

General Terms of Sales and Delivery of Roche Diagnostics Deutschland GmbH

(hereinafter referred to as "Roche")

As of September 1st, 2025

1. General – Scope

- 1.1 The General Terms of Sale and Delivery listed below apply to all sales of Roche's products and services unless otherwise provided for in these terms, other terms are provided for in the text of the order confirmation or a different agreement has been reached in an individual agreement between the parties. In addition, the INCOTERMS of the International Chamber of Commerce in Paris, as applicable at the time when the supplies and services are being provided, apply to any cross-border transaction.
- 1.2 Any of the Buyer's general terms of business which may deviate from or contradict these terms are hereby explicitly waived. They will not become part of the contract unless Roche consents to their applicability expressly and in writing on an individual basis.
- 1.3 These General Terms of Sale and Delivery shall also apply if Roche makes delivery without reservation despite being aware of conditions of the Buyer which contradict or deviate from these terms of business.
- 1.4 All agreements concluded between Roche and the Buyer on the sale of goods must be made in writing. This also applies to the parties' waiver of the written form requirement.

2. Prices, Ordered Quantities and Delivery Deadlines

- 2.1 All deliveries and purchase prices are ex works. All prices are net and plus value-added tax at the legally valid rate.
- 2.2 All listed prices (including any discounts) and other conditions listed in catalogues, brochures and price lists merely reflect the status on their date of issue. Orders placed by the Buyer shall be in accordance with the prices and conditions valid on the day of receipt of the order by Roche. Roche will notify the Buyer of the prices and conditions currently applicable.
- 2.3 Orders are placed electronically in a standardized data format via the usual providers or via the e-ordering solutions offered by Roche.
- 2.4 For order that are not transmitted electronically, Roche reserves the right to charge the purchaser for any additional expenses incurred.
- 2.5 There are no fixed delivery deadlines. Delivery dates are non-binding. They only become binding if Roche has confirmed them in writing.
- 2.6 Roche's deliveries are subject to correct and timely delivery from its suppliers.

3. Packaging and Shipment

- 3.1 Packaging materials will be taken back and disposed of within the scope of Roche's legal obligations under the provisions of the German Packaging Regulation (*Verpackungsverordnung*), as amended from time to time. Even if sales packaging is not marked with the recycling symbol "*Der Grüne Punkt*", it will in general be disposed of by Der Grüne Punkt - Duales System Deutschland AG (DSD). Sales packaging containing harmful substances will be disposed of by respective service provider. The Buyer must ensure that sales packaging is completely emptied before it is taken to a DSD collection point or – in case of packaging containing harmful substances - handed over to respective service provider.
- 3.2 If Roche uses reusable load carriers (RLCs) to supply the Buyer, one of Roche's system partners will pick up the RLCs in coordination with the Buyer, depending on the quantity. The Buyer consents to have the RLCs disposed of by one of Roche's system partners and/or their auxiliary personnel per separate arrangement within usual working hours. The Buyer declares his willingness to store the RLCs properly prior to pick up and to make them available for pick up in general on the second working day after delivery, but no later than 14 days thereafter.
- 3.3 The Buyer is obliged to handle the RLCs carefully, to protect them from contamination, damage and loss and to use them solely for the transport and storage of the delivered goods within his own business premises. The Buyer is also obliged to check the information given by Roche's system partner regarding the type and quantity of RLCs delivered or picked up. If the Buyer fails to give notification of an error in this information within an appropriate period of time the details given will be binding upon the Buyer. This shall only be the case if the Buyer has been informed by the system partner in advance that a failure to notify of erroneous information might have such legal effect.
- 3.4 Roche reserves the right to select the type of delivery. Roche charges a flat-rate shipping fee per customer order in accordance with the DiaDirekt price list valid at the time of the order. Irrespective of a minimum order value and the number of deliveries, the flat-rate shipping fee shall only be charged once per order and consignee. For subsequent and partial deliveries arranged by Roche due to a complaint, bottleneck or underdelivery, no flat-rate shipping fee shall be charged. In addition, Roche charges a flat rate for dry ice shipments and special logistical services.
- 3.5 Analysis systems are always delivered ex works at the expense of the Buyer. Set-up or assembly are charged separately, and are subject to the General Terms and Conditions for Services of Roche. If the Buyer has any special dispatch requests (e.g. express goods, fast freight, express courier package, air mail, etc.), delivery will be ex works at the expense of the Buyer without any prepayment of postage by Roche.

