1.4 the Customer fails to remedy a breach of its obligations under the Contract within the timescale reasonably required by Roche.
- 15.1.5 any sum payable under the Contract is not paid within 14 days of its due date.
- 15.1.6 any distress or execution is levied upon any of the Customer's goods.
- 15.1.7 the Customer enters into bankruptcy, individual voluntary arrangement, liquidation, receivership, administration or into a corporate voluntary arrangement as defined by the Insolvency Act 1986 or the Irish Companies Act 2014.
- 15.1.8 the Customer ceases or threatens to cease to carry on all or a material part of its business.
- 15.1.9 Roche reasonably believes that any of the events specified in clause 15.1.7 is about to occur in relation to the Customer.
- 15.1.10 the Customer stops or suspends or threatens to suspend payment of all or a material part of its debts or is unable to pay its debts, or is deemed unable to do so under section 123 of the Insolvency Act 1986 or section 570 of the Irish Companies Act 2014.
- 15.1.11 there is a change of control of the Customer (within the meaning of section 1124 of the Corporation Act 2010 or section 432 of the Taxes Consolidation Act 1997).

15.2 Without affecting any other right or remedy available to it, Roche may terminate the Contract on giving not less than 3 months' notice to the Customer.

15.3 Notwithstanding any termination or suspension in accordance with these Terms, the Customer shall pay Roche for all costs incurred by Roche in providing the Goods and Services up to and including the date of suspension or termination.

15.4 Termination of the Contract for any reason shall be without prejudice to the rights and remedies of either party which have accrued up to termination.

16. Import and Export Control

16.1 The Customer shall not actively solicit orders for Goods for territories outside of the UK and the Republic of Ireland that have been exclusively reserved to Roche or any of its Affiliates or exclusively allocated by Roche or any of its Affiliates to a third party.

16.2 If the Goods are being exported to the Customer outside the United Kingdom the provisions of this clause 16 shall apply notwithstanding any other provision of the Contract.

16.3 Unless the context otherwise requires, any term or expression which is defined in or given a particular meaning by the provisions of Incoterms 2020 shall have the same meaning for the purposes of the Contract. In the event of conflict between Incoterms 2020 and the Contract, the Contract shall prevail.

16.4 Unless stated otherwise in the Contract any Goods being exported to the Customer shall be delivered, "Delivered At Place" (DAP).

16.5 The Customer shall:

- 16.5.1 not actively supply any Goods to customers outside the Territory without the prior written consent of Roche; and
- 16.5.2 refer to Roche all enquiries it receives for Goods for sale or ultimate delivery outside of the Territory.

16.6 Nothing in these Terms shall prevent the Customer from meeting any unsolicited or passive orders for Goods both within and outside of the Territory, including territories that have been exclusively reserved to Roche or any of its Affiliates or exclusively allocated by Roche or any of its Affiliates to a third party.

16.7 The Customer shall be responsible for complying with any legislation, regulations, guidelines, codes of practice or directions governing the export, re-export, re-transfer or import of the Goods and the use or sale of the Goods in the country of destination.

16.8 Roche shall be under no obligation to give notice under section 3(2) of the Sale of Goods Act 1979.

16.9 The parties agree that all Goods, including software and technology, delivered under the Contract may be subject to foreign trade controls. The Customer is responsible for and shall strictly comply with all applicable national and international laws and regulations for the control of import, export or re-export, transfer, brokering and transit. Prior to any delivery of Goods, the Customer shall guarantee that all necessary import and/or export licences are obtained as may be required throughout the duration of the Contract.

16.10 Roche shall provide such information as the Customer reasonably requires to ensure compliance with their obligations under applicable export and customs regulations.

16.11 Any costs incurred from the obligations in this clause 16 shall be borne by the Customer.

17. Data Protection

17.1 For the purposes of these Terms, the following terms shall have the following meanings:

Data Protection Legislation means:

- (i) the UK General Data Protection Regulation ("UK GDPR");
- (ii) the Data Protection Act 2018 ("DPA");
- (iii) the Privacy and Electronic Communications (EC Directive) Regulations 2003 ("PECR");
- (iv) any successor legislation to the UK GDPR, the DPA or PECR;
- (v) the EU Data Protection Regulation 2016/679 ("EU GDPR") and
- (vi) any national implementing laws, regulations and secondary legislation relating to data protection as amended or updated from time to time, in the UK and in the Republic of Ireland.

