

## General Terms and Conditions (“GTC”) Molecular Health MH Guide® (“MH Guide”)

### PREAMBLE

These GTC contain terms and conditions govern the access and use of MH Guide and is an agreement between (i) Molecular Health GmbH, Kurfuersten-Anlage 21, 69115 Heidelberg, Germany (Commercial Register: Mannheim District Court HRB 338037), or as may be stated in the applicable offer, its subsidiary Molecular Health, Inc., a Delaware corporation having its principal place of business at 1 Beacon St, 15th floor, Boston, MA 02108, USA, and (ii) you or the entity or organization that you represent (“Customer”). Molecular Health GmbH and Molecular Health, Inc. are hereinafter collectively referred to as “MH”.

MH Guide is a software developed by Molecular Health GmbH. It annotates complex genetic data from tumor samples from patients and helps to find targeted therapies, immunotherapies and clinical studies for them.

In the EU, MH Guide is approved for clinical use as an in vitro diagnostic (IVD Medical Device) according to Regulation (EU) 2017/746 (IVDR). The modules MH Guide/BRCA (“MH Guide/BRCA”) and MH Guide/Mendel for the analysis of germline mutations (“MH Guide/Mendel”) are components of the IVD Medical Device MH Guide. The quality management system of MH is certified according to ISO 13485 and MDSAP and has been CAP and CLIA accredited since 2016.

The Customer, who is not a consumer within the meaning of §13 BGB (*Bürgerliches Gesetzbuch* (German Civil Code)), intends to acquire a license for the fee-based use of MH Guide via the Internet (*Software as a Service*).

### 1 DEFINITIONS

- 1.1 **User** designates (i) the User of the Medical Device who is acting as the treating physician/pathologist/laboratory physician or (ii) the responsible physician acting as a consulting physician on behalf of the treating physician or (iii) other responsible physician designated by the Customer, provided that the latter has been instructed by MH with regard to the use and application of MH Guide.
- 1.2 **Application** means the intended use of the Medical Device in accordance with the Product Documentation.
- 1.3 **Medical Advice** refers to advice given exclusively by the User to a patient or a treating physician with consideration of all current knowledge of medical science, all rules of medical care and medical professional law with a diagnostic, therapeutic or other background or context that is subject to the physician’s reservation.
- 1.4 **Evaluation** means the summary of the results of the comparison of samples with the databases generated with the aid of the Medical Device in the form of an interactive result, which can be used within the framework and scope of Clause 3.7 of these GTC.
- 1.5 **Treating Physician** means the physician responsible for the treatment of the patient whose Sample is sequenced and then analyzed using the Medical Device.
- 1.6 **Authorized User** means an additional user of MH Guide selected by a User who possesses the professional qualification required for the respective user role in accordance with the specifications of the Product Documentation.
- 1.7 **Data** describes the data volumes generated by sequencing the DNA isolated from a Sample.
- 1.8 **Medical Device** means the database-supported solution to support clinical decisions in oncology or human genetics by means of genomic patient data in the form of the functional unit designated as MH Guide, including the modules MH Guide/Mendel and MH Guide/BRCA.

- 1.9 **Sample** means snap-frozen or formalin-fixed tumor tissue embedded in paraffin and/or blood sample – depending on the commissioned analysis, whereby the tissue sample must be suitable for isolation of a tumor or germline genome of the patient. Samples are made available to the sequencing laboratory qualified according to the Product Documentation via the Customer or the treating physician.
- 1.10 **Product Documentation** refers to the documentation of the Medical Device listed in **Annex A** (*Product Documentation MH Guide*) of these GTC consisting of the (i) Instructions for Use for MH Guide, MH Guide/Mendel and MH Guide/BRCA (*MH Guide Instruction for Use*); the (ii) *MH Guide Product Description*; as well as the (iii) *MH Guide Support Description* in its current version in English.
- 1.11 **Sequencing Laboratory** means a laboratory commissioned with the sequencing of the sample, which must be qualified according to **Annex B** (*MH Guide Sequencing Guidelines*) of these GTC and must comply with the quality requirements for genomic sequencing according to **Annex B** (*MH Guide Sequencing Guidelines*). The Sequencing Laboratory can also be a laboratory of the Customer.
- 1.12 **Storage Space** means the physical or virtual location determined by MH (e.g., in the form of a so-called cloud solution) in which the Medical Device, including the Data, is made available to the Customer by MH and is accessible to the User and Authorized User for use.
- 1.13 **Agreement** is the offer signed by the Customer that together with these GTC and the annexes mentioned herein forms the legal framework for the use of the Contract Products.
- 1.14 **Contract Product(s)** is/are the product(s) of MH specified in the offer that is/are provided to the Customer for use in accordance with the offer. MH and the Customer are hereinafter referred to individually and jointly as “Parties”.

