



EirMed TERMS AND CONDITIONS AGREEMENT

Effective as of 1st of December 2020

This Terms and Conditions Agreement explains the terms and conditions under which you can use the Platform and Services provided by EirMed Ltd. Please read carefully this Terms and Conditions document, and keep a copy of it for your reference.

BY USING OUR SERVICES OR ACCESSING ANY CONTENT THAT IS MADE AVAILABLE BY EIRMED LTD YOU EXPRESS YOUR AGREEMENT TO BE LEGALLY BOUND BY OUR TERMS AND CONDITIONS STATED IN THIS DOCUMENT, SO PLEASE READ THESE TERMS CAREFULLY BEFORE USING OUR SERVICES AS YOU ARE ENTERING INTO A BINDING CONTRACT WITH EIRMED LTD, STR. 6th OF SEPTEMBER 32/2/2, SOFIA 1000, BULGARIA. IF YOU DO NOT AGREE WITH (OR CAN NOT COMPLY WITH) THE TERMS AND CONDITIONS SET FORTH BELOW, DO NOT USE OR ACCESS OUR SERVICES.

These Terms do not interfere with any obligation or authorization provided in any other agreement concluded between you and EirMed Ltd.

1. DEFINITIONS

1.1 The following definitions explain some of the terminology and abbreviations used throughout our Terms and Conditions Agreement:

- **'Terms/Agreement'** refers to the latest version of this Terms and Conditions Agreement document.
- **'Site'** refers to the website of EirMed SaaS available at <eudamed.com>, EudaMed Plus servers hosted by EirMed Ltd or internally hosted on a client's infrastructure, or any other URL which may host any EirMed Ltd websites or Services.
- **'Platform'** refers to the Site and Services collectively.
- **'User/You'** refers to any person using or accessing our Platform.
- **'We/Us/EirMed'** refers to EirMed Ltd, the Site, and their partners and affiliates.
- **'Privacy Policy'** refers to the Privacy Policy document governing the rules of collecting, using and storing information provided by Users.
- **'Third-Party'** refers to any application, website, natural or legal entity other than EirMed Ltd.
- **'Content'** refers to all images, text, audio and video data or any other information located on the Platform.
- **'Data'** refers to the Content provided by Users.
- **'Services'** refers to the services provided by EirMed Ltd, through Eudamed SaaS, EudaMed Plus, EudaMed+, and EudaMed Check as advertised on the Site.
- **'Subscription'** refers to paid the use of the 'Services' for one Production SRN. You may terminate your Subscription only in accordance with Section 11 (*Termination*) or as permitted under applicable law.
- **'Effective Date'** refers to the date on which the payment of the Subscription Fee is processed.
- **'Information'** refers to information about the Users themselves provided for the purpose of using our Services, contacting support or anonymous statistical information collected from the Users through cookies or third-party services.

- ‘**Confidential Information**’ refers to any and all information disclosed between the parties of this Agreement concerning the Services, and especially, without limiting,

Content is available only for registered Users. Confidential Information does not cover information that was known to either party before disclosure, information that was made available to the public or information which is intended and disclosed for the purpose of publishing.

2. GENERAL PROVISIONS

(A) SCOPE OF THE SERVICES

2.1 EirMed offers a Platform through which Users can upload their Data, have their Data sorted and validated with the EC business rules, upload and validate their sorted Data to the European Database on Medical Devices, and other services fully described on the Site. Access to these Services is available upon registration which is done through proper forms on the Site. EirMed does not guarantee the results of the Services only the means for achieving the results. Actual registration of the medical devices is conducted by the European Database on Medical Devices (EUDAMED) and EirMed do not make any warranties or guarantees as to the successful registration.

2.2 EirMed cannot guarantee or warrant that the Services will meet your requirements or be available on an uninterrupted, secure, or error-free basis. We will undertake and implement all reasonable measures to maintain the security and integrity of the Data provided by Users. EirMed cannot and does not guarantee the 100% uptime for its Services. Services may be down (i) for scheduled maintenance, (ii) force majeure events, (iii) for specific Users because of the account suspension or termination, (iv) internet problems outside of the EirMed area of influence, (v) bugs in code, hardware or Services without a commercially known fix.

2.3 During the use of the Services, EirMed undertakes to provide customer support to the User as necessary and within its possibilities. User agrees that EirMed is not responsible for issues whose cause does not come out of the Services, or Platform.

