



Terms & Conditions USA

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Introduction

Thank you for choosing to use our platform. Please note that use is subject to the following Terms and Conditions (hereinafter referred to as “**Terms**”). Therefore, we ask you to carefully read and accept these Terms, as well as our Privacy Policy, before beginning to use our platform. It's not possible to use our platform without accepting these Terms.

These Terms describe your rights and responsibilities with regard to the LEVY Health Services. Your access to and use of the Services is subject to these Terms and Conditions, our Privacy Policy, as well as all applicable laws and regulations. While using certain parts of the Services, you may be presented with additional or supplementary terms regarding the use of those specific Services, and you agree to review and be bound by these additional terms.

PLEASE READ THESE TERMS OF USE CAREFULLY BECAUSE THEY SET FORTH THE IMPORTANT TERMS YOU WILL NEED TO KNOW ABOUT THE SERVICES.

BY CLICKING “I AGREE,” CHECKING A RELATED BOX TO SIGNIFY YOUR ACCEPTANCE, OTHERWISE CONSENTING TO AND ACCEPTING THE TERMS AND CONDITIONS WITHIN THIS AGREEMENT, YOU ACKNOWLEDGE THAT YOU HAVE READ, ACCEPTED, AND AGREED TO BE BOUND BY THIS AGREEMENT. IF YOU DO NOT AGREE TO THESE TERMS AND CONDITIONS, DO NOT CREATE AN ACCOUNT OR USE THE SERVICE.

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) that is exempt from FDA approval under FDA-2017-D-6569. The software, entitled the 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 and any associated sub-domains.

Levy Health GmbH

Torstraße 223

10115 Berlin

Germany

represented by the management

E-mail: hello@levy.health

Phone: (415)-969-3373

What can LEVY Health do for you?

LEVY Health distributes its software to clinics, payors, benefits providers and health care professionals in the United States to support them with diagnostic and therapeutic decisions regarding patients' reproductive health. Using a Reproductive Health Assessment and advanced lab work, LEVY Health's algorithms help prepare patients for artificial reproductive treatment and/or shorten the time to diagnose up to 65 health conditions that lead to fertility problems in women. The LEVY Fertility Code recommends further diagnostics, and treatment options. Once these recommendations are approved by a healthcare provider, they are being made available to you.

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 emailing us at 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 of the LEVY Fertility Code at the beginning to facilitate 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.

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 at any time.

(1) These Terms apply to our entire range of services, which you can access at 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.

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 a variety of services as outlined in the following paragraphs. The LEVY Fertility Code is a clinical decision support software that employs data from in vitro diagnostic equipment and your health information to provide recommendations to healthcare professionals. Our service range is connected to additional services, for which we handle the administrative aspects.

(2) The LEVY Fertility Code serves to:

a. Reduce the time required for diagnosing health conditions that impact fertility and/or cause fertility issues.

b. Prepare for artificial reproductive treatments.

(3) The initial step of the LEVY Fertility Code involves completing an interactive medical questionnaire via a web browser, known as the Reproductive Health Assessment. This questionnaire consists of numerous questions that react dynamically based on your answers. The goal is to supply the software with specific details about your health and current life situation for fertility analysis. The algorithm was developed through a thorough evaluation of clinical guidelines, studies on natural fertility, research on artificial reproductive treatments, and economic analyses concerning treatment returns on investment. By submitting the completed questionnaire, you initiate the analysis process using the LEVY Fertility Code. To complete the LEVY Fertility Code, you are required to honestly and fully answer all questions within the framework of this process, and also undergo any necessary medical evaluations, including laboratory assessments, conducted by a third-party lab. Prompt notification to LEVY Health about any changes in your health status that could affect the evaluation is mandatory. Providing complete and truthful responses is an essential prerequisite for the accurate functioning of the analysis process.

(4) The outcome of the initial analysis performed by the LEVY Fertility Code is a set of recommended biomarkers for testing in a certified laboratory. These recommendations will be reviewed and approved by an assigned Healthcare Provider. Subsequently, the LEVY Fertility Code generates a lab requisition form that you need to bring to the testing facility.

If you are not introduced/referred to LEVY Health via a healthcare provider, LEVY Health can match you with one.

(5) Depending on the party informing you about or forwarding you to LEVY Health, blood tests can be conducted either in a laboratory of your choice, in recommended laboratories, or a specific lab designated by the collaborating clinic. In either case, you will find out about your lab choices within the LEVY Dashboard.