Personal Data Breach: means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, Personal Data transmitted, stored or otherwise processed.

Personal Data: shall have the meaning given to it in the applicable Data Protection Legislation and shall include Special Categories of Personal Data.

Special Categories of Personal Data: means Personal Data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and genetic data, biometric data, data concerning health or data concerning a natural person's sex life or sexual orientation. 'Genetic data', 'biometric data' and 'data concerning health' shall have the meanings given to them in the UK and EU GDPR.

17.2. Both parties will comply with all applicable requirements of the Data Protection Legislation. This clause 17 is in addition to, and does not relieve, remove or replace, a party's obligations under the Data Protection Legislation. In this clause 17, Controller, Processor, processing and Data Subject shall have the meanings given to them in the applicable Data Protection Legislation and process and processed shall be construed accordingly.

17.3 In order to extinguish their respective obligations under the Contract, Roche may be required to process Personal Data belonging to the Customer. The duration of any such processing shall be equal to the term of the Contract, unless expressly stated otherwise. The parties acknowledge that for the purposes of the Data Protection Legislation, the Customer is the Controller and Roche is the Processor.

17.4 The Customer confirms its general authorisation to the appointment of all sub-processors engaged by Roche to fulfil its obligation under the Contract (the Existing Sub-Processors). Roche shall inform the Customer of any intended change(s) to the Existing Sub-Processors and the Customer shall inform Roche in writing within seven (7) days of the date of such notice if it has any objections to the proposed Existing Sub-Processor change(s). If the Customer does not object to the Existing Sub-Processor change(s) then the change(s) shall have effect no earlier than the eighth (8th) day after the date of the relevant notice from Roche. The parties will discuss any objection to the Existing Sub-Processor change(s) in good faith to resolve the issue.

17.5 Roche shall, in relation to any Personal Data processed in connection with the performance by Roche of its obligations under the Contract:

17.5.1 save for any specific authorisation provided under these Terms by the Customer, process that Personal Data only on the written instructions of the Customer (including, but not limited to, with regard to the transfer of Personal Data outside of the Territory) unless Roche is required by the applicable laws of any state in the Territory to process Personal Data ("**Applicable Data Laws**"). Where Roche is relying on Applicable Data Laws as the basis for processing Personal Data, Roche shall, to the extent legally permissible, promptly notify the Customer of this before performing the processing required by the Applicable Data Laws;

17.5.2 ensure that all personnel who have access to and/or process Personal Data are obliged to keep the Personal Data confidential;

17.5.3 ensure that it has in place technical and organisational measures to protect against any Personal Data Breach appropriate to the harm that might result from the Personal Data Breach and the nature of the data to be protected, having regard to the state of technological development and the cost of implementing any measures (those measures may include, where appropriate, pseudonymising and encrypting Personal Data, ensuring confidentiality, integrity, availability and resilience of its systems and services, ensuring that availability of and access to Personal Data can be restored in a timely manner after an incident, and regularly assessing and evaluating the effectiveness of the technical and organisational measures adopted by Roche);

17.5.4 save for the authorisation provided under clause 17.4 of these Terms by the Customer, not appoint any third party processor of Personal Data under this Contract (a "**Third Party Processor**") unless:

17.5.4 (A) the prior specific written consent of the Customer has been obtained; and

17.5.4 (B) the Third Party Processor is bound by terms which are substantially similar to those set out in this clause 16 under (i) a written agreement between Roche and the Third Party Processor or (ii) Applicable Data Laws.

As between the Customer and Roche, Roche shall remain fully liable for all acts or omissions of any Third Party Processor appointed pursuant to this clause 17.5.4;

17.5.5 assist the Customer, by appropriate technical and organisational measures, in responding to any request from a Data Subject and in ensuring compliance with its obligations under the Data Protection Legislation with respect to requests for exercising a Data Subject's rights, security, breach notifications, impact assessments and consultations with supervisory authorities or regulators;

17.5.6 at the written direction of the Customer, delete or return Personal Data and copies thereof to the Customer on termination of the Contract unless required by Applicable Data Law to store the Personal Data;

17.5.7 maintain and make available to the Customer all information necessary to demonstrate its compliance with this clause 17 and allow for and contribute to audits by the Customer or the Customer's designated auditor;

17.5.8 as soon as reasonably practical inform the Customer if, in Roche's opinion, an instruction infringes any Data Protection Legislation or Applicable Data Law;

17.5.9 save for any specific authorisation provided under these Terms by the Customer (including, but not limited to, clause 17.9), not transfer any Personal Data outside of the Territory unless the prior written consent of the Customer has been obtained and the following conditions are fulfilled:

17.5.9 (A) the Customer or Roche has provided appropriate safeguards in relation to the transfer;

17.5.9 (B) the Data Subject has enforceable rights and effective legal remedies;

17.5.9 (C) Roche complies with its obligations under the Data Protection Legislation by providing an adequate level of protection to any Personal Data that is transferred; and

17.5.9 (D) Roche complies with reasonable instructions notified to it in advance by the Customer with respect to the processing of the Personal Data; and

17.5.10 notify the Customer without undue delay on becoming aware of a Personal Data Breach with sufficient detail to enable

the Customer to identify the facts relating to the Personal Data Breach, its effects and Roche's proposed remedial action.

17.6 The Customer confirms that it authorises all forms of data transfer and processing as described in this clause 17 or elsewhere in the Contract and warrants that:

17.6.1 it has received all requisite consent from the Data Subjects (or is otherwise permitted by the Data Protection Legislation) to disclose the Personal Data to Roche; and

17.6.2 its disclosure of, and Roche's subsequent use, processing and/or transfer of, Personal Data under or in relation to this Contract is permitted under the Data Protection Legislation.

17.7 Roche may, at any time on not less than 30 days' notice, revise this clause 17 by replacing it with any applicable controller to processor standard clauses or similar terms forming part of an applicable certification scheme (which shall apply when replaced by attachment to this Contract).

17.8 Roche is hereby authorised by the Customer to download and use data which does not constitute Personal Data (such as performance data) via a secure gateway system for purposes including but not limited to optimisation of the Roche service, anticipation and preparation for potential epidemics and analysis of regional testing behaviour.

17.9 The Customer acknowledges and agrees that:

17.9.1 in order to provide technical support including, but not limited to, remote technical support, Roche will need to view, store and/or transfer (including outside of the Territory) data which may contain Personal Data. When the data has been evaluated and the technical support case has been closed, any data stored will be deleted; and

17.9.2 the majority of technical support will be offered from the UK and Republic of Ireland by Roche, however where second and third line escalations are required, Roche may utilise global expertise by safely and securely transferring data (which may include Personal Data), employing infrastructure that has been specially implemented for this purpose and which is fully certified against ISO 27001.

17.10 The Customer shall indemnify Roche in full against all liabilities, costs, expenses, damages or losses (including, but not limited to, any direct, indirect or consequential losses, loss of profit, loss of reputation and all interest, penalties and legal costs (calculated on a full indemnity basis) and all other reasonable professional costs and expenses) suffered or incurred by Roche arising out of or in connection with any act or omission by or on behalf of the Customer resulting in a breach of the Data Protection Legislation by Roche. Liability under this indemnity is unlimited.

18. Anti-bribery, anti-slavery and human trafficking

18.1 The Customer will, and will procure that any of its Affiliates, employees, subcontractors, permitted assigns, agents or any other persons who perform any obligations under the Contract will fully comply with, and not commit any act or omission which causes or could cause the Customer or Roche or any of its or their Affiliates to breach or commit an offence under, all laws, statutes, regulations and codes of practice relating to:

18.1.1 anti-bribery and/or anti-corruption, including the Bribery Act 2010—and the Irish Criminal Justice (Corruption Offences) Act 2018; or

18.1.2 anti-slavery and human trafficking in the UK and elsewhere, including the Modern Slavery Act 2015 and the Irish Criminal Law (Human Trafficking) Act 2008 as amended or updated from time to time.

19. Intellectual Property

19.1 All intellectual property rights in or arising out of or in connection with the Goods and Services shall be owned by Roche.

19.2 No right or licence is granted under the Contract to the Customer under any patent, trade mark, copyright, registered design or other intellectual property right, except the right to use or re-sell the Goods.

19.3 The Customer shall not sub-licence, assign or otherwise transfer the rights granted under clause 19.2.

19.4 All Goods may be sold or re-sold by the Customer only in the packages and packaging in which the Goods were supplied by Roche and in no case may any trademark other than the trademark carried by the Goods at the time of delivery be marked or applied in relation to the Goods by the Customer.

20. Confidentiality

20.1 A party ("**Receiving Party**") shall keep in strict confidence: (i) all technical or commercial know-how, specifications, inventions, processes or initiatives which are of a confidential nature and have been disclosed to the Receiving Party by the other party ("**Disclosing Party**"), its Affiliates, employees, subcontractors, permitted assigns or agents, (ii) any other confidential information concerning the Disclosing Party's business, its products and services which the Receiving Party may obtain as part of the Contract, (iii) any information that is marked or has been otherwise indicated to be confidential and (iv) all information in whatever form which would be regarded as confidential by a reasonable business person (together, the "**Confidential Information**").

20.2 The Disclosing Party warrants that it has the full and unconditional right to disclose the Confidential Information to the Receiving Party.

20.3 The Receiving Party shall:

20.3.1 only use the Confidential Information to discharge its obligations under the Contract;

20.3.2 disclose the Confidential Information only to those of its Affiliates, employees, subcontractors, permitted assigns or agents who need to know it for the purpose of discharging the Receiving Party's obligations under the Contract; and

20.3.3 ensure that all Affiliates, employees, subcontractors, permitted assigns or agents who receive Confidential Information under Condition 20.3.2 comply with the obligations of confidentiality set out in this clause 20 as if they were a party to the Contract.

20.4. The obligations of confidentiality in this clause 20 shall not extend to any information which the Receiving Party can demonstrate:

20.4.1 is publicly available or becomes publicly available through no act or omission of the Receiving Party;

20.4.2 was independently disclosed to the Receiving Party by a third party entitled to disclose the same;

20.4.3 is required to be disclosed by the Receiving Party under any applicable law, or by legal order of a court or governmental body or authority of competent jurisdiction.

20.5. Upon termination or expiration of the Contract for any reason, unless otherwise agreed in writing between the parties, the Receiving Party shall cease all use and make no further use of the Confidential Information and shall upon receipt of a written request from the Disclosing Party and at the Receiving Party's sole cost and expense promptly deliver up to the Disclosing Party or destroy (at the Disclosing Party's sole option) all Confidential Information, including any documents, materials and records in any medium containing or reflecting the Confidential Information. Notwithstanding the obligations set out in this clause 20.5, the Receiving Party may retain one copy of the Confidential Information to the extent it

is required to do so to comply with any law or regulation provided always that any retained Confidential Information is kept always in full compliance with the provisions of this clause 20.

20.6 The provisions of this clause 20 shall survive expiry or termination of the Contract.

20.7 Roche acknowledges that the Customer may be subject to the Freedom of Information Act 2000 and/or the Irish Freedom of Information Acts 1997 and 2014 (“**FOIA**”), and the Customer acknowledges that any information disclosed to the Customer which relates to financial issues or technical specifications not in the public domain should be held in the strictest of confidence. The Customer acknowledges that such information is exempt from disclosure under the FOIA as it has been provided in confidence and disclosure would constitute an actionable breach of confidence and/or that the information provided is a trade secret and in all the circumstances the public interest in maintaining the exemption outweighs the public interest in disclosure. If the Customer receives a request under FOIA relating to the Goods or the Services, it shall notify Roche and give Roche a reasonable opportunity to make any submissions in relation to disclosure before responding to the applicant. Roche’s submissions shall be taken into account by the Customer before a final decision on disclosure is made. If the Customer decides to disclose information relating to the Goods or the Services contrary to any submissions by Roche, it will notify Roche of its decision at least three (3) days prior to such disclosure being given to the applicant.

21. Force Majeure

21.1 If Roche is prevented from or delayed in delivering any Goods or Services by an event of Force Majeure, Roche shall be entitled to cancel or suspend deliveries of such Goods or Services without prejudice to its right to payment for any Goods or Services already delivered. Roche shall not be liable for any loss or damage arising directly or indirectly as a result of an event of Force Majeure.