4. Transfer of Software Programs

- 4.1 To the extent services of Roche (also) comprise software programs (computer programs), the Buyer is granted the non-exclusive, perpetual and geographically unrestricted right to make use of the software program in the object code and for the contractual and agreed purpose. This also applies to any modification to programs by Buyer, which however is only permitted if it serves to remove defects and is not carried out by Roche against reasonable remuneration or free of charge.
- 4.2 Decompilation is only allowed if required under statutory law and when Roche does not make, or has not made, available the information required for establishing interoperability of an independently developed computer program even though the Buyer has requested Roche in writing to do so. In such a case the information is limited to those parts of the original program which are necessary to ensure interoperability.
- 4.3 The Buyer is obliged to inform Roche about any defect or error he has found in the software program, even if such defect or error does not impair the intended use of the software program.
- 4.4 Copyright information, serial numbers or any other identification feature must never be removed.

5. Limitations of Use

- 5.1 Deliveries from Roche might contain products, which are limited in their use by the Customer due to patent or license restrictions. Details of such limitations can be found in the respective catalog, the respective package insert or, if applicable, Roche's websites. They can further be obtained from Roche prior or subsequent to execution of the contract.
- 5.2 The products may be operated or used exclusively in accordance with the intended use, specifications and the indication/field of use as defined in the package insert and the operator manual ("Intended Use"). The products may not be altered, nor combined with other products / parts beyond the Intended Use. The Intended Use also comprises the labeling for Research Use Only and for General Laboratory Use. The Buyer is liable for any changes made to the product after purchase. Roche does not assume any liability to the Buyer or ensure any legal or regulatory compliance concerning products which were operated or used and / or changed and / or combined with other products / parts.

6. Risk of Loss

6. Upon dispatch (including freight-free delivery), the risk of perishing, loss or damage of the goods is transferred to the Buyer upon handing over to the person charged with their consignment, and in the event of default on the side of the Buyer (*Annahmeverzug*) not later than on occurrence of the default.

7. Force Majeure, Contractual Obstacles

7. Force Majeure of all kinds, unforeseeable disturbances to operations, transport or dispatch, fire damage, flooding, unforeseeable shortages of power, energy, raw materials or auxiliary materials, strikes, lock-outs, epidemics, pandemics, war, official orders and other impairments not attributable to the party obliged to perform, which delay or prevent manufacture, shipment, delivery and acceptance or render them unreasonable shall exonerate the party affected from its obligation to make delivery/acceptance for the duration and extent of the disturbance. This also applies if these circumstances occur with suppliers. The above-mentioned circumstances can also not be blamed on the party obliged to perform if they occur during an already existent default. If delivery or acceptance is delayed by more than 8 weeks as a result of the disturbance, both parties are entitled to rescind from the agreement without being entitled to claim for damages.

8. Notification of Defects and Claims Based on Defects

- 8.1 Roche and the Buyer will perform their contractual duties with the diligence of a prudent businessman. The Buyer must examine incoming goods carefully regarding quantity, condition and defects immediately upon receipt. He must notify Roche of obvious defects in writing to the address of Roche Diagnostics Deutschland GmbH, Sandhofer Str. 116, 68305 Mannheim immediately, but no later than 5 calendar days after receipt of the goods, stating the invoice number and date of receipt. Notification of hidden defects must also be given immediately, not later than within 5 calendar days of their being detected.
- 8.2 To enable the counterchecking of the complaint, on Roche's request the Buyer must either send Roche documentary evidence, such as bills of delivery and packing slips in the original or as a copy, and inform Roche of any markings on the packaging, or send the goods back to Roche for correct and proper rectification of the defects.
- 8.3 If notification of defects is justified, given duly and in the proper manner, Roche will be held liable for defects for a period of 12 months beginning with the delivery of the new or used products. In his notification of defects the Buyer shall provide for a description of the defect such as to enable Roche to recon-

- struct the defect. The regular statutory three-year limitation period will apply if Roche has fraudulently concealed the defect.
- 8.4 If defective goods are delivered, Roche in its own discretion can either rectify the defects or make a replacement delivery (subsequent fulfillment). Roche is entitled to repeat the subsequent fulfillment if it has failed. Roche can refuse to perform subsequent fulfillment if it involves unreasonable costs for Roche.
- 8.5 Claims by the Buyer for defects are excluded if the defects are insignificant. An insignificant fault is considered in particular to exist if the value of the goods or their suitability for normal use is only reduced to an insignificant extent.
- 8.6 If subsequent fulfillment has failed, been refused or cannot be reasonably expected, or if the Buyer has set Roche an appropriate deadline for subsequent fulfillment which has not been met, or if it is not necessary to set a deadline, the Buyer is entitled to demand reduction of the purchase price or rescind from the contract. The right to demand compensation or indemnification for expenses without avail shall remain unaffected.
- 9. Withdrawal and Compensation instead of Performance**
- 9.1 If Roche fails to effect a due performance or the performance is not in accordance with the terms of contract ("breach of contract"), the Buyer is only entitled to rescind from the contract or claim for damages in lieu of performance if,
- the breach of contract by Roche is not insignificant,
 - he has requested Roche in writing to effect the performance within an appropriate deadline of at least 14 days, and
 - Roche has still not effected the performance within this set period.
- 9.2 This Section 9 does not affect any legal regulations
- in cases where the setting of a deadline is not required (i.e. when the obligor seriously and finally refuses performance; if circumstances justifying immediate assertion are existent; in case of fixed-date transactions; if the obligor is not obliged to perform as performance is impossible or the obligor is not able to perform and, as a result, the obligee is entitled to rescind from the contract; Section 323, Paragraph 2, Section 326, Paragraph 5, Section 281, Paragraph 2 German Civil Code);
 - in cases where, as a result of the type of the breach of contract, a warning is required in lieu of setting a deadline (Section 323, Paragraph 3, Section 281, Paragraph 3 German Civil Code);
 - in cases where recession is permissible even before due date (Section 323, Paragraph 4 German Civil Code);
 - in cases where, despite partial performance provided, recession from the overall performance is permissible (Section 323, Paragraph 5 German Civil Code);
 - in cases where recession is excluded (Section 323, Paragraph 6 German Civil Code);
 - in cases where the claim for performance is excluded due to claims for damages (Section 281, Paragraph 4 German Civil Code); as well as regarding the right of the obligor to claim the return of the performance provided in case that damages in lieu of performance are claimed (Section 281, Paragraph 5 German Civil Code).
