



# Terms & Conditions USA EN

- [Levy Health GmbH](#)
  - [Who is LEVY Health?](#)
  - [What can LEVY do for you?](#)
  - [Who can you turn to?](#)
- [1. Scope of Agreement and Services, General Terms](#)
- [2. Our Range of Services](#)
- [3. Contractual Relationship](#)
- [4. User Obligations](#)
- [5. User Data, Data Protection & Privacy](#)
- [6. Disclaimer](#)
- [7. Final Provisions](#)
- [8. Amendment of these Provisions](#)
- [Approval](#)
- [Change History](#)

Thank you for choosing to use our platform. Please note that use is subject to the following General Terms of Use (hereinafter referred to as **“Terms”** ). Therefore, we ask you to carefully read and accept these terms and conditions, as well as our privacy policy, before beginning to use our platform. It’s not possible to use our platform without prior acceptance of these provisions.

## Levy Health GmbH

### Who is LEVY Health?

LEVY Health is a medical software company focusing on women’s health. It developed a web-based clinical decision support software (CDSS), exempt from FDA approval under FDA-2017-D-6569. The software, called LEVY Fertility Code, is offered to clinicians in the United States and operated by us, Levy Health GmbH, Torstraße 223, 10115 Berlin, and its subsidiaries, represented by the management (hereinafter referred to as **“LEVY”** ) under [www.levy.health](http://www.levy.health) and any associated sub-domains.



## What can LEVY do for you?

LEVY Health distributes its software to clinicians in the United States to support them to rapidly ascertain what is getting in the way of your ability to get or stay pregnant on your own. Using a smart health questionnaire and advanced lab work, the company developed evidence-based algorithms to shorten the time to diagnose up to 65 health conditions that lead to fertility problems in women from years to weeks. The LEVY Fertility Code can recommend further diagnostics to uncover other conditions the software can not predict, recommend referrals to specialists for physical examination and/ or recommend evidence-based therapy/treatment options.

## Who can you turn to?

If you have any questions or encounter technical problems while using our platform, you can contact us at any time by email at [support@levy.health](mailto:support@levy.health).

This also applies if a term used by us in the context of these provisions is unclear to you or if you have questions about these provisions or our range of services.

**Note:** We provide a brief summary of what's entailed in each section at the beginning to facilitate a better understanding. Please note that these summaries are for convenience only and do not have any legally relevant explanatory content. Each section is numbered in ascending order.

# 1. Scope of Agreement and Services, General Terms

In this section you will find out more about the purpose of these regulations and to whom they apply in detail. It also tells you where you can find the current version of these terms and conditions at any time.

(1) These terms and conditions apply to our entire range of services which you can access at [www.levy.health](http://www.levy.health), and any associated sub-domains, and are intended to govern the contractual relationship between you and us, Levy Health GmbH.

(2) Deviating provisions shall not be recognized by us as a matter of principle. Anything to the contrary can only apply by express written agreement.



(3) You may only use our range of services if you are a customer and aged 18 or over.

(4) If you need to be represented by a third party in business matters (limited legal capacity), the use of our range of services is only permitted if the consent (approval) of the third party authorized to represent you has been obtained beforehand.

You can access, download and print the current version of the terms and conditions at any time at [www.levy.health](http://www.levy.health).

## 2. Our Range of Services

In this section you will find out what services we offer you and where you can find information about our full range of services at any time.

(1) LEVY Health offers you a range of services in accordance with the following paragraphs. Our range of services is linked to additional services. We only organize the administrative side.

(2) You and your doctor are using the LEVY Fertility Code (more details in the following paragraphs 3 to 4) to determine the possible causes of fertility problems.

(3) The LEVY Fertility Code is a software with algorithms developed by doctors that can shorten the time to diagnose health conditions that cause fertility problems and help you narrow down treatment options to improve fertility. The LEVY Fertility Code is a clinical decision support software that uses results from in vitro diagnostic equipment and your health data to help doctors diagnose conditions that affect fertility. In this way, the LEVY Fertility Code combines algorithm-based medical fertility analysis with individualized blood value diagnostics (see paragraph 4 below for more details).

