

Terms of Use - Prof. Valmed®

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These Terms govern access to Prof. Valmed® by qualified professional users and the use of its medical decision-support functions, Valmed A(I)cademy® AI Module and any agreed API integration.

I. SUBJECT MATTER.

Prof. Valmed® is CE-marked Class IIb medical device software that processes natural-language questions and inputs and provides source-referenced information and recommendations to support qualified healthcare professionals in the diagnosis, treatment and monitoring of human diseases. Responses are generated from Prof. Valmed's curated and validated medical database. The applicable Instructions for Use (IfU) define the intended purpose, intended users, contraindications, warnings and limitations of the relevant deployment variant.

The Service supports clinical decision-making. Its Output must not be used as the sole basis for a diagnostic or therapeutic decision. The qualified healthcare professional remains responsible for assessing the individual case, checking the cited sources and exercising independent professional judgement. Users shall follow the applicable IfU and report suspected serious incidents and relevant malfunctions in accordance with it.

Each authorized User receives personal, non-transferable access to the AI literacy module of Valmed A(I)cademy® (the "AI Module") for the duration of their access to Prof. Valmed®, without a separate Academy fee. Other Academy modules require a separate agreement. Any CME points or completion certificate depend on the accreditation and completion requirements stated for the AI Module at enrollment. Completion of the AI Module alone does not establish compliance with Article 4 of Regulation (EU) 2024/1689 (AI Act).

II. GENERAL TERMS.

These Terms of Use ("Terms") are between Prof. Valmed – validated medical information GmbH ("Prof. Valmed") and the individual or entity booking the Service ("You" or "Customer"). They govern professional use of the Service. If You accept these Terms on behalf of an organisation, You represent that You have authority to bind it. The Customer is responsible for its authorized Users and their compliance with these Terms.

The commercial terms accepted at booking or set out in an Order Form or separate written agreement prevail over these Terms for the matters they expressly regulate. The applicable IfU governs the medical device's intended purpose and safe use. For an API integration, the Integration IfU, API Integration Guide and applicable acceptance test specification govern technical and regulatory integration requirements. A concluded data processing agreement (DPA) governs processing carried out by Prof. Valmed on the Customer's behalf. The API Integration FAQ is supporting information and does not override those controlling documents. No document alters the agreed price or term merely by being updated.

Prof. Valmed may propose amendments to these Terms by email at least six (6) weeks before their proposed effective date. Amendments shall be deemed accepted after one (1) month without objection only if the notice expressly explains the effect of silence and the right to object. If You object, the existing Terms continue to apply for the current Subscription Term. Changes to agreed base fees, included token allowances, token rates, Subscription Terms or renewal arrangements during a current Subscription Term require express agreement. Changes to the IfU needed for safety or regulatory compliance are governed by the applicable regulatory procedures.

Prof. Valmed may use subcontractors to perform the Service, subject to its contractual responsibilities and, where Personal Data is processed, the applicable DPA.

III. DEFINITIONS.

“Aggregated Data” means statistical data, trends and signals lawfully derived from Content or Usage Data, aggregated across a sufficient number of records or events and anonymized so that no natural person, Customer, healthcare organisation or individual User can reasonably be identified, singled out or inferred, including by combination with reasonably available data. Aggregated Data must not reveal Confidential Information or reproduce identifiable individual Inputs or Outputs. Mere aggregation or pseudonymization does not suffice.

“Anonymized Data” means information relating to no identified or identifiable natural person, assessed by reference to all means reasonably likely to be used for identification. Data is Anonymized Data only after a documented assessment confirms effective anonymization under applicable law.

“Authorized User” means a named individual permitted to access the Service under an allocated, personal user account and within the user groups specified in the applicable IfU.

“Confidential Information” means non-public information disclosed by a Party in connection with the Service that is identified as confidential or reasonably understood to be confidential, including Customