

# General Terms and Conditions for Services of Roche Diagnostics Deutschland GmbH

(hereinafter referred to as "Roche")

As of September 1<sup>st</sup>, 2025

## 1. General - Scope

1.1 These General Terms and Conditions shall apply to all services provided by Roche for or in connection with Roche Diagnostics analysis systems and the device software contained therein ("Systems"). They shall apply to both services for Systems covered by a maintenance contract, comfort contract or agreed additional services to a maintenance or comfort contract (each referred to as the "Service Contract") between Roche and the Customer, as well as services based on individual orders of the Customer. They shall not apply insofar as otherwise agreed between the contracting parties in individual contracts. IT-Solutions of ROCHE (e.g. navify®) are not part of these terms and conditions.

1.2 Any of the Customer's general terms and conditions 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 and Conditions for Services shall also apply if Roche unconditionally performs the services despite being aware of terms and conditions of the Customer which contradict or deviate from these Terms and Conditions.

1.4 Any agreements concluded between Roche and the Customer for performing services, in particular the conclusion or amendment of Service Contracts, must be made in writing. This also applies to the parties waiver of the written form requirement.

## 2. Scope of Services

### 2.1 General

The scope and the content of services for systems and device software shall be defined in the relevant Service Contract, the relating specification (if any), as well as the applicable service brochure (available at [www.roche.de/service](http://www.roche.de/service)) and these General Terms and Conditions, each of them forming an integral part of the relevant Service Contract. The scope and content of services not covered by any Service Contract ("Individual Orders") shall be defined in the Individual Order, the applicable service brochure (available at [www.roche.de/service](http://www.roche.de/service)) and these General Terms and Conditions. To the extent the contents of the individual contract parts contradict each other, the following priority order shall apply: Service Contract (with the relating specification, if any) respectively Individual Order and these General Terms and Conditions. The conditions applicable for additional services not included in the Service Contract can be viewed in the "Price List" section under the above link.

In the event of a total economic loss of a system owned by the customer, Roche is not obliged to repair it, even if a comfort contract is in place.

### 2.2 Remote Service Solution

For customers who have concluded a service contract, a remote maintenance solution is available for the systems marked accordingly in the service brochure (available at [www.roche.de/service](http://www.roche.de/service)), which enables remote diagnosis, remote control and remote maintenance in the event of a default by means of direct data communication between the customer's system and Roche. The provision of remote maintenance activities by Roche requires the prior consent of the customer. Within the scope of remote maintenance, Roche shall, in particular, eliminate system malfunctions at the customer's request and, if necessary, restore the availability of the system. If remote maintenance is not possible because the customer does not provide the necessary technical requirements or does not agree to its use, Roche shall invoice any on-site service required for this reason - also within the framework of a comfort contract - at the remuneration rates valid at the time and available in the service brochure (available at [www.roche.de/service](http://www.roche.de/service)).

### 2.3 On-Site Service

On-site assignments shall only be provided if and insofar as they are necessary for technical reasons. The timing of such assignments shall be subject to agreement with Roche.

### 2.4 Limitations of Use

To the extent required by applicable medical device regulations to which the use of the products is subject, the products may only be operated or used in accordance with the purpose, specifications and areas of application as defined in the offer, the respective package insert or operating instructions ("Intended Use"). The products may not be modified or combined with other products/components contrary to the Intended Use. The Intended Use also includes the determination as products for research use only and as general laboratory supplies. If the customer makes any changes to the products, he does so at his own risk. Roche does not assume any liability towards the customer and does not guarantee any legal or regulatory conformity with regard to products that are operated or used contrary to their Intended Use and/or are modified and/or combined with other products/components; this also applies in the event that such modifications are carried out by Roche service employees on the basis of an express order by the customer.

2.5 Roche shall be entitled to entrust any subcontractor with the provision of Services.

2.6 Roche is authorized by the customer to collect, process and use non-personal data (such as for example performance data of the analytical systems used).

2.7 Roche will provide the following services only upon written agreement (cost estimate) and at the remuneration rates valid at the time and available in the service brochure (available at [www.roche.de/service](http://www.roche.de/service)):

a) Elimination of failures attributable to Force Majeure, negligent or willful conduct of the Customer or any third party, in particular improper use and the use of the Systems for purposes other than defined in the System description and operating instructions. This shall also apply to the use of reagents, operating materials, auxiliaries and other components not complying with the specifications of Roche or not being compatible with the System as well as in the case of unauthorised modifications of the software.

b) Activities for which the Customer has received instructions as can be demonstrated by means of training and instructions records, and the execution of which can be reasonably required from the Customer. In particular, this shall apply to activities in connection with the use of reagents, consumables and spare parts indicated as saleable items in the current Roche price lists or specified as maintenance duties of the Customer ("*Wartungsaufgaben des Kunden*") in the relevant user manual.

2.8 If circumstances for which the customer is responsible result in increased service costs (e.g. failure to meet deadlines, only partial participation in training by customer employees, special safety requirements, insufficient parking spaces, etc.), Roche is entitled to charge for the increased service costs and to adjust the response times.

2.9 Any necessary postponements of installation or training dates for which the customer is responsible (e.g. failure to meet the installation requirements) will be charged by Roche per day of delay and scheduled Roche employee at the daily on-site flat rate at the remuneration rates valid at the time and available in the service brochure (available at [www.roche.de/service](http://www.roche.de/service)).

## 3. Provision of Services by Roche and Duty of the Customer to Cooperate

3.1 Any Services are generally solely being performed by service personnel of Roche or subcontractors entrusted by Roche in writing. However, the Customer himself shall be obliged to become active in cases mentioned under 2.7 (b).

3.2 The customer shall ensure the system-specific environmental conditions in accordance with Roche's installation and manufacturer's specifications, provide the necessary supply and disposal facilities in the required quality (e.g. electricity, water and compressed air) and telephone or network access to ensure remote maintenance service on the systems as well as guest Internet access (preferably WLAN) for Roche's service activities.

3.3 If services are to be carried out in areas where X-ray, radioactive or other ionizing radiation is to be expected, the customer must notify Roche hereof in good time in advance. The customer shall comply with all radiation protection obligations arising from the German Radiation Protection Ordinance (*Strahlenschutzverordnung*) under the German Atomic Energy Act (*Atomgesetz*) or the German X-Radiation Ordinance (*Röntgenverordnung*), as amended from time to time, for Service work in the above-mentioned areas.

In pandemic situations, the customer guarantees Roche risk-free access to equipment and a secure laboratory environment for the provision of services. The customer undertakes to provide adequate protective equipment. It is in Roche's discretion to decide whether the customer's safety precautions are sufficient and whether services can be provided.

3.4 The Customer shall ensure that any supplied and/or provided auxiliaries, in particular technical instruments, maintenance schedules as well as manuals and System documentations are available for the performance of Services. If not provided otherwise, any such auxiliaries shall remain the property of Roche. This shall also apply if they are kept at the place of installation.

3.5 Roche shall be entitled in their own discretion to replace or repair defective System components or assemblies. Title to replaced System components and assemblies shall be passed on to Roche.

3.6 Any intended relocation of Systems or connection of other devices require the written consent of ROCHE and must be notified to Roche in writing in good time in advance.

## 4. Payment (Service Remuneration) and Terms of Payment

4.1 The customer shall pay Roche the service fees agreed with the Customer in the respective Service Contract or in the Individual Order. If the specific services are not covered by the Service Contract or are not listed in the service brochure, Roche shall prepare a cost estimate at the customer's request with the remuneration rates valid at the time and available in the service brochure (available at [www.roche.de/service](http://www.roche.de/service)).

Cost estimates up to a net value of € 15,000 are valid without signature by Roche and can be accepted by the customer by informal declaration (telephone, e-mail, fax, letter). Above a net value of € 15,000, a written agreement between the parties is required.