### 2 OFFER AND CONTRACT

- 2.1 Offers and the provision of MH Guide to the Customer are made exclusively with the inclusion of these GTC, unless another written agreement has been expressly made. The GTC also apply to future business relationships.
- 2.2 Deviating, conflicting or supplementary general terms and conditions of the Customer are hereby rejected. These will not become part of the Agreement unless their validity is expressly agreed in writing.
- 2.3 Offers are always non-binding. MH reserves the right to make minor technical deviations from the offer even after acceptance of the offer by the Customer.
- 2.4 The Agreement shall come into effect upon receipt of the order confirmation from the Customer by MH, at the latest upon the establishment of the Customer’s access to the MH Order Portal.

### 3 USE OF THE MEDICAL DEVICE

- 3.1 The Customer is fully responsible for the contractual use of the Medical Device and shall ensure that the Medical Device is used exclusively by sufficiently qualified personnel. In addition to the role of the medically qualified User, the Customer can assign further pre-defined user roles and associated authorizations that support the medically qualified User in the context of his/her use of the Medical Device (MH Guide, MH Guide/Mendel, MH Guide/BRCA). Details of the required qualifications of the medically qualified User, the Authorized User and types and number of user roles are specified in the Product Documentation.
- 3.2 Within the limits of Clause 6 of these GTC, the use of the Medical Device may be made exclusively for the intended purpose and in consideration of the specifications of MH, which are summarized in Product Documentation. The Product Documentation and **Annex B** (*MH Guide Sequencing Guidelines*) are part of these GTC in their current version and are provided for download in the Medical Device,

- among other things. The Customer is aware that the Product Documentation is upon conclusion of this Agreement only available in English. There is no contractual claim to the provision of a translation. If the Customer or the User or the Authorized User deviates from the specifications of the Product Documentation, the Customer shall indemnify MH in the event of a claim with regard to all resulting consequences. This also includes the reimbursement of any costs that must be incurred by MH to eliminate the consequences of incorrect operation by the User or the Authorized User.
- 3.3 In accordance with the specifications of the Product Documentation, the Customer has the right to appoint additional persons as Users or Authorized Users after the conclusion of this Agreement and the determination of a medically responsible User, provided that the respective named person has all qualifications to be fulfilled in accordance with the respective user role. The precondition for the activation of each User account is that the Customer shall first transmit to MH an updated list of the Users selected from the Customer's point of view in accordance with **Annex D** (*List of Users / Authorized Users*) of these GTC together with a declaration signed by the respective User in accordance with **Annex E** (*Declaration of the User / Authorized User*) of these GTC. Each User and each Authorized User is granted their own user account by MH.
- 3.4 The Customer can at any time dismiss a User or Authorized User determined by it. If one of the prerequisites pursuant to Clause 3.1 of this Agreement is omitted, the Customer is entitled to dismiss the User or Authorized User. The dismissal must be declared to MH in writing. After receiving the notification, MH will terminate the dismissed User's or Authorized User's ability to use the Medical Device and block their access data.
- 3.5 MH will process all evaluations commissioned by the dismissed User or Authorized User up to the point in time when the dismissal becomes effective and invoice this in accordance with this Agreement.
- 3.6 In the case of the determination of further Users or the removal of Users or Authorized Users in accordance with Clause 3.3 and Clause 3.4 of these GTC, the Customer shall immediately transmit to MH an updated version of **Annex D** (*list of Users/Authorized Users*) of these GTC, if necessary, together with a declaration of the additional User in accordance with **Annex E** (*declaration of the User/Authorized User*) of these GTC.
- 3.7 The evaluation prepared with the Medical Device serves only as support for finding Medical Advice. The professional assessment of the evaluation is the exclusive responsibility of the medically responsible User. MH is not involved in the communication between the User and, if different persons, the treating physician and the patient.
- 3.8 The medically responsible User must have the necessary license for his/her work (license to practice ; if necessary, specialist examination).
- 3.9 The User and any other Authorized Users must complete training on the intended use of the Medical Device before the Medical Device is used for the first time.
- 3.10 The Sequencing Laboratory commissioned for the sequencing of the Sample will work exclusively and directly for the Customer or the patient and not for MH within the scope of the application. The Data obtained in this way are not part of MH's service. The Customer shall ensure that for the analysis of next-generation sequencing or additional supported genetic and molecular data with the Medical Device, the data will meet the requirements of **Annex B** (*MH Guide Sequencing Guidelines*) of these GTC, as otherwise the high-quality evaluation of the Data by the Medical Device cannot be ensured.
- 3.11 Only Users and Authorized Users who have their own user data are entitled to use the Medical Device using their user data. The Customer is responsible for protecting the user data provided for the use of the Medical Device against access by unauthorized third parties according to the state of the art and to the same extent as its own operational and business secrets. In particular, the Customer shall ensure that standard software for the protection of the IT systems (in particular virus scanners, firewalls, etc.) is (i) installed on the IT systems which are used for initiating and retrieving an analysis with the Medical Device, and (ii) is always up-to-date.
- 4 RESPONSIBILITY OF MH**
- 4.1 MH is the manufacturer within the meaning of the German Medical Devices Act (Section 4, Section 15 MPG (*Medizinproduktegesetz* (German Medical Device Act))) and operator of the Medical Device within the meaning of the German Medical Devices Operator Ordinance (Section 2, Section 2 MPBetreibV, *Medizinproduktebetrieberverordnung* (German Medical Devices Operator Ordinance)).
- 4.2 MH grants the Customer access to the contractual use of the Medical Device in accordance with Clause 6 of these GTC.
- 4.3 MH shall enable access to the Medical Device and the functionality of the Medical Device including maintenance and care (update) according to the state of the art and pursuant to Clause 6 of these GTC.
- 4.4 MH assumes no responsibility for the properties of a Sample obtained from a patient, in particular not with regard to its suitability for sequencing in the context of the application. As part of the application, the data generated by the Sequencing Laboratory can be fed into the Medical Device on behalf of the Customer via an encrypted connection.
- 4.5 Neither the Medical Device nor the evaluation may be made directly and without further medical-technical evaluation as the subject matter of Medical Advice. No medical services are provided by MH. The Parties agree that MH cannot be responsible for the usability of the evaluation of the Medical Device for further medical analysis or as the basis of Medical Advice.
- 5 RESPONSIBILITY OF THE CUSTOMER**
- 5.1 The Medical Device may only be used by the User or by persons who have been selected by or on behalf of the Customer and are sufficiently qualified ("**Authorized Users**"). The Customer shall ensure that the User:
- 5.1.1 has the technical qualifications described in the Product Documentation and maintains them for the duration of the Agreement;
- 5.1.2 complies with all applicable laws, guidelines and ordinances, in particular the medical due diligence obligations, the technically required quality and regulations of the medical professional law.
- 5.1.3 fulfills existing information and documentation obligations to the patients and their relatives on his own responsibility and, if necessary, in cooperation with the Treating Physician.
- 5.2 The Customer shall ensure that all legal requirements relevant for the treatment of the patient at the place of treatment are complied with, in particular with regard to the required information of the patient and the compliance with data protection requirements with regard to all personal data of the patient (to the extent applicable in the sense of the GDPR (General Data Protection Regulation), the German BDSG (*Bundesdatenschutzgesetz* (Federal Data Protection Act)) or social data within the meaning of the German SGB X (*Sozialgesetzbuch X* (Social Security Code X)) or ensures compliance with these by the treating physician; this also concerns, to the extent applicable, any special requirements required by the the German GenDG (*Gendiagnostik-Gesetz* (Genetic Diagnosis Act)) (e.g. §§9, 10, 11 GenDG) for informing and advising the patient and his/her consent in compliance with the physician's reservation for genetic testing. When using MH Guide/Mendel or MH Guide/BRCA, the requirements regarding the genetic counseling of the patient according to GenDG or equivalent provisions of foreign laws must be considered, if applicable. MH will at no time be in direct contact with the patient during the use of the Medical Device.
- 5.3 The Customer guarantees to MH that, prior to the start of use, the patient has, to the extent necessary, effectively declared his/her