21.2 Either party may terminate a Contract if an event of Force Majeure continues for a period of 6 months.

22. Assignment and other dealings

22.1 Roche may at any time assign, mortgage, charge, subcontract, delegate, declare a trust over or deal in any other manner with any or all of its rights and obligations under the Contract.

22.2 The Customer shall not assign, transfer, mortgage, charge, subcontract, declare a trust over or deal in any other manner with any of its rights and obligations under the Contract.

23. General

23.1 The parties agree to comply with all applicable laws, regulations and guidelines in relation to the provision of Goods and/or Services under the Contract including, but not limited to the Medical Devices Legislation and the MedTech Europe Code of Ethical Business Practice.

23.2 The rights and remedies of Roche under these Terms are cumulative and not exclusive of any other rights or remedies that may be available to Roche under applicable law.

23.3 Without prejudice to clause 2.3, each Contract constitutes the entire agreement between the parties and supersedes and extinguishes any previous drafts, agreements, undertakings, representations, warranties and arrangements of any nature, whether in writing or oral relating to the relevant supply of Goods and/or Services. By making an offer in accordance with clause 3.2, the Customer acknowledges that it has not been induced to enter into a Contract by any representation or warranty other than those contained in the Contract and agrees that it shall have no remedy in respect of any other such representation or warranty except in the case of fraud.

23.4 Nothing in the Contract is intended to, or shall be deemed to, establish any partnership or joint venture between the parties, constitute either party the agent of the other, or authorise either party to make or enter commitments for or on behalf of the other party.

23.5 A waiver of any right or remedy under the Contract or by law is only effective if given in writing and shall not be deemed a waiver of any subsequent breach or default. A failure or delay by a party to exercise any right or remedy provided under the Contract or by law shall not constitute a waiver of that or any other right or remedy, nor shall it prevent or restrict any further exercise of that or any other right or remedy. No single or partial exercise of any right or remedy provided under the Contract or by law shall prevent or restrict the further exercise of that or any other right or remedy.

23.6 If any provision or part-provision of the Contract is or becomes invalid, illegal or unenforceable, it shall be deemed modified to the minimum extent necessary to make it valid, legal and enforceable. If such modification is not possible, the relevant provision or part-provision shall be deemed deleted. Any modification to or deletion of a provision or part-provision under this clause 23.6 shall not affect the validity and enforceability of the rest of the Contract.

23.7 Any notice or other communication given to a party under or in connection with the Contract shall be in writing, addressed to that party at its registered office (if it is a company) or its principal place of business (in any other case) or such other address as that party may have specified to the other party in writing in accordance with this clause, and shall be delivered personally, sent by pre-paid first class post or other next working day delivery service, commercial courier, or email. A notice or other communication shall be deemed to have been received: if delivered personally, when left at the address referred to in this clause; if sent by pre-paid first class post or other next working day delivery service, at 9.00 am on the second Working Day after posting; if delivered by commercial courier, on the date and at the time that the courier’s delivery receipt is signed; or, if sent by email, one Working Day after transmission. The provisions of this clause shall not apply to the service of any proceedings or other documents in any legal action.

23.8 All Contracts shall be non-exclusive and shall not confer any distribution or agency rights unless otherwise specifically agreed in writing.

23.9 A person who is not a party to this Contract has no right under the UK Contracts (Rights of Third Parties) Act 1999 to enforce any terms of the Contract.

23.10 The parties agree that electronic signatures as defined in Regulation (EU) 910/2014 on electronic identification and trust services for electronic transactions in the internal market (“**EU eIDAS**”), and in EU eIDAS to the extent that it was retained in UK law under the European Union (Withdrawal) Act 2018 and amended by The Electronic Identification and Trust Services for Electronic Transactions (Amendment etc.) (EU Exit) Regulations 2019 (“**UK eIDAS**”) shall have the same legal force and effect as original signatures.

23.11 The Contract and any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with it or its subject matter or formation shall be governed by and construed in accordance with the laws of England and Wales.

23.12 Each party irrevocably agrees that the Courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with the Contract or its subject matter or formation.

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