The blood tests are carried out based on the LEVY Fertility Code's recommendations, which can be accepted or adjusted by your assigned Healthcare Provider. It's important to note that the actual lab testing is not part of our service range. Nevertheless, you consent that LEVY Health will receive your blood test results, either through your submission or directly from the laboratory.

(6) As part of our service offering, your blood test results will be combined with your responses from the medical questionnaire and analyzed using another set of algorithms within the LEVY Fertility Code. Once this analysis is complete, your assigned Healthcare Provider will be notified to review and approve the recommended

diagnoses and subsequent steps for further diagnostics, diagnosis confirmation, and treatment. Once the results and recommendations are approved, you will be notified and can access them through your LEVY Health Dashboard.

(7) You will have the choice to share your data with your preferred doctor (e.g., your OB-GYN). You are required to share your data with healthcare professionals at the clinics partnered with LEVY Health if you use the LEVY Fertility Code to prepare for treatment(see point 11). If a care team call or physician's call within the LEVY network is part of the offering you bought, LEVY care team members and physicians/physician networks in contractual relationships with LEVY will be able to access your results and recommendations on the LEVY Clinic Dashboard and discuss them with you.

(8) We retain the right to modify our service range at any time, affecting future offerings. Therefore, we cannot guarantee the permanent availability of specific services. However, this does not apply to services within an existing contractual agreement.

(9) Additional information about our service range can be found at www.levy.health.

(10) By accessing or using the Service, or by sending emails or text messages to us or any Healthcare Provider, you are communicating electronically. You provide consent to receive electronic communication from us and the Healthcare Provider. We will communicate with you via email, text messages, or through the Service. You agree that any agreements, notices, disclosures, and other communications provided electronically fulfill any legal requirements for written communications. You further acknowledge that notices provided electronically by us are considered as given and received on the date of transmission as described in this Agreement.

(11) If you have been referred to the LEVY Fertility Code by your clinic, doctor, insurance, or benefits provider, you consent to LEVY Health sharing your data with them.

(12) You acknowledge that your data will be shared and assigned to one of LEVY's medical service providers for the purpose of creating lab requisitions and approving your recommendations.

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) Utilizing our array of services is contingent upon the successful establishment of an effective usage contract based on these provisions.

(2) Kindly be advised that you must confirm your comprehension and acceptance of these Terms and our Privacy Policy by checking the relevant box prior to proceeding with your registration as a LEVY Health user.

(3) As a precaution, we wish to highlight that the usage contract, established through the binding registration process between you (the user) and LEVY Health (the service provider), exclusively applies within the context of availing our service range. This contract explicitly does not pertain to the provision of medical services, which, in accordance with legal or comparable regulations, are to be exclusively offered by duly qualified medical service providers.

(4) Any third parties, including medical service providers, are explicitly not considered contractual partners within the usage contract established on the basis of these provisions. Should third parties offer medical services, this is exclusively carried out based on an individual contractual arrangement between the respective medical service provider and you (treatment contract).

(5) The user contract terminates automatically after the service has been provided. The service is deemed to have been provided once you have received an email from us confirming that your recommendations are ready for review with your doctor.

(6) Upon registering with the LEVY Health software, you expressly agree to share your data and analysis results with our Healthcare Providers and Levy Health GmbH. You retain the right to withdraw this access at any time by sending a written request to support@levy.health.

(7) Levy Health GmbH reserves the right to terminate your usage of the Service, its features, or any of our services at any time and for any reason, without prior notice. This may include instances of conduct violating this Agreement, termination of our agreement with Healthcare Providers of the labs, or discontinuation of the Service. The provisions in this Agreement related to disclaimers, liability limitations, arbitration,

dispute resolution, indemnification, and jurisdictional matters shall persist despite any such termination or the conclusion of this Agreement or your association with Levy Health GmbH.

Prices and Payment Processing

In this section, you will find out how the prices for our range of services are determined and how the payment process works.

(1) All prices displayed within our service range already incorporate the applicable statutory value-added tax. However, this tax will also be itemized separately.

(2) You will only receive an invoice from us for services that you reserve through our platform. It's important to differentiate between billing for services provided by medical service providers. Numerous clinics, payors, and benefits providers have established direct agreements with us, potentially resulting in reduced or no costs to you. Please be aware that laboratory services and related expenses are not included in the LEVY Fertility Code.

(3) Should you opt for additional services provided by external medical service providers (including doctors, naturopaths, or fertility coaches) under a treatment contract, payment will be made directly to the respective service provider mentioned above, subsequent to the provision of the relevant medical service.