(B) ELIGIBILITY

2.4 By registering for the use of the Services, you confirm that you are at least 18 years of age. By using our Services, you confirm that you (i) have the full legal capacity to enter into a binding relation, (ii) that you will provide true, accurate, current, and complete information where requested and information which is otherwise compatible with these Terms, (iii) that you will not use Services contrary to these Terms or applicable laws. If you are accessing our Services on behalf of a legal entity, you further confirm that (i) you have the appropriate authorization to accept the terms of this Agreement, (ii) you have the appropriate authorization to bind such legal entity by accepting this Agreement, (iii) legal entity on behalf of whom you accept this Agreement has full power to enter into this agreement and to perform obligations as defined herein.

2.5 We may not control who uses the Platform, so it is upon you to assess whether using the Platform complies with any local laws and regulations. Whenever you are using our Platform, you will need to comply with these Terms and any applicable laws,

regulations, and policies. If any part of the Platform is not in compliance with your local laws, you may not use the Platform. Any such Service will be considered as 'not available in your region.'

(C) REGISTRATION

2.6 During the registration process, you will be asked to provide some personal information, the collection, use, and storage of which is regulated by our Privacy Policy document and applicable laws. Users are required to provide true, accurate, current and complete information about themselves as prompted by the forms provided. If you provide information contrary to the aforementioned conditions, we may deny you or terminate your access to parts of our Services. We are not responsible for any failure to provide the Services which result from information that is not true, accurate, current, and complete.

2.7 You understand that it is your responsibility to keep your login information confidential. You are responsible for all activity under your account. If you ever find out or suspect that someone accessed your account without authorization, you are advised to inform us immediately.

(D) CONTACT

2.8 By allowing us access to your e-mail address, you agree that we may contact you using such contact information, for any matters relating to the Services (**Service e-mails**). These e-mails do not constitute "unsolicited commercial e-mail advertisements," and you are not able to opt out of receiving them. You may opt-in or subscribe to receive e-mails about content, promotions, special offers and or other topics of interest related to EirMed Ltd and our affiliates (**Promotional e-mails**). You may choose to stop receiving these promotional e-mails at any time by following the instructions contained in promotional emails.

2.9 If you have any questions or suggestions you can contact us at support@eudamed.com.

3. ACCEPTABLE USE POLICY

3.1 You agree that you will not misuse our Platform. A misuse constitutes any use, access or interference with the Platform contrary to the Terms, Privacy Policy and applicable laws and regulations. We can, in our sole discretion, suspend or terminate access to all or parts of the Platform to any User, without prior notice or need to deliberate on reasons for such measure. We reserve the right to deny Services to anyone at any time. During your use of our Platform, you will not behave contrary to the Terms, Policies, applicable laws and regulations, and you will especially not, without limitation, do any of the following:

- (i) Send or otherwise post unauthorized commercial communications (such as spam) through the Platform;
- (ii) collect Users' content or information, or otherwise access the Platform using automated means (such as harvesting bots, robots, spiders, or scrapers) without our permission;
- (iii) upload viruses or other malicious code;
- (iv) bully, intimidate, or harass any other User;
- (v) post or transmit content which is illegal, hateful, obscene, threatening, incites violence, insulting, defamatory, infringing on intellectual property rights, invasive of privacy, or contains graphic or gratuitous violence or is otherwise objectionable to third parties;
- (vi) harass, threaten, embarrass or cause distress or discomfort to another individual or entity or impersonate any other person or entity or otherwise restricting or inhibiting any other person from using or enjoying the Platform;
- (vii) take any action creating a disproportionately large usage load on our Platform unless expressly permitted by EirMed Ltd ;
- (viii) post or transmit misleading content.
- (ix) communicate any information or content that you do not have a right to make available under any law or under contractual or fiduciary relationships, or otherwise infringes or violates someone else's rights;
- (x) encourage participation in or promote any contents, pyramid schemes, surveys, chain letters or spamming, or unsolicited emailing through the Platform;
- (xi) post or transmit hyperlinks to other websites that violate these Terms;
- (xii) facilitate or encourage any violation of these Terms.