- When setting deadlines it is of particular importance that the due performance for which the deadline has been set be described in detail (qualified setting of deadlines).
- 9.3 In the event that Roche has failed to perform within the deadline set by the Buyer or if the performance effected is not in accordance with the terms of contract, Roche can set an appropriate deadline by which the Buyer must declare whether he continues to insist on the effecting of the performance. Roche is not then obliged to effect the performance until the Buyer has reached a decision.
- 9.4 In cases of sales transactions of consumer goods the rights of the Buyer as under Sections 478 (Recourse of Entrepreneur) and 479 (Limitation of claims asserting a right of recourse) German Civil Code remain unaffected.
- 10. Liability**
- 10.1 Roche's liability – irrespective of the legal ground – shall be limited to cases where the damage was caused by slightly negligent infringement of an essential contractual obligation or by gross negligence or intent on the side of Roche.
- 10.2 If Roche is held liable for an infringement of an essential contractual obligation without the existence of gross negligence or intent, liability shall be limited to the extent of the damage which Roche could typically expect to arise at the time the contract was signed on the basis of the circumstances of which it was aware at this point in time.
- 10.3 Damage claims in accordance with the (German) Product Liability Act (*Produkthaftungsgesetz*) and the (German) Pharmaceuticals Act (*Arzneimittelgesetz*) and those due to the injury of life, limb and health or the assumption of a guarantee remain unaffected.
- 10.4 If the liability of Roche is excluded or limited, this shall also apply to the personal liability of its employees, representatives and vicarious agents.
- 10.5 Roche will not be held liable for the consequences of incorrect modification or treatment of the goods nor – particularly where medical technology devices are concerned – for the damage caused through the use of unsuitable reagents, nor for the consequences of inadequate maintenance on the part of the Buyer or a third party, and not for any defects attributable to normal wear and tear or transport.
- 10.6 Claims against Roche based on defects and the liability of Roche are excluded in particular for damages and the consequences thereof caused by the Buyer using the supplied hardware or software in combination with any hardware or software or any other components not tested and released by Roche. The same applies to any modification to hardware or software provided by Roche. This Section 10.6 does not apply to the extent Roche has previously agreed in writing to such action or use.
- 10.7 For any loss of data and programs and their recovery Roche can also only be held liable within the scope of this Section 10. The liability of Roche for such damage is excluded if and to the extent this damage is attributable to the fact that the Buyer did not take appropriate precautions against loss of data, in particular by making back-up copies of all programs and data. Back-up copies must be made at the time intervals customary in the Buyer's field of activity, however at least once a day.
- 11. Invoicing and Payment**
- 11.1 Invoices are sent to the buyer electronically in a standardised data format (currently: Zugferd, X-invoice, PDF invoice). Alternatively, it is also possible to send an invoice in paper form. Roche reserves the right to charge the purchaser for any additional expenses incurred.
- 11.2 Payment must be made within 30 calendar days from the date of invoice.
- 11.3 If payment is made within 10 calendar days from the date of invoice by check, per bank transfer or SEPA business-to-business direct debit, Roche will grant the Buyer a cash discount of 1.5 %. This discount will not be granted on usage fees, installment payments for service prices and service fees, nor if the Buyer is in arrears with the payment of an earlier invoice. With non-cash payments, the day on which the sum is finally credited to Roche's account shall be regarded as the time of receipt of payment.
- 11.4 Roche reserves itself the right to use payments to settle the oldest due outstanding accounts plus the default interest and costs accrued thereon; this will be done in the order of costs, interests, due receivables.