(5) For these purposes, LEVY Health employs various financial service providers, such as Stripe, Paypal, Google Pay and Apple Pay. Further details regarding the management of your personal data during payment processing can be found in our privacy policy. You can access, download, and print the current version of the privacy policy at any time on www.levy.health.

(6) If your insurance company covers some or all of the costs associated with the LEVY Fertility Code, please ensure that you obtain an invoice from us.

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 are responsible to answer all questions in the Reproductive Health Assessment to the best of your knowledge and make sure you do everything possible to obtain the correct answers. Incorrect answers may lead to recommendations not applicable to you.
- (4) 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.
- (5) Furthermore, 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.

User Data, Data Protection, and Privacy

LEVY Health understands the importance of confidentiality and privacy regarding your health information. Please see our Privacy Policy available at [for information about how we collect and use your information](#). The Privacy Policy is hereby incorporated into these Terms by reference and constitute a part of these Terms.

Protected Health Information - When you create an account with Levy Health GmbH, you are beginning a direct customer relationship with Levy Health GmbH that enables you to access and/or utilize the various functions of the Service as a user. As part of that relationship, you provide information to Levy Health GmbH, including but not

limited to your name, email address, and phone number, that we may collect, use, and disclose in accordance with our Privacy Policy, and that we do not consider to be “health” or “medical” information.

However, in using certain components of the Service, you may also provide certain medical information that may be protected under applicable laws. Levy Health GmbH is not a “covered entity” under the Health Insurance Portability and Accountability Act of 1996 and its related regulations (HIPAA). The Labs and Healthcare Providers are “covered entities” under HIPAA. Levy Health GmbH is, in some cases, operating as a “business associate” of the Labs or Healthcare Providers. Any health information you provide that is subject to specific protections under HIPAA or applicable state laws (collectively, with PHI, “Protected Information”), will be used and disclosed only in accordance with such applicable laws. However, any information that does not constitute Protected Information under applicable laws may be used or disclosed in any manner permitted under our Privacy Policy. Protected Information does not include information that has been de-identified in accordance with HIPAA.

Warranty Rights, Guarantees and availability

In this section, we explain what rights you can invoke in the event of problems and inform you about any guarantees offered (including with regard to the availability of our platform).

(1) Our warranty for material defects and title defects shall be governed exclusively by the applicable statutory provisions.

(2) We expressly do not guarantee that the use of our range of services will result in an improvement in your well-being or state of health. In particular, we do not guarantee any specific success in this regard.

(3) As a matter of principle, we do not give any guarantees. If, in exceptional cases, we do advertise guarantees, the details of these are set out in the respective guarantee conditions which we provided to you in text form before conclusion of the contract.

(4) We ensure a 98 percent availability of our range of services. Excluded from this are times when maintenance work is being carried out on servers and/or software. We will inform you about planned maintenance work and any downtimes that may be associated with it in due time.

User Content and LEVY's License to Use Such Content

Except as provided in our Privacy Policy, or information governed by applicable federal and state-specific privacy laws and regulations, you understand and agree that any information you provide through the Services, whether by direct entry, submission, email or otherwise, including, but not limited to, data, questions, comments, forum communications, or suggestions/feedback, will be treated as non-confidential and non-proprietary and will become the property of LEVY Health and/or (i) the affiliated physician practices, or (ii) individual health providers utilizing the Services ("**User Content**").

Except as provided in our Privacy Policy or subject to any applicable laws, User Content may be used by LEVY Health for any purpose, including, without limitation, reproduction, solicitation, disclosure, transmission, publication, broadcast, and posting. LEVY Health is free to use such User Content for any purpose whatsoever, including, without limitation, developing and marketing products, without any compensation owed to you. You hereby grant LEVY Health, our service providers, our successors and assigns, our affiliated HealthCare Providers, and their affiliated physician practices, the fully transferable and sublicenseable right and license to use, reproduce, modify, analyze, perform, display, distribute, and otherwise disclose to third parties, any data or information you submit on or through the Services for the purposes of providing Services to you; marketing Services to you; conducting research or analyses of such data; and designing, developing, implementing, modifying and/or improving new, current or future features, products and services of LEVY Health using such data. You understand that any User Content you publish in public forums will be viewable and copyable by other users of the forum and potentially the public at large.