consent to the sequencing of his/her Samples and transfer of data in accordance with §8 (2) GenDG or the use of the Medical Device to the extent required for this. The Customer shall ensure that the User informs MH immediately if the patient has revoked his/her consent to use the application. The information and advice that may be required prior to consent must comply with all applicable legal requirements and must include, in particular, the reference to the sequencing of the Samples and use of the Medical Device and a sufficient clarification of the components and the sequence of the application as well as the use of the results of the sequencing generated from this, as well as the evaluation by the Medical Device. The Customer shall ensure that the consent of the treated patient also includes, to the extent necessary, the forwarding of sequencing results (i.e., a genetic analysis) to MH both by the Customer and the sequencing laboratory in accordance with §11 (2) GenDG or equivalent provisions of foreign laws.

## 6 RIGHTS OF USE

6.1 With the conclusion of this Agreement, MH grants the Customer in return for payment of the respectively agreed usage fee, for the duration of this Agreement the non-exclusive and non-transferable and territorially agreed:

- 6.1.1 to use the Medical Device exclusively in accordance with the provisions of this Agreement;
- 6.1.2 to make a request for research via MH Guide, MH Guide/Mendel, MH Guide/BRCA;
- 6.1.3 To gain access to the research results generated by the Medical Device, including filter function, and to use them for treatment purposes.

The Customer shall exercise the right of use in accordance with sent. 1 exclusively by Users and Authorized Users named by the Customer (improper contract in favor of third parties, §328 para. 2 BGB). The Customer is not permitted to transfer the right of use granted under these GTC without the consent of MH or to grant sub-licenses.