4.2 Within the framework of existing Service Contracts Roche shall be entitled to

- modify the service remuneration in its own discretion by giving the Customer a one-month's written notice in advance. If the Customer does not agree to the new service remuneration, he shall be entitled to terminate the Service Contract within 4 (four) weeks upon receipt of the notice with effect of the date of effectiveness of the modified service remuneration.
- 4.3 Service fees for services for system extensions subsequently included in the Service Contract shall be included in the Service Contract at the remuneration rates valid at the time of inclusion and which can be viewed in the service brochure (available at [www.roche.de/service](http://www.roche.de/service)).
- 4.4 Prices and other conditions in service brochures, catalogs, leaflets and price lists only reflect the status of the respective edition. Individual orders placed by the customer are subject to the prices and conditions valid on the day the order is received by Roche in accordance with the respective valid service brochure (available at [www.roche.de/service](http://www.roche.de/service)).
- 4.5 Individual orders for system maintenance are offered to the customer upon request.
- 4.6 The service fees incurred as part of Service Contracts are invoiced either for a contract year or on a monthly, quarterly or half-yearly basis at the beginning of each billing period, depending on the agreement.
- 4.7 All prices quoted are subject to VAT at the statutory rate. Invoice amounts are payable immediately upon receipt of invoice without deduction.
- 4.8 Roche reserves the right to use payments to settle the oldest claims due plus the default interest and costs accrued thereon, in the following order: costs, interest, claim.
- 4.9 The customer may only offset claims of Roche by written declaration to Roche if his counterclaim is undisputed or a legally binding title exists.
- 4.10 The assertion of a right of retention due to counterclaims that are not recognized or have not been legally established is excluded, unless these claims are based on the same contractual relationship.
- 4.11 Roche has the right to refuse performance if after conclusion of the Service Contract it becomes apparent that the claim for payment is jeopardized by the customer's inability to pay. The right to refuse performance shall lapse if payment is effected or the customer provides appropriate security. Roche has the right to set the customer a reasonable deadline within which the customer must either make payment concurrently with the provision of the service or provide security for the service. If the deadline expires without result, Roche has the right to terminate the Service Contract without notice or, in the case of an individual order, to withdraw from the contract. Furthermore, in the aforementioned case of a deterioration in the customer's financial situation, Roche has the right to provide the service only against advance payment or the provision of appropriate security.
- 5. Late Payment**
- 5.1 If the customer is in arrears with a payment, if a check is not properly cashed, if no settlement is made under the SEPA business-to-business direct debit procedure or if there is a significant deterioration in the debtor's financial circumstances, all outstanding claims, including any deferred claims of Roche against the customer, shall become due for immediate payment.
- 5.2 If the customer defaults on payment or, in the case of a mutual commercial transaction, exceeds the payment term granted, interest shall be due at a rate of 9 percentage points p.a. above the applicable base interest rate (*Basiszinssatz*). Roche reserves the right to claim compensation for further damages.
- 6. Force Majeure, Impediments to Performance**
- 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.
- 7. Liability for Defects**
- 7.1 Within the scope of maintenance contracts, agreed additional services and individual orders, Roche shall perform its services with the diligence of a prudent businessman. There is no liability for defects in this respect.
- 7.2 The liability for defects under comfort contracts and Individual Orders for contracted work shall be subject to the provisions under Sections 7.3. – 7.7.
- 7.3 Roche shall be liable for the defectiveness of the contracted work for a period of 12 months starting from the acceptance of the work, or upon completion if such acceptance is excluded or has not occurred.
- 7.4 Claims of the customer for defects shall be excluded in case of minor faults. Minor faults include, in particular, any minor impairment of the value or fitness for a common purpose.
- 7.5 Claims by the customer 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.
- 7.6 If subsequent fulfillment has failed, been refused or cannot be reasonably expected, or if the customer 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 customer 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.
- 7.7 Any claims for defects shall be excluded if and to the extent (a) Systems have been used or repaired by a person not instructed or not properly qualified, or (b) Systems have been loaded with unsuitable samples, or (c) defects are attributable to the installation or connection of components (hardware and software programs) not provided, tested released by Roche, or d) have been caused by the use of reagents not complying with the quality requirements of Roche or being not compatible with the System. The exclusion of claims for defects as provided under this section shall not apply if the defect is not attributable to circumstances mentioned under (a) to (d).
- 8. Withdrawal and Damages Instead of Service**
- 8.1 The Customer shall not be entitled to rescind from the contract if the contract parties have signed a Service Contract. The termination of Service Contracts shall be subject to the provisions under Section 11.
- 8.2 If Roche fails to effect a due performance or the performance is not in accordance with the terms of contract ("breach of contract"), the Customer 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.
- 8.3 This Section 8 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 232, 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).
- 8.4 In cases of sales transactions of consumer goods the rights of the Customer as under Sections 478 (Recourse of Entrepreneur) and 479 (Limitation of claims asserting a right of recourse) German Civil Code remain unaffected.
- 9. Liability**
- 9.1 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.
- 9.2 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.
- 9.3 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.
- 9.4 If the liability of Roche is excluded or limited, this shall also apply to the personal liability of its employees, representatives and vicarious agents.
- 9.5 The Customer shall be obliged to inform Roche immediately and in detail about any damage. In particular, the Customer shall inform Roche immediately and in detail about cases in which third parties raise claims against the Customer, to give Roche the opportunity to exert its influence on the development of the incidence. Roche shall be entitled to modify on its own account any software programs supplied by Roche in the premises of the Customer to prevent or eliminate any infringement or alleged infringement of third-party industrial property rights.
- 9.6 Roche shall not be held liable for the consequences of any improper modification or handling of Systems, in particular with regard to any damage caused by the use of unsuitable reagents, or the consequences of improper maintenance by the Customer or any third party as well as for damage caused by normal wear and tear.
- 9.7 Claims against Roche based on defects and the liability of Roche are excluded in particular for damages and the consequences thereof caused by the Customer