- 11.5 The Buyer can only offset against claims by Roche by means of a written declaration to Roche if his counterclaim is uncontested or a non-appealable title has been obtained.
- 11.6 The assertion of a right of retention due to counterclaims which are either unacknowledged or have not become res judicata is excluded provided that these claims do not arise from the same contractual relationship.
- 11.7 Roche has the right to refuse performance if after conclusion of the contract it becomes apparent that its claim for payment of the delivery is jeopardized by the Buyer's poor financial standing. This right to refuse performance shall cease once payment has been made or the Buyer has put up adequate collateral. Roche has the right to set the Buyer an appropriate deadline within which the Buyer has either to make payment upon tender of delivery, or provide collateral for the delivery. Once the deadline has expired without success, Roche has the right to rescind from the contract. In addition, Roche has the right in the above-mentioned event of the deterioration of the Buyer's assets, to deliver the goods only on the basis of advance payment or the provision of appropriate collateral.
- 12. Delayed Payment**
- 12.1 If the Buyer is in default of payment, a check cannot be properly cashed, the balance is not provided in the SEPA business-to-business direct debit system or a significant deterioration of the debtor's assets occurs, all open claims – including any deferred claims of Roche against the Buyer – shall become due for immediate payment.
- 12.2 Should the Buyer be in default of payment or if he exceeds the period allowed for payment in a mutual commercial transaction, interest will be charged at a rate of 9 percentage points p.a. above the currently valid base interest rate (*Basiszinssatz*). Roche reserves the right to claim further damages.
- 13. Retention of Title**
- 13.1 Roche retains title to delivered goods until all payments resulting from the business relation with the Buyer have been received. Title of Roche also extends to the new products created through the processing of the reserved goods. The goods are processed for Roche as the manufacturer. If they are processed, connected or mixed with items that do not belong to Roche, Roche will acquire co-ownership at the ratio of the invoice value of its reserved goods to the invoice values of the other materials.
- 13.2 The retention of title will remain in effect even if the relevant claim(s) of Roche is (are) included in a current invoice and the balance has been struck and recognized.
- 13.3 If the Buyer is in breach of contract, especially as regards default of payment, Roche is entitled to rescind from the contract and take back the goods. The seizure of the reserved goods by Roche always means the declaration of recession from the contract.
- 13.4 The Buyer must take care of the reserved goods. He is obliged to insure them sufficiently at his own costs at their purchase value against fire, water damage and theft, and transfers his compensation claims from these insurance policies to Roche here and now.
- 13.5 In the event of seizure or other intrusions by third parties, the Buyer must notify Roche in writing without delay to enable Roche to bring in third-party action (*Drittwiderspruchsklage*) against execution as provided under Section 771 German Code of Civil Procedure. To the extent the third party is not in a position to refund Roche the judicial and extra-judicial costs of a legal action as provided under Section 771 German Code of Civil Procedure the Buyer will be held liable for any loss incurred by Roche.
- 13.6 The Buyer is entitled to resell the goods in the course of orderly business, but it assigns to Roche here and now all claims to the amount of the invoice value (including VAT) resulting from the sale of the goods, including the bills of exchange and checks provided as security for each claim. If goods are sold to which Roche has the right of co-ownership, the assignment is limited to the percentage of its share in the joint product. The Buyer shall remain entitled to recover these claims, even after the assignment. This does not affect Roche's entitlement to recover the claim itself. Roche is obliged, however, not to recover the claim as long as the Buyer meets its payment obligations towards Roche, does not get into default of payment and, in particular, no application for the opening of insolvency proceedings has been lodged. If this is the case,