3.2 Users are solely responsible for their own Data and the consequences of making the Data available to third parties.

3.3 If for any reason, your account, or any part thereof, is suspended, banned, restricted, blocked, terminated or otherwise disabled by EirMed, you agree to abide by such decision. You may not create another account with the intent to bypass these limitations or attempt to circumvent any limitation imposed on your account without our permission. Any effort to evade these limitations may result in the termination of all current and future accounts you register.

4. INTELLECTUAL PROPERTY

(A) PROPRIETARY RIGHTS

4.1 The copyright and all intellectual property rights in the Platform belong to EirMed Ltd or are used with appropriate permissions. It includes design, all database rights, trademarks, text, graphics, code, files and links, service marks, and the selection and set-up thereof. All rights are reserved. Nothing in this agreement shall be understood or intended for the transfer of such intellectual property rights to you or any other third party.

4.2 Subject to your compliance with this Agreement, we grant you a limited, nonexclusive, non-transferable, non-sublicensable license to access and use the Platform. Except as expressly permitted in this Agreement, you may not:

- copy, modify or create derivative works based on the Platform;
- distribute, transfer, sublicense, lease, lend or rent the Platform to any third party;
- reverse engineer, decompile or disassemble the Platform; or
- make the functionality of the Platform available to multiple users through any means.

(B) NOTIFICATION OF INFRINGEMENT

4.3 If you believe that your work has been copied in a way that constitutes copyright infringement, or your intellectual property rights have been otherwise violated, please provide the following information to the Site's Copyright Agent:

1. An electronic or physical signature of the person authorized to act on behalf of the owner of the copyright or other intellectual property interest;
2. A description of the copyrighted work or other intellectual property that you claim has been infringed;
3. A description of where the material that you claim is infringing is located on the Site or the App;
4. Your name, address, telephone number and e-mail address;
5. A signed statement by you that you have a good faith belief that the disputed use is not authorized by the copyright owner, its agent, or the law; and
6. A statement by you, made under penalty of perjury, that the information provided in your Notice is accurate and that you are the copyright or intellectual property owner or authorized to act on the copyright or intellectual property owner's behalf.

4.4 Our copyright agent can be reached as follows:

Email: support@eudamed.com



(C) DATA

4.5 Users retain all rights, title, and interest in the User Data they provide through the Platform. By providing the Data, Users grant us a limited, non-exclusive, non-transferable license to host, reproduce, and process such Data for the sole purpose of providing the Services or customer support. EirMed Ltd shall not use Data contrary to these terms and will treat such Data as Confidential Information. Insofar as such assistance is necessary for compliance with laws, regulations, and requests made within the scope of EU GDPR, EirMed Ltd shall assist the User with appropriate technical and organizational measures. We will also provide Users with any information necessary to demonstrate compliance with the obligations laid down in EU GDPR.

(D) THIRD-PARTY CONTENT

4.6 Some content on the Platform, such as advertisements, may be provided by the Third-Parties. We are not responsible for such content, nor do we monitor or control content provided by the Third-Parties.

(E) CONFIDENTIAL INFORMATION

4.7 During the term of this Agreement, Users may be required to provide or volunteer to provide certain Confidential Information to EirMed Ltd and EirMed Ltd may disclose certain Confidential Information to the Users. Regarding such information both parties hereby agree (i) to keep Confidential Information in strict confidence, (ii) to undertake all reasonable measures to protect the confidence of Confidential Information, (iii) not to disclose, or otherwise make available, Confidential Information to any third party without obtaining prior written consent, (iv) to use Confidential Information only for the purposes intended, (v) to return all Confidential Information and any and all copies, extracts or derivative works resulted from Confidential Information upon written request or upon termination of the Agreement, and to destroy or erase all remaining copies of the Confidential Information regardless of the form or media on which the Confidential Information is stored.

5. PAYMENT AND PRICING

5.1 EirMed will issue an estimate of the costs when the User requests Services. If the estimate is accepted EirMed will issue an Invoice for Services, due for payment within thirty (30) days from the issuing.

5.2 User understands and agrees that the actual price may differ from the estimated price. EirMed hereby agrees that the total costs of the Services will not exceed the amount equal to 15% of the costs indicated in the estimate. In the event that actual costs for the Services exceed the previously mentioned limit, EirMed will, together with the User, determine which non-essential services may be terminated to decrease the costs.

5.3 If any amount owed is not paid by the due date, we reserve the right to charge an interest on the due amount at the rate of 1.5% per month or the maximum allowed interest rate under the law, whichever is less.

5.4 Subscriptions will automatically reoccur annually and be automatically invoiced unless otherwise directed in accordance with Section 11 (*Termination*) or as permitted under applicable law.

6. THIRD-PARTY SERVICES

6.1 The Services may be made available or accessed in connection with Third-Party services and content (including advertising) that EirMed Ltd does not control. We may also provide you with links leading to the Third-Parties. You acknowledge that different Terms and Conditions and privacy policies may apply to your use of such Third-Party services and content. EirMed Ltd does not endorse such Third-Party services and content and in no event shall EirMed Ltd be responsible or liable for any products or services of such Third-Party providers.

7. INDEMNITY

7.1 You will indemnify and hold harmless EirMed Ltd, and its employees and affiliates, from and against any claims, disputes, demands, liabilities, damages, losses, and costs and expenses, including, without limitation, reasonable legal and accounting fees arising out of or in any way connected with your access to or use of the Site and our Services, content which you provide, or your violation of these Terms.

7.2 In any case, total liability of EirMed Ltd is limited to the aggregate amounts paid to EirMed Ltd by the User for the Services provided within twelve (12) months preceding the date of the event that is the basis for the first claim.

8. LIMITATION OF LIABILITY

8.1 YOU AGREE THAT, TO THE EXTENT PERMITTED BY APPLICABLE LAW, YOUR SOLE AND EXCLUSIVE REMEDY FOR ANY PROBLEMS OR DISSATISFACTION WITH THE EIRMED LTD SERVICE IS TO STOP USING THE SERVICES.

8.2 TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW EIRMED LTD, ITS EMPLOYEES, OFFICERS, AGENTS, AFFILIATES, SUCCESSORS, SUPPLIERS, ASSIGNEES OR LICENSORS SHALL NOT BE LIABLE FOR ANY INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE, EXEMPLARY OR CONSEQUENTIAL DAMAGES, OR ANY LOSS OF PROFITS OR REVENUES, WHETHER INCURRED DIRECTLY OR INDIRECTLY, OR ANY LOSS OR CORRUPTION OF DATA, UNAUTHORIZED ACCESS TO OR ALTERATION OF YOUR TRANSMISSIONS OF USER DATA, USE, GOOD-WILL, OR OTHER INTANGIBLE LOSSES, ARISING OUT OF YOUR ACCESS OR USE OR INABILITY TO ACCESS OR USE THE PLATFORM, THIRD-PARTY APPLICATIONS OR THIRD-PARTY APPLICATION CONTENT, INCLUDING WITHOUT LIMITATION ANY OFFENSIVE OR ILLEGAL CONDUCT OF OTHER USERS OF THE PLATFORM, REGARDLESS OF LEGAL THEORY, EVEN IF EIRMED LTD HAS BEEN ADVISED OF THE POSSIBILITY OF THOSE DAMAGES AND EVEN IF A REMEDY FAILS OF ITS ESSENTIAL PURPOSE.

8.3 EirMed Ltd, its employees, agents, and its directors do not accept any liability and you hereby agree to release us of any liability arising (whether directly or indirectly) out of the information provided through the Platform, or any errors, in or omissions from information on the Platform. EirMed Ltd is not liable for loss (whether directly or indirectly) caused by your actions or decisions based on your reliance on the information provided to you through the Site, nor caused by the delay, malfunction of the operation or the availability of the Platform.

9. DATA SECURITY

9.1 EirMed Ltd takes all reasonable measures considering the current state of technology to protect and keep secure the Data provided by Users. Users understand and agree that no security measure is 100% effective and that in some cases a data breach, data corruption, failed transfer or other errors may occur. To the furthest extent permissible under law, Users release EirMed Ltd from any damage or liability caused by such data breach, data corruption, failed transfer or other errors and EirMed Ltd shall not be liable to pay any compensation or to reimburse any damage caused to the User for such happenings.

9.2 Users are solely responsible to take and maintain any commercially reasonable steps regarding the integrity and security of the Data including creating backups or using encryption technologies. Users are responsible for any losses or other consequences arising from User's failure to encrypt or back up Data.