- 6.2 Within the framework of the right of use, the Medical Device may only be used by the User or Authorized User (single use) in accordance with the specifications of MH, as described in Clause 6 of these GTC.
- 6.3 The Customer must refrain from, and will oblige the Users and Authorized Users accordingly to refrain from:
  - 6.3.1 copying or modifying the Medical Device,
  - 6.3.2 decompiling the software used for the Medical Device or adjusting it contrary to the terms of use or the Product Documentation,
  - 6.3.3 changing the information and data stored in the databases or adding information and data without MH's consent or downloading, distributing or selling data volumes in an inappropriate scope that is not necessary for the intended use of the Medical Device according to this Agreement,
  - 6.3.4 making the Medical Device or parts thereof accessible to third parties, passing it on to third parties free of charge or selling it in the form of sub-licenses,
  - 6.3.5 installing malware ("virus") into the Medical Device or into parts thereof or otherwise gaining damaging access or interfering with the intended use,
  - 6.3.6 using the Medical Device or parts or components thereof to generate or derive own databases from it, or designing, creating or distributing another Medical Device or parts or components essentially identical to the Medical Device, or
  - 6.3.7 circumventing the restrictions provided for in the Medical Device with regard to use such as access blocks or the like.

6.4 Trademark notices (such as copyright names or brand names) regarding the Medical Device may not be supplemented, changed or removed either in electronic format or in printouts.

6.5 MH processes the personal data received from the Customer for the purpose of providing its contractual obligations. To the extent permitted by law, after anonymization of the data, MH may process these data (i) for scientific or research-related purposes; (ii) for clinical trials and (iii) for quality control, including the improvement of MH products and/or services.

## 7 PRICES AND USAGE FEE

7.1 The prices and term for the Contract Products are determined in accordance with the offer. The usage fee shall be paid to MH for the following individual services:

- 7.1.1 automated transfer of the Data transmitted by the respectively active Sequencing Laboratory;
- 7.1.2 automated review of the quality of the Data;
- 7.1.3 automated import of the data into the Medical Device and commencement of the bioinformatic Evaluation;
- 7.1.4 Notification of the Customer after completion of the result of the Evaluation;
- 7.1.5 Facilitation of access to the Evaluation via the internet application of the Medical Device by the User or Authorized User in accordance with the provisions of this Agreement.

7.2 The usage fee also includes updates of the Medical Device, i.e., such changes to the Medical Device, which result from ongoing maintenance work, improvements or troubleshooting and other measures, are available to all Users of the Medical Device and have no significant new or different features or functionalities compared to the previous version (marked by maintaining the version number and adding a continuous count of the updates such as 2.1). On the other hand, new upgrades of the Medical Device that have significant new or different properties or functionalities compared to the previous version and are identified by a new version number (e.g., X.0) are not included. These can be used if agreement has been reached between the Parties regarding a corresponding adjustment of the usage fee.

7.3 A fee-based Evaluation of the Data transmitted by the Sequencing Laboratory is also carried out for technical reasons if the quality requirements for genomic sequencing specified in **Annex B (MH Guide Sequencing Guidelines)** of these GTC are not met.

## 8 INVOICING

8.1 MH shall invoice the Customer for the Evaluations and any other potentially requested services. For this purpose, MH creates an invoice after providing the Evaluation of MH Guide, MH Guide/Mendel, MH Guide/BRCA, which contains the name of the User or Authorized User who initiated the respective Evaluation.

8.2 To simplify the invoicing process, MH can summarize the usage fees incurred for several analyses in one invoice as individual invoice items.

8.3 The payment term is thirty (30) days after the invoice date; there is no discounting.

## 9 QUALITY, WARRANTY

9.1 The Parties are aware that the Medical Device is a highly innovative diagnostic aid and, in particular, the quality of the Evaluation prepared with the aid of the Medical Device, depends on the quality of the Sample and sequencing by the Sequencing Laboratory. Due to this multitude of factors, the Parties agree that no specific condition can be agreed with regard to the Evaluation and no specific agreement can be made with regard to the medical significance of the

Evaluation. The Parties agree that MH cannot be responsible for the usability and applicability of the Evaluation, for example for further medical analysis or as the basis of medical advice. However, if the usability and applicability of the Evaluation is repeatedly restricted through no fault of the Customer, this constitutes grounds for termination.

9.2 The information stored in the databases is third-party content or information based on third-party content or derived from third-party content for which MH assumes no warranty or liability with regard to its accuracy or completeness.

9.3 During the term of the Agreement, MH shall provide the Customer with the functionality of the Medical Device according to the state of the art, whereby the functionality is described in the Product Documentation. Furthermore, MH shall ensure the technical availability of the Medical Device under the access requirements and the access times as described in the Product Documentation. If the Product Documentation is updated, MH will provide the Customer with a current version electronically via the Medical Device. MH is not responsible for ensuring a functioning data transfer via a communication network, but only owes the provision for use via sufficiently recognized communication networks (state of the art: Internet).

9.4 MH assumes no guarantee or liability in the context and in connection with the sequencing, in particular not for the quality of the Data; the sequencing of the Samples according to the state of the art and compliance with the quality requirements for the genomic sequencing by the Sequencing Laboratory according to **Annex B (MH Guide Sequencing Guidelines)** of these GTC.

9.5 The obligation assumed by MH in section 9.3 of this Agreement with regard to the Medical Device is final. According to this Agreement, possible claims are exclusively due to the Customer and not to the User, who acts exclusively in the interests of the Customer and in the context of his/her employment or contractual relationship for the Customer. In the event of a culpable breach of duty on the part of MH, the Customer has predominantly a claim to rectification of the Medical Device, e.g., by an update of the software.

## 10 MAINTENANCE TIMES

10.1 MH reserves the right to restrict access to the Medical Device for the purposes of maintenance, for the purposes of updating the Medical Device and its components (software, databases, MH-side hardware, etc.) and for other purposes in connection with the provision of the Medical Device at any time at short notice and to the extent required. MH shall inform the Customer by email to the Customer's email address known at the time of conclusion of the Agreement about access restrictions that are expected to not exceed a duration of approximately two hours, at short notice, but within a reasonable period as far as technically possible. Regular maintenance should be preceded by an electronic notice to the User about the planned maintenance time window at least one week before the maintenance-related access restriction.

## 11 FORCE MAJEURE

MH assumes no liability in the event that access to the Medical Device, or the Evaluation is caused by unplanned or unplannable maintenance work, system failures or other events that are not caused intentionally or through gross negligence by MH (such as "virus" or "hacker" attacks, cases of force majeure). This also applies in the event that the communication networks used for the Medical Device, in particular the Internet, are no longer or partially or temporarily no longer usable due to interventions by third parties, strikes or failures of national or regional infrastructures (such as energy supply) or other technical failures.

## 12 DOCUMENTATION OF USE

12.1 Within the framework of the medical diligence obligations with regard to the use of the Medical Device, the Customer shall ensure in

the patient file with regard to all treatment steps, compliance with the documentation obligations.

12.2 The Customer shall inform MH as the operator of the Medical Device about possible or observed defects of the Medical Device. For this purpose, the contact details of the Customer support provided in the Product Documentation must be used.

## 13 COMMISSIONING OF ANALYSES

13.1 MH acts during the Evaluation as a non-medical person and agent of the Customer. An order is the basis of this commissioning. This is triggered in the name and on account of the Customer by the User via the online order form or via SFTP upload of the order of the analysis of a Sample.

13.2 The Sample must be transmitted in conjunction with partial information from the patient file (see also information according to the online order form), for each Sample transmitted to the Sequencing Laboratory with an order number transmitted by MH to the User or the Customer and, if necessary, with another unique identification feature (e.g., barcode).

13.3 The Customer has the option at any time to revoke the commissioning of MH or to discontinue the use of the Medical Device. Furthermore, the Customer has the right at any time to limit the input of Data or the use of the Medical Device in accordance with the instructions of the patient. Insofar as the Customer makes use of the rights of this paragraph, MH assumes no liability whatsoever with regard to the Medical Device or the Evaluation in the cases concerned. Nevertheless, the Customer is obligated to reimburse MH for all additional costs and expenses incurred in connection with a revocation or termination and to pay the usage fee.

13.4 The Customer shall ensure that the commissioning of MH in accordance with these GTC (in particular in accordance with this Clause 13) is carried out in mutual agreement. MH is not responsible for compliance with the Customer's internal organizational provisions and does not have to verify the User's authorization to commission MH according to these GTC. Any knowledge by MH about internal organizational provisions and procedures does not conflict with this regulation.

## 14 PROCEDURE AFTER SEQUENCING OF THE SAMPLES

14.1 The Customer instructs the Sequencing Laboratory to forward the determined data to MH in pseudonymized form after completion of the sequencing, i.e., with the order number assigned by MH to the Customer and, if necessary, a unique identification feature (e.g. barcode) marked to MH.

14.2 MH feeds the Data transmitted by the Sequencing Laboratory into the Medical Device. The Customer shall ensure, to the extent applicable, that the consent of the treated patient also extends to a sufficient extent to the activity of MH as a "commissioned institution" within the meaning of §7 (2) GenDG. MH shall provide the Customer with the archived Data under the pseudonym transmitted by the Sequencing Laboratory and/or communicated by the User. MH is not responsible for ensuring that the pseudonymized Data can be assigned to the respective patient again after use of the Medical Device and creation of the Evaluation. The User has access to the raw data and the program for proper handling in order to check and validate the automatically generated data.

## 15 INDUSTRIAL PROPERTY RIGHTS

15.1 All current and future rights to the Medical Device and to the contractual products, including the associated software and databases, in particular all patented, patentable and non-patentable as well as registered, registerable and non-registerable property rights, including expertise, are the exclusive property of MH, or MH is the owner of the exclusive rights of use. By concluding a contract with the inclusion of these GTC, there is no transfer of rights in any way, with

- the exception of the granting of the right of use as defined in this Agreement.
- 15.2 The Parties mutually undertake not to challenge any existing property rights in favor of one Party in connection with the use of the Medical Device and the Contract Products unless these property rights have been established in violation of the provisions of this Agreement. Insofar as third parties attack property rights in connection with the Medical Device, the Parties shall mutually support each other in the defense against such claims.
- 15.3 The Parties may only use industrial property rights, in particular copyrights and trademark rights, which are the property of the Customer or MH or its exclusive right of use, with the express consent of the respective owner.
- 16 LIABILITY**
- 16.1 Within the framework of the statutory provisions, MH shall be liable without limitation for damages
- 16.1.1 that are based on injury to life, body or health;
- 16.1.2 due to the absence or omission of an assured characteristic or non-compliance with a guarantee;
- 16.1.3 which are based on an intentional or grossly negligent breach of duty or otherwise on intentional or grossly negligent conduct by MH or one of its legal representatives or vicarious agents.
- 16.2 In addition, MH shall be liable under limitation of compensation for foreseeable damages typical for such kind of contracts, for such damages that are based on a slightly negligent breach of material obligations of MH or its legal representatives or vicarious agents. Material obligations are obligations whose fulfillment makes the proper implementation of the Agreement possible in the first place and the Customer may rely on compliance with those.
- 16.3 In the event of a loss of data caused by slight negligence, MH shall only be liable for the damage that would have been incurred by the Customer or the User in the event of proper and regular data backup appropriate to the significance of the data; this limitation shall not apply if the data backup was hindered or impossible for reasons for which MH was responsible.
- 16.4 The aforementioned provisions shall also apply *mutatis mutandis* to the liability of MH with regard to the reimbursement of futile expenses.
- 16.5 Liability under mandatory law (e.g., product liability law) remains unaffected.
- 17 CONFIDENTIALITY**
- 17.1 The Medical Device is an in vitro diagnostic and therefore a Medical Device that MH has developed with considerable time and economic effort and which, according to the mutual understanding of the Parties, is exclusively a business secret attributable to MH. Therefore, the Customer, also with regard to Users and Authorized Users, must ensure that all data (in the general sense) and information relating to the Medical Device, in particular with regard to use and functionality, which are made accessible to the Customer and (in particular) Users and Authorized Users of MH, as well as own business secrets, are protected; this also includes the maintenance of technical security measures adapted to the current state of the art, in particular against unauthorized access by third parties.
- 17.2 The Customer is committed to comprehensively maintaining confidentiality with regard to the Medical Device as well as all commercially, legally, fiscally or technically sensitive or beneficial information of MH that becomes known to the Customer or the respective User or Authorized User during the term of the Agreement (“**Confidential Information**”). Confidential information can be such information that is identified in any way as confidential or protected by law or whose confidential content is obvious. The term includes all illustrative material such as documents, writings, notes, digital records, etc. as well as verbal communications.
- 17.3 In the context of confidentiality, the Customer is prohibited from making the Confidential Information accessible to third parties, in any form whatsoever, or from using it for purposes other than the intended use of the Medical Device as specified in these GTC and the annexes. The aforementioned provision shall not apply, only if and to the extent that the Customer can prove that
- 17.3.1 the Confidential Information is generally publicly accessible at the time of disclosure within the framework of this Agreement, or becomes publicly known after disclosure through no fault of the Customer;
- 17.3.2 the Confidential Information was already available to the Customer in a lawful manner at the time of disclosure within the framework of this Agreement;
- 17.3.3 the Customer has lawfully received the Confidential Information from a third party, and it can be disclosed to others by the third party according to the Customer’s knowledge without breach of a confidentiality obligation; or
- 17.3.4 the Confidential Information was developed independently by the Customer or the User, without reference to the Confidential Information disclosed to them under this Agreement.
- 17.4 Notwithstanding the aforementioned obligations, the Customer may disclose Confidential Information to the extent necessary to comply with the requirements of authorities or relevant laws or provisions, if the Customer has informed MH in good time in advance of such requirements and its intention to disclose, in order to grant MH the opportunity to counteract a disclosure in a timely manner.
- 17.5 The Customer shall inform MH immediately after becoming aware of an imminent or actual breach of confidentiality and take all reasonable measures to prevent or end such a breach – if necessary with the support of MH.
- 17.6 The Parties are entitled to demand the surrender or destruction of all Confidential Information available to the other Party with a notice period of twenty-one (21) days after written request. This does not apply if there is an obligation to retain data by law, under medical professional law or due to official/judicial orders, or if Confidential Information is medically required for further treatment of the respective patient. In the latter case, the further storage of Confidential Information by the Customer and the User is only permitted for the purpose of fulfilling these obligations. Upon request, the Customer must inform MH which Confidential Information was sent back, or destroyed and which information was stored. The notification that certain documents or information have been stored must be justified in compliance with medical confidentiality. MH is entitled to monitor compliance, in particular with this Clause 17.6, to the extent required or to have it monitored.
- 17.7 The obligation to maintain confidentiality pursuant to this Clause 17 shall also apply to the protection of the business secrets and industrial property rights of MH for a period of ten (10) years after the Agreement has been fully terminated.
- 18 DATA PROTECTION/DATA SECURITY**
- 18.1 The Parties are aware that compliance with data protection laws, in particular data protection regulations, e.g. according to the GDPR, and to the extent applicable the BDSG, SGB X and GenDG, are of decisive importance for the legally compliant collaboration and the legally compliant operation of the Medical Device. The Parties therefore undertake to comply with the relevant data protection regulations and agree in connection with this Agreement to the application of the “Data Processing Agreement”, which is attached as **Annex C (Data Processing Agreement)** to these GTC.

- 18.2 The Customer shall ensure that MH does not receive any personal data/social data (e.g. in the sense of the GDPR and BDSG or SGB X) of the patients via the Sequencing Laboratory, the Customer, the User or Authorized User him/herself, unless they are absolutely necessary for the fulfillment of the Agreement.
- 18.3 MH voluntarily agrees, if applicable without prejudice, until the question is clarified as to whether MH is a “*commissioned institution*” within the meaning of §7 (2) of the GenDG (e.g. by a legal regulation or a legally binding court decision), to be regarded vis-a-vis the Customer as a “*commissioned institution*” within the meaning of §7 (2) of GenDG and to fulfill the associated obligations (obligations in the event of revocation of the patient consent according to § 8 (2) GenDG).
- 18.4 In order to ensure that MH can comply with the obligations of this Agreement, the Customer undertakes to inform MH immediately, if a patient requests the destruction of his/her data in accordance with §12 (1) sent. 2 no. 2 GenDG or equivalent provisions of foreign laws or has effectively revoked a longer storage in accordance with §12 (1) sent. 3 GenDG or equivalent provisions of foreign laws or consent in accordance with §8 (3) GenDG or equivalent provisions of foreign laws.
- 18.5 The Customer must also inform MH immediately, if a patient asserts other data protection-related rights.
- 18.6 The Customer is responsible for ensuring that patient data are collected, processed and used in a legally permissible manner, in particular in the case of contract data processing, that all necessary data protection contracts (agreements on order data processing and transmission to countries outside the EU without an appropriate level of data protection, e.g. EU standard contract clauses) are concluded, so that the data can be processed and stored by MH in the database in compliance with data protection regulations.

**19 CHANGES TO PRICES, GTC AND ANNEXES**

- 19.1 MH reserves the right to amend the prices and these GTC, including the annexes.
- 19.2 In the event of price increases and other changes to the detriment of the Customer, the Customer may terminate the contractual relationship at the time the change takes effect. MH shall specifically point out this special right of termination in the change notification. The termination must be received in text form within six weeks after receipt of the notification by MH.
- 19.3 If the Customer does not terminate the Agreement within six weeks after receipt of the change notification, the changes shall become part of the Agreement at the time of the effective date. MH shall expressly inform the Customer of this consequence in the change notification.

**20 TERMINATION, TEMPORARY BLOCKING**

- 20.1 The Agreement can be terminated with a notice period of 6 weeks. The right to extraordinary termination remains unaffected by this.
- 20.2 The right to extraordinary termination exists in particular in the case of material breaches of contract. Material breaches of contract apply in particular – whereby the Customer must allow breaches of contract caused by the User or Authorized Users to be attributed to it – including:
- 20.2.1 repeated violation of the provisions of Clause 6 of these GTC regarding the intended use of the Medical Device;
- 20.2.2 definitive loss of the required medical or professional qualifications (in the sense of Clause 3.8 of these GTC) of all Users;
- 20.2.3 violation of the obligation to ensure the qualified operation of the Medical Device;
- 20.2.4 violation of the provisions for maintaining confidentiality

and data protection;

20.2.5 repeated delay or failure to supply the Medical Device by MH.

20.3 A material breach of contract shall only entitle to extraordinary termination, if the party in breach of contract has been issued a warning in advance and has been given an appropriate period of time to remedy the breach of contract.

20.4 In the event of an imminent material breach of contract within the meaning of Clause 20.2 of these GTC, MH is entitled to temporarily restrict the use of the Medical Device by the User or Authorized User for an appropriate period of time, at the latest until the imminent breach of contract is averted (temporary block); MH must inform the Customer of this immediately in writing (§ 126b BGB). The right to extraordinary termination and the right of MH to restrict access remain unaffected by this.