- Roche is entitled to demand that the Buyer notify him of the assigned claims and their debtors, provide him with all of the information required for collection, hand over the related documentation and notify the third parties of the assignment.
- 13.7 If the delivered object is delivered as agreed to a destination outside the Federal Republic of Germany or transported by the Buyer to such destination, the following provisions have priority over Sections 13.1 to 13.6: The Buyer undertakes to effectively protect Roche's retention of title in the country where the delivered object is or where it is delivered to. To the extent specific action is required (e.g. special labeling of the delivered object or any local registration), the Buyer is obliged to carry out such action in favor of Roche. If any cooperation of Roche is required, the Buyer informs Roche immediately. Moreover, the Buyer informs Roche about any material circumstances of relevance to provide the widest range of protection of Roche's ownership. In particular, he makes all documents and information available to Roche which are required to enforce these ownership rights. The provisions of this Section 13.7 apply accordingly if under the competent legislation a retention of title cannot be effectively agreed upon at the place where the delivered object is located, to put Roche into a legal position in which its interests and claims are protected in an equally effective or other appropriate manner, to the extent legally possible.
- 14. Resale and Provision**
- 14.1 The Buyer is obliged to comply with the (German) Act Against Unfair Competition (*Gesetz gegen den unlauteren Wettbewerb*) and, if applicable, with the regulations for medicinal products when reselling or providing the goods.
- 14.2 He is not permitted to utilize any of Roche's protected trademarks for goods manufactured by third parties or processed original goods without obtaining the prior express written consent of Roche.
- 14.3 The Buyer is obliged to sell or provide the supplied goods only in their completeness (i.e. including packaging, insert, operating manuals, warning instructions, etc.). Clinic packs are intended for use in hospitals and may only be sold further as a whole and not in sub-quantities and only with their original seal. Exceptions to this are deliveries made within the scope of an officially approved supply contract in accordance with Section 14 German Pharmacy Act (*Apothekengesetz*). The supply of other Buyers with clinic packs is only permitted on the condition that these Buyers only resell the clinic packs to hospitals or dispensaries as provided under Section 14 German Pharmacy Act.
- 14.4 The Buyer understands that goods or supplied objects (and the know-how as may be contained in such goods or objects) may be subject to an export or import control. Either contract party bears the responsibility to comply with the relevant export and import control regulations. Moreover, the Buyer understands that the US export control laws also apply if the goods or supplied objects, or parts thereof, are of US origin. This may happen even if the contract does not include any further relation to the United States.
- 15. Confidentiality**
- 15.1 Both contracting parties undertake to treat the information and documents made accessible to them by the other contracting party within the scope of this agreement as strictly confidential for the duration of this agreement and thereafter and not to make them accessible to third parties as long as and insofar as they have not become public knowledge through no fault of their own.
- 15.2 The customer further undertakes to use the information made available exclusively for the purposes provided for in this agreement and not to exploit it commercially or in any other way without the express prior written consent of Roche.
- 15.3 The confidentiality obligations shall not apply if and to the extent that the receiving party can prove that the information in question:
- were generally known at the time of disclosure or become generally known through no fault of the receiving contracting party, or
 - was already demonstrably available to the receiving contracting party at the time of disclosure (on the basis of written documentation), or
 - were developed independently, without reference to or on the basis of the information to be kept secret, or
 - was duly disclosed by order of a public authority or court or must be disclosed by law or for the purposes of health and price registration of the contractual product.
- 15.4 The customer undertakes to include persons consulted in the above-mentioned confidentiality obligation.
- 16. Foreign Trade**
- Foreign Trade Controls. The Parties agree that all Products, including software and technology, delivered may be subject to foreign trade controls. The Buyer shall strictly comply with all applicable national and U. S. laws and regulations for the control of import, export/ re-export, transfer, brokering and transit. Prior to any transfer of Products, The Buyer shall in particular guarantee that all necessary import and/or export licenses are obtained as may be required throughout the duration of this Agreement.
- 17. Place of Performance and Jurisdiction, Applicable Law, Miscellaneous**
- 17.1 The place of performance is Mannheim.
- 17.2 The exclusive place of jurisdiction for all disputes between the parties arising from or in connection with this contract or their business relations is Mannheim.