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 does not apply to the extent Roche has previously agreed in writing to such action or use.

- 9.8 The liability of Roche is particularly excluded if and to the extent that the damage is attributable to the fact that the Customer 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 Customer's field of activity, however at least once a day.
- 9.9 If the Customer is in default of acceptance (*Annahmeverzug*) or violates any other duty of the Customer to cooperate, Roche shall be entitled to claim compensation for the damage incurred by Roche, including extra expenses, if any.

## 10. Confidentiality

- 10.1 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.
- 10.2 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.
- 10.3 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.
- 10.4 The customer undertakes to include persons consulted in the above-mentioned confidentiality obligation.

## 11. Duration of Service Contracts and Termination

- 11.1 Any Service Contract shall be deemed concluded for the term indicated in such Service Contract. Either contract party shall be entitled to terminate a Service Contract to the end of a calendar year by giving six-months' notice, however not before the end of the first year of contract.
- 11.2 Either contract party shall be entitled to terminate the Service Contract without notice for good cause. Such good cause on the part of either contract party shall include, in particular, any violation by the other contract party of a material duty under the Service Contract, which is not remedied within fifteen (15) calendar days upon receipt of a written notification of such violation.
- 11.3 Good causes for Roche to terminate such Service Contract shall include, without limitation,
- payment in arrears of more than thirty (30) calendar days if such due payment has not been made within fifteen (15) calendar days upon receipt of a written reminder; and/or
  - additional Service expenses are incurred, in particular with regard to time and/or materials, caused by (i) the use of Systems by non-instructed persons, (ii) violation of the Customer of his duties as provided under Section 3.1, or (iii) the loading of unsuitable reagents or samples; and/or
  - additional Service expense, in particular with regard to time and/or materials, caused by modifications to Systems, the use of non-compatible or non-approved components or their connection to the Systems, or relocation without the prior consent of Roche.
- 11.4 Any termination to become effective shall be made in writing.

## 12. Data protection

Due to the use of Roche's services by the Customer, both contracting parties are obliged to conclude a data processing agreement (DPA). If no DPA exists between the contracting parties, please send the customer's contact details and a contact person for the DPA to [mannheim.datenschutz-rdd@roche.com](mailto:mannheim.datenschutz-rdd@roche.com) and Roche will be happy to prepare and send a DPA to the customer. Further data protection information can be found in the information letter for RDD customers (available at [Informationsschreiben für RDD-Kunden](#)).

## 13. Place of Performance, Place of Jurisdiction, Applicable Law, Miscellaneous

- 13.1 Any claims and other rights of the Customer resulting from Service Contracts or Individual Orders shall not be assignable without the prior consent of Roche.
- 13.2 The place of performance is Mannheim.
- 13.3 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.
- 13.4 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.
- 13.5 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 consist 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.

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 Telefon: (0621) 759-0  
 Fax: (0621) 759-2890  
[www.roche.de/diagnostik](http://www.roche.de/diagnostik)