**21 PROCEDURE FOR TERMINATION OF THE AGREEMENT**

21.1 Upon termination of the Agreement, the right of use granted in this Agreement, in particular in Clause 6 of this Agreement, shall expire without further ado. In the event of an extraordinary termination, the cancellation of the right of use already occurs upon the announcement of the termination. Termination or expiry of the Agreement shall have no effect on orders already placed with MH.

21.2 In the event of a temporary restriction, unless otherwise agreed in writing in individual cases, the granting of the right of use shall be suspended with immediate effect for the duration of the restriction.

21.3 In the event of termination of the Agreement, neither the Customer nor, if applicable, the User or Authorized User shall have a right to the surrender of data or their deletion, unless they assert a justified claim of the patient to (i) surrender of data to the patient or (ii) data erasure (e.g. according to GenDG).

21.4 In the event of termination of the Agreement, MH has the right, unless a different agreement is made between the Parties, to store the data provided by the Customer within the framework of this Agreement for a maximum of ten years in compliance with any deviating provisions of the relevant data protection laws and the Genetic Diagnostics Act as well as deviating provisions on the part of the treated patient, which the Customer must also transmit to MH after termination of this Agreement, and to delete it at its own discretion after expiry of the deadline in compliance with the legal requirements.

**22 FINAL PROVISIONS**

22.1 All annexes and attachments named in an offer and these GTC are an integral part of the Agreement between MH and the Customer and apply in the version valid at the time of conclusion of the Agreement in the following order:

• Offer
• Annex A ( <i>Product Documentation MH Guide</i> )
• Annex B ( <i>MH Guide Sequencing Guidelines</i> )
• Annex C ( <i>Data Processing Agreement</i> )
• Annex D ( <i>List of Users / Authorized Users</i> )
• Annex E ( <i>Declaration of the User/Authorized User</i> )
• GTC

22.2 Amendments or supplements to the Agreement must be made in writing, unless a stricter form is prescribed by law, as well as the explicit reference to the respective regulation in the Agreement. This also applies to a waiver of this written form requirement.

22.3 The exclusive place of jurisdiction for all legal disputes arising from or in connection with this Agreement is Heidelberg, Germany to the

extent that this can be permissibly agreed.

- 22.4 The Agreement and all rights and obligations established by it are subject to the laws of the Federal Republic of Germany without regard to (i) its conflict of law provisions, or (ii) the UN Convention on Contracts for the International Sale of Goods.
- 22.5 Should a provision of the GTC or the Agreement be or become invalid or unenforceable, the validity of the remaining provisions shall not be affected.

Rather, the Parties already now undertake to agree to replace the invalid or unenforceable provision with a provision that comes closest to what the Parties intended economically in accordance with the meaning and purpose of the invalid or unenforceable provision within the scope of the legal possibilities. The same applies to any gap.

#### Annexes:

##### **Annex A: Product Documentation MH Guide**

The Product Documentation of MH Guide includes the following documents at the time of validity of these GTC:

1. **MH Guide Instruction for Use** for MH Guide, MH Guide/Mendel and MH Guide/BRCA in their current version in English, available at:  
[kundendienst@molecularhealth.com](mailto:kundendienst@molecularhealth.com)
2. **MH Guide Product Description** in its current version in English, available at:  
[https://www.molecularhealth.com/files/product/mhguide/pd/MH\\_Guide\\_Product\\_Description.pdf](https://www.molecularhealth.com/files/product/mhguide/pd/MH_Guide_Product_Description.pdf)
3. **MH Guide Support Description** (technical product support, including information on system availability) in its current version in English, available at:  
[https://www.molecularhealth.com/files/product/mhguide/sd/MH\\_Guide\\_Support\\_Description.pdf](https://www.molecularhealth.com/files/product/mhguide/sd/MH_Guide_Support_Description.pdf)

**Annex B: MH Guide Sequencing Guidelines** in their current version in English, available at:  
[https://www.molecularhealth.com/files/product/mhguide/USSeqGL/MH\\_Guide\\_Sequencing\\_Guidelines.pdf](https://www.molecularhealth.com/files/product/mhguide/USSeqGL/MH_Guide_Sequencing_Guidelines.pdf)

**Annex C: Data Processing Agreement**  
available at:  
[kundendienst@molecularhealth.com](mailto:kundendienst@molecularhealth.com)

**Annex D: List of Users/Authorized Users**  
available at:  
[kundendienst@molecularhealth.com](mailto:kundendienst@molecularhealth.com)

**Annex E: Declaration of the User/Authorized User**  
available at:  
[kundendienst@molecularhealth.com](mailto:kundendienst@molecularhealth.com)

As of: October 13, 2022