- 17.3 The legal relationships of the parties arising from or connected with this contract are subject to the Law of the Federal Republic of Germany. The United Nations Convention on Contracts for the International Sale of Goods of 11 April 1980 does not apply.
- 17.4 Should any of the individual provisions of this contract be or become completely or partially invalid or void, this will not affect the validity of the remaining provisions. Such invalid or void provisions shall automatically be replaced by a legally effective regulation which comes closest to the economic purpose. The same applies to any gap.

Annex: Data Sharing Terms

Regulation (EU) 2023/2854 ("Data Act") aims to promote sharing of data generated by or in relation to products connected to the internet. To this end, it grants users of such products and related services new rights, i.e. to access data directly or via the data holder and to share data with third parties. This set of terms is meant to address this condition and related contractual matters that may arise between the Data Holder - as defined by the Data Act - (hereinafter "ROCHE") and the "User" - as defined by the Data Act - (hereinafter "CUSTOMER").

1. Agreed use of non-personal Data

- 1.1 The data covered by these terms consists of any readily available Product Data or Related Service Data within the meaning of the Data Act (the 'Data').
- 1.2 ROCHE and Roche Affiliates will use the Data that are non-personal Data only for the purposes agreed with the CUSTOMER as follows:
- performing any agreement with the CUSTOMER or activities related to such agreement (e.g. issuing invoices, generating and providing reports or analysis, financial projections, impact assessments, calculating staff benefit, workflow efficiency);
 - monitoring and maintaining the functioning, safety and security of the Product or Related Service and ensuring quality control;
 - improving the functioning of any Product or Related Service offered by ROCHE;
 - providing support, warranty, guarantee or similar services (incl. targeted communication) or to assess CUSTOMER's, ROCHE's or third party's claims related to the Product or Related Service;
 - developing new products or services and improving operational efficiency;
 - aggregating these Data with other data or creating of derived data, for any lawful purpose, including making available such aggregated or derived data to third parties, provided such data do not allow specific data transmitted to ROCHE from the connected product to be identified or allow a third party to derive those data from the dataset.

As the manufacturer or distributor of a medical device, ROCHE is subject to elevated requirements for monitoring the functionality of its products, including reporting obligations. This vigilance system required for regulatory purposes may also involve the processing of Data.

- 1.3 ROCHE and Roche Affiliates will not use the Data:
- to derive insights about the CUSTOMER's economic situation, assets and production methods of the CUSTOMER, or in any other manner that could undermine the commercial position of the CUSTOMER on the markets in which the CUSTOMER is active; or
 - in a manner that is otherwise significantly detrimental to the legitimate interests of the CUSTOMER, in particular when such Data contains commercially sensitive data or are protected by trade secrets or by intellectual property rights.

2. Direct Data access from the Product or Related Service

The CUSTOMER may access Data directly from the Product or Related Service as far as this is foreseen by the design of the Product or Related Service, in accordance with the information given to the CUSTOMER by ROCHE.

3. Data access by the CUSTOMER upon request

- 3.1 Where the Data cannot be accessed directly from the Product or Related Service, the Data, together with the relevant metadata necessary to interpret and use those Data shall be made accessible to the CUSTOMER by ROCHE, at the request of the CUSTOMER or a party acting on its behalf. ROCHE provides the necessary information on the modalities of such a request at <https://go.roche.com/eu-data-act>.
- 3.2 If the CUSTOMER considers the access right under Article 4 (1) Data Act to be infringed, the CUSTOMER is entitled to lodge a complaint with the competent authority, designated in accordance with Article 37 (5), point (b) of the Data Act.

4. Data sharing with a third party upon the CUSTOMER's request

- 4.1 The Data, together with the relevant metadata necessary to interpret and use those Data, shall be made available to a Data Recipient (as defined by the Data Act) by ROCHE, upon request presented by the CUSTOMER or a party acting on its behalf. ROCHE provides the necessary information on the modalities of the request at <https://go.roche.com/eu-data-act>.
- 4.2 Where the CUSTOMER submits such a request, ROCHE will agree with the Data Recipient (as defined by the Data Act) the arrangements for making the Data available under fair, reasonable and non-discriminatory terms and in a transparent manner in accordance with the Data Act. The CUSTOMER acknowledges that from such a request a third party considered as a gatekeeper cannot benefit under Article 3 of the Regulation (EU) 2022/1925 and does not apply in the context of the testing of new connected products that are not yet placed on the market.
- 4.3 When the CUSTOMER is not the data subject under the Regulation (EU) 2016/679,

- ROCHE may not make the Data which are personal data available to the CUSTOMER or to a Data Recipient, following a request from the CUSTOMER, unless there is a valid legal basis for this purpose under Article 6 of Regulation (EU) 2016/679 and unless, where relevant, the conditions set out in Article 9 of that Regulation and of Article 5 (3) of Directive (EU) 2002/58 are met;
- the CUSTOMER may only use Data which are personal data, share them with third parties or otherwise process them to the extent permitted under Regulation (EU) 2016/679 and, where relevant, Directive 2002/58/EC.

In that respect, the CUSTOMER must indicate to ROCHE, in each request the legal basis for processing under Article 6 of Regulation (EU) 2016/679 and, where relevant, the applicable derogation under Article 9 of that Regulation and Article 5 (3) of Directive (EU) 2002/58 upon which the making available of Product Data and/or Related Service Data is requested.

5. Protection of trade secrets

- 5.1 Where the CUSTOMER submits a request for data access, the parties must agree on protective measures, when the Data or metadata to be shared contain trade secrets within the meaning of the Trade Secrets Directive, held by ROCHE or another trade secret holder within the meaning of the same directive.
- 5.2 These protective measures, as well as the related rights agreed in this agreement, apply exclusively to Data or metadata included in the Data to be shared by ROCHE with the CUSTOMER, and which were brought to the attention of the CUSTOMER (referred to below as '**Identified Trade Secrets**').
- 5.3 The protective measures remain in effect after any termination or expiration of the agreement, unless otherwise agreed by the parties.
- 5.4 Before the Data is made accessible to the CUSTOMER, ROCHE may apply any appropriate technical and organisational protection measures to preserve the confidentiality of the shared and otherwise disclosed Identified Trade Secrets.
- 5.5 Where the protection measures do not materially suffice to adequately protect a particular Identified Trade Secret, ROCHE may, by giving notice to the CUSTOMER with a detailed description of the inadequacy of the measures:
- unilaterally increase the protection measures regarding the specific Identified Trade Secret in question, provided this increase is compatible with its obligations under this agreement and does not affect the CUSTOMER, or
 - request that additional protection measures be agreed. If there is no agreement on the necessary additional measures after a reasonable period of time, ROCHE may suspend the sharing of the specific Identified Trade Secret by giving notice to the CUSTOMER and to the competent authority designated pursuant to Article 37 of the Data Act, with copy of this sent to the CUSTOMER.
- 5.6 If, in exceptional circumstances, ROCHE is highly likely to suffer serious economic damage from disclosure of a particular Identified Trade Secret to the CUSTOMER despite the protection measures, ROCHE may stop sharing the specific Identified Trade Secret in question. ROCHE may do this only by giving a duly substantiated notice to the CUSTOMER and to the competent authority designated pursuant to Article 37 of the Data Act, with a copy being sent to the CUSTOMER.
- 5.7 If the CUSTOMER fails to implement and maintain agreed protective measures for Identified Trade Secrets, ROCHE is entitled to withhold or suspend the sharing of the specific Identified Trade Secrets, until the CUSTOMER has resolved the incident. ROCHE must, without undue delay, give duly substantiated notice to the CUSTOMER and to the competent authority designated pursuant to Article 37 of the Data Act, with a copy sent to the CUSTOMER.

6. Unauthorized use and/or disclosure by the CUSTOMER

- 6.1 The CUSTOMER undertakes not to engage in the following:
- use the Data received to develop a connected product that competes with the Product, nor share the Data with a third party with that intent;
 - use such Data to derive insights about the economic situation, assets and production methods of the manufacturer or, where applicable, ROCHE;
 - use coercive means to obtain access to Data or, for that purpose, abuse gaps in ROCHE's technical infrastructure data which is designed to protect the Data;
 - share the Data with a third-party considered as a gatekeeper under Article 3 of Regulation (EU) 2022/1925;
 - use the Data received for any purposes that infringe EU law or applicable national law.
- 6.2 Furthermore and in accordance with Article 4 (2) of the Data Act, the CUSTOMER and ROCHE may agree to restrict the processing, which could undermine security requirements for the Product, as laid down by EU or national law, resulting in a serious adverse effect on the health, safety or security of natural persons.
- 6.3 ROCHE may apply appropriate technical protection measures to prevent unauthorized access to Data and to ensure compliance with this agreement. The CUSTOMER agrees not to alter or remove such technical protection measures unless agreed by ROCHE in advance.