(4) The first step of the LEVY Fertility Code is to fill out an interactive medical questionnaire using a web browser. Our questionnaire contains a large number of questions that react interactively based on your responses. The aim is to provide the software with specific information about your health and current life situation for the intended analysis. The algorithm stored in the software draws on our clinical knowledge database, which was developed based on an extensive evaluation of specialist medical literature, studies, clinical practice guidelines and similar sources. By submitting the completed questionnaire, you initiate the analysis process with the LEVY Fertility Code. You are obliged to answer all questions posed to you truthfully



and completely within the framework of this process as well as to carry out the (laboratory) medical evaluation by third party labs. You must inform LEVY Health immediately of any changes in your state of health which are or could be likely to influence the evaluation. Giving complete and truthful answers is a mandatory prerequisite for the analysis process and result to function properly.

(5) The result of the initial analysis by the LEVY Fertility Code is a set of recommended biomarkers that will be verified and approved by your doctor. The LEVY Fertility Code then creates a lab requisition form ready for your doctor to be signed.

(6) The blood test in a laboratory of your or your clinician's choice is carried out based on your clinician's ordering of the labs and based on your own request by concluding a consent to receive the laboratory results. It is not part of our range of services. After receiving the result of this blood test, you will independently submit your results to LEVY Health.

(7) As part of our service offer, your blood test results are then combined with your individual analysis result and additionally analyzed by the LEVY Fertility Code. Once the second analysis is complete, your doctor will be notified to review and approve the recommended diagnoses and therapeutic next steps. Once your doctor has approved the recommendations, they will be stored in your LEVY Health dashboard.

(8) Your treating doctor can view your entire result and recommendations of the LEVY Fertility Code and release it for you to view and advise you on it if needed. The medical consultation itself is carried out directly by the doctor treating you and not by us, i.e. it is not part of our range of services.

(9) All medical consultation services are provided by appropriately qualified medical service providers in their name and responsibility. You therefore conclude a separate treatment contract with them in advance. We ourselves expressly do not provide any medical services.

(10) We reserve the right to adjust our range of services at any time with effect for the future. We can therefore not guarantee the permanent existence of certain offers. However, this does not apply to services within an existing contractual relationship.

(11) Further information on our range of services can be found at [www.levy.health](http://www.levy.health).

### **3. Contractual Relationship**



In this section you will find out how a user agreement is concluded between you and us on the basis of these provisions, who is expressly not a contractual partner nor is to become a contractual partner, and when the user agreement ends.

(1) The use of our range of services is only possible after the conclusion of an effective contract of use on the basis of these provisions.

(2) Please note that you must confirm that you have read and accepted these terms and conditions and our privacy policy by ticking the relevant box before proceeding with your registration as a LEVY Health user.

(3) As a precautionary measure, we would like to point out that the contract of use, which comes into effect through the binding registration process between you, the user, and us, LEVY as the service provider, applies exclusively in the relationship between you and us for the purpose of making use of our range of services. The contract of use expressly does not apply to the provision of medical services which, according to legal or comparable regulations, may only be provided by appropriately qualified medical service providers.

(4) Any third parties, such as medical service providers are and shall expressly not be contractual partners of the contract of use concluded on the basis of these provisions. If third parties provide medical services, this is done exclusively on the basis of an individual contractual agreement between the respective medical service provider and you (treatment contract).

(5) The user contract ends automatically after the service has been provided. The service is deemed to have been provided after you have received an email from us stating that your recommendations are ready to be reviewed with your doctor.

(6) Upon registration of the LEVY Health software, you expressly agree to share your data and results of our analysis with your doctor, LEVY personnel and third party providers of Levy Health GmbH to offer our services in the United States. You may revoke this access at any time by writing to [support@levy.health](mailto:support@levy.health).

## 4. User Obligations

In this section, you will find out what obligations you have as a user of our platform and the services we offer.



(1) As a user of our platform and thus of our range of services, you are exclusively entitled to the rights to our range of services granted in accordance with these provisions.

(2) All content published via our platform (e.g. texts, images and videos) is fundamentally protected by copyright and is generally our property or licensed by us accordingly.

(3) You may only use our platform as well as our range of services appropriately and in particular not disseminate any prohibited, disparaging, insulting, violence-glorifying and/or pornographic content.

(4) Furthermore, we would like to point out once again that our range of services is intended exclusively for use in the private sphere of life and may therefore not be used by you for professional or commercial purposes.

## 5. User Data, Data Protection & Privacy

In this section, we inform you that we collect and process personal data from you in connection with our platform and our range of services within the meaning of the General Data Protection Regulation (GDPR). We also show you where you can find further information on this.

(1) We collect and use your personal data within the meaning of Art. 4 No. 1 of the General Data Protection Regulation to initiate and process the contractual relationship with you. Accordingly, personal data is all information that can be assigned to a specific person (e.g. you). This includes, among other things, your billing address or payment information.