10. CHANGES

10.1 EIRMED LTD MAY MAKE CHANGES OR REPLACE OUR TERMS AND CONDITIONS AGREEMENT AT ANY TIME. WE WILL POST SUCH CHANGES, REPLACEMENTS AND UPDATES ON THE PLATFORM AND SUCH CHANGE, REPLACEMENT AND UPDATE TO OUR TERMS AND CONDITIONS AGREEMENT WILL BE APPLICABLE TO ANY SUBSEQUENT ORDER MADE UNDER THE EFFECTIVE VERSION OF THE AGREEMENT. YOU ARE CONSENTING TO KEEP YOURSELF UP TO DATE WITH THE LATEST POSTED TERMS AND CONDITIONS AGREEMENT AND YOU ACCEPT AND ARE BOUND BY SUCH CHANGE, REPLACEMENT AND UPDATE IF YOU ACCESS OR USE OUR SERVICE AFTER WE HAVE POSTED UPDATED TERMS AND CONDITIONS.

11. TERMINATION

11.1 Either party may terminate this Agreement with notice for any reason whatsoever with a ninety days (90) days written notice period. EirMed Ltd may terminate this agreement with notice and with immediate effect if User:

- (i) breaches this Agreement;
- (ii) fails to make due payments;
- (iii) misuses the Services or uses Services contrary to Acceptable Use policy;
- (iv) engages in fraudulent or illegal activities.

11.2 Upon termination of this Agreement, the User will not be able to use the Services and we may immediately delete any Data collected through the Platform. If the Agreement has been terminated, the user shall be liable to pay to EirMed Ltd any outstanding fees due for payment immediately. EirMed Ltd shall not be responsible for any damage caused by the termination of this Agreement.

11.3 Users are advised to download all Data to the storage independent of the Platform in the event that they wish to terminate this Agreement.

12. GOVERNING LAWS AND CHOICE OF FORUM

12.1 This Agreement shall be governed by and construed under the laws of Bulgaria, without regard to its conflict of law provisions, as applied to agreements entered into and to be performed in Bulgaria by the Bulgarian residents. You agree that if you have any dispute with EirMed Ltd you will contact us in order to settle through negotiations and mutual understanding. If the solution can not be reached in negotiations you agree and hereby submit to the exclusive jurisdiction of the official courts in Bulgaria.

13. FINAL PROVISIONS

13.1 Publicity. All media releases, public announcements and public disclosures by the User relating to this Agreement or its subject matter, including promotional or marketing material, shall be coordinated with and approved by EirMed Ltd and User prior to release. EirMed Ltd can display the User's logo, marks or other information on the Site or any other marketing material without prior written consent by the User. User may publish EirMed logo insofar as necessary to identify the User as a client of the EirMed. EirMed Ltd may request that User remove EirMed's logos from their respective websites and Users agree to comply immediately upon reception of such request.

13.2 Assignment. Either party may only assign or transfer its rights or obligations under this Agreement with the other party's prior written consent (such consent not to be unreasonably withheld).

13.3 Entire Agreement. The terms of this Agreement constitute the entire agreement between the parties regarding its subject matter and supersede and replace any and all prior agreements, understandings or arrangements between the parties, whether oral or in writing, with respect to the same. Neither party shall have any remedy in respect of any untrue statement made by the other upon which that party relied in entering into this Agreement (unless such untrue statement was made fraudulently) and that party's only remedies shall be for breach of contract as provided in this Agreement.

13.4 Severance. If any part of these Terms is found to be invalid, illegal or unenforceable in any respect, it will not affect the validity or enforceability of the remainder of the Terms.

13.5 Titles. The section titles in the Terms are for convenience only and have no legal or contractual effect.

13.6 Force Majeure. For the purpose of this Agreement, Force Majeure Event shall mean any event arising that is beyond the reasonable control of the affected party (including any industrial dispute affecting any third party, governmental regulations, fire, flood, disaster, civil riot or war). A party who becomes aware of a Force Majeure Event which gives rise to, or which is likely to give rise to, any failure or delay in performing its obligations under this

Agreement shall forthwith notify the other and shall inform the other of the period for which it is estimated that such failure or delay shall continue. The affected party shall take reasonable steps to mitigate the effect of the Force Majeure Event.

13.7 Waiver. Any failure to exercise or enforce any right or the provision of this agreement shall not constitute a waiver of such right or provision.

13.8 Language. These Terms may be available on multiple languages, however English version will be considered as the authentic and official version.