WITHOUT LIMITATION OF THE FOREGOING, LEVY HEALTH DOES NOT ASSUME RESPONSIBILITY OR LIABILITY FOR THE USER CONTENT FOUND IN ANY PUBLIC

FORUM, NOR FOR ANY CLAIMS, DAMAGES OR LOSSES RESULTING FROM ANY USE OF ANY PUBLIC FORUM OR THE USER CONTENT CONTAINED THEREIN.

You acknowledge, consent, and agree that we may access, monitor, preserve, and disclose your information and/or any User Content you submit or make available for inclusion on the Services, if required to do so by law or in a good faith belief that such access, preservation, or disclosure is permitted by law or reasonably necessary or appropriate for any of the following reasons: (1) to comply with legal process; (2) to enforce these Terms, our Privacy Policy, or other contracts with you, including investigation of potential violations thereof; (3) to respond to claims that any content violates the rights of third parties; (4) to respond to your requests for customer service; and (5) to protect the rights, property, or personal safety of LEVY Health, its agents and affiliates, its users, and the public. This includes exchanging information with other companies and organizations for fraud protection, and spam/malware prevention, and similar purposes.

Copyright Notices

LEVY Health reserves the right to remove any content or any other material or information available on or through our Services, at any time, for any reason. If you have objections to copyrighted content or material made available on or through our Services, you may submit a notification to the following address:

hello@levy.health

Cancellation Policy

In this section, we inform you – as a consumer in the sense of § 13 BGB – about your statutory right of withdrawal. Your right of withdrawal is not unlimited, but may be excluded under certain conditions. Please note that in the following we use “you” to address you. We do this because we are not allowed to deviate from the legally prescribed sample text.

(1) Right of withdrawal:

You have the right to withdraw from this contract within fourteen days without giving any reason **in case you have not started engaging with the LEVY Fertility Code, i.e. you have not started the Reproductive Health Assessment.** The withdrawal period is fourteen days from the day of the conclusion of the contract. To exercise your right of withdrawal, you must inform us of your decision to withdraw from this contract by means of a clear declaration (e.g. an email or letter sent by post). You can use the attached model withdrawal form for this purpose, but this is not mandatory. To comply with the withdrawal period, it is sufficient for you to send the notification of the exercise of this right of withdrawal before the expiry of the withdrawal period. If our service has been provided free of charge, you are not entitled to a refund.

(2) Consequences of cancellation:

If you cancel this contract, we must refund all payments we have received from you immediately and at the latest within fourteen days of the day on which we received notification of your cancellation of this contract. For this repayment, we will use the same means of payment that you used for the original transaction unless expressly agreed otherwise with you.

(3) **Sample cancellation form:**

I/we (*) hereby revoke the contract concluded by me/us (*) for the purchase of the following goods: _____ (*) / the provision of the following service:
_____ (*)

Ordered on: _____ (*)/ received on: _____ (*)

Name of consumer(s): _____

Address of consumer(s): _____

Signature of consumer(s): _____

(only if communication is on paper)

Date: _____

(*) Delete where inapplicable

You can send your cancellation either by post to

Levy Health GmbH

Torstraße 223

10115 Berlin

or by e-mail to hello@levy.health

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 are only 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 healthcare professionals and medical partners) 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.

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 in Berlin, Germany.

(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 are not obliged or willing to participate in a dispute resolution procedure that takes place online.

(5) Changes to these Terms must be made in writing. This also applies to the amendment of this clause.

Binding Arbitration / Class Waiver

You and we expressly agree that any legal claim, dispute, or other controversy between you and us or any of LEVY Health's parties, the Healthcare Providers, or Labs arising out of or otherwise relating in any way to LEVY Health's parties, our platform, the content for the Service, or any other goods, services, or advertising by LEVY Health or any of LEVY Health's parties, Labs, or Healthcare Providers including controversies relating to the applicability, enforceability or validity of any provision of this Agreement (collectively "Disputes"), shall be resolved in confidential binding arbitration conducted before a commercial arbitrator from the American Arbitration Association ("AAA"), rather than in a court, as described herein. The arbitration will be governed by the AAA'S commercial arbitration rules and, if the arbitrator deems them applicable, the supplementary procedures for consumer related disputes (collectively "rules and procedures"). You acknowledge that you are voluntarily and knowingly forfeiting your right to a trial by jury and to otherwise proceed in a lawsuit in state or federal court, except as expressly provided herein.

Amendment of These Provisions

In this section, we explain how we will notify you of proposed changes to these Terms 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 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.

Effective date: 2023/07/07