(2) Details about the use of and our handling of your personal data can be found in our privacy policy at any time. You can access, download and print the current version of the data protection declaration at any time at.

(3) The data protection policy of Levy Health GmbH applies to the processing of personal data. This can be viewed at: <https://www.levy.health/en/privacy/>. By accepting the Terms & Conditions and the Data Privacy Policy, the customer expressly agrees to the collection, processing and use of personal data in accordance with the Terms & Conditions and the Data Privacy Policy.



(4) Personal data collected will be used to improve our Site, Software and Services and to identify you as a potential candidate for research studies which would require your consent under IRB protocols.

(5) De-identified, aggregate use of your data may be used for research studies that could benefit the world. This use may or may not require your consent under IRB protocols. Identifiable data will never be shared with third party research partners.

(6) To enable us to provide our service, we share necessary personal data with the doctor treating you.

(7) In order to provide the best possible service to you, we provide your doctor, the LEVY personnel and third party service providers by Levy Health GmbH access to our software and your personal data.

## 6. Disclaimer

In this section, we explain to you the extent to which we are liable to you as the provider of our platform and the associated range of services.

(1) We shall only be liable to you in accordance with the following provisions.

(2) Any claims for damages by you against us are excluded. Excluded from this are your claims for damages arising from injury to life, limb or health, as well as liability for other damages based on an intentional or grossly negligent breach of duty by us, one of our legal representatives or vicarious agents. Furthermore, liability for the breach of obligations, the fulfilment of which is essential for the proper performance of the contract and on the observance of which you may regularly rely (so-called cardinal obligations), shall remain unaffected. In the event of a slightly negligent breach of these contractual obligations, LEVY Health shall only be liable for the foreseeable damage typical for the contract, unless it is a matter of claims for damages arising from injury to life, limb or health.

(3) We accept no liability whatsoever for services provided by third parties identified as such, in particular those provided by qualified medical service providers (such as doctors) who are neither our legal representatives, employees nor vicarious agents. If these services are provided on the basis of a contract with you, reference is made to the respective contractual conditions of the relevant third party provider with regard to liability. In particular, we shall not be liable for damages that arise due to faulty or



incorrect data records or incorrect handling by a service provider. The respective service provider is solely responsible to you for this.

(4) Any existing statutory liability privileges remain unaffected by this exclusion of liability.

(5) Paragraph 1 also applies in favor of our legal representatives and vicarious agents if you should assert claims directly against them.

(6) A change in the burden of proof to your disadvantage is not associated with the above provisions.

## 7. Final Provisions

In this section we cover various points that are relevant to your contractual relationship with us.

(1) The language available for concluding a contract with you is English. However, we reserve the right to offer other contract languages in the future. If we already offer several contractual languages at the time of concluding the contract with you, the English language version of these provisions shall prevail in the event of contradictions.

(2) The contract of use shall be governed exclusively by German law to the exclusion of the UN Convention on Contracts for the International Sale of Goods (CISG).

(3) The place of performance for all contractual obligations arising from or in connection with an agreement concluded on the basis of these provisions is our registered office (determination of the place of performance).

(4) According to applicable law, we are also obliged to inform you as a consumer within the meaning of Section 13 of the German Civil Code (BGB) of the existence of the EU dispute resolution platform (called the ODR platform). This platform can be used for the settlement of disputes between entrepreneurs and consumers without having to go to court. The European Commission is responsible for setting up the ODR platform. You can access the ODR platform via the following link:

<https://ec.europa.eu/odr>. We would like to point out that we are not obliged or willing to participate in such a dispute resolution procedure (online dispute resolution).





(5) Changes to these terms and conditions must be made in text form. This also applies to the amendment of this clause.

## 8. Amendment of these Provisions

In this section, we explain how we will notify you of proposed changes to these Terms and Conditions and advise you of your right to object to such changes.

(1) We reserve the right to amend these provisions with effect for the future in order to be able to react appropriately to changes in the law, changes in case law or changes in economic circumstances.

(2) We will notify you in good time of any change we intend to make to these provisions and make the specific change available to you as a full text.

(3) An amendment to these terms and conditions will only become effective if you do not expressly object to it, i.e. in writing (e.g. by email or letter), within 4 (in words: four) weeks of receipt of our notification of the intended amendment. We will also expressly point this out to you again within the scope of the notification. Please note that your objection entitles us to terminate agreements concluded with you on the basis of these provisions within a reasonable period of time.

Assessed on 31 Aug 2022 20:08 Europe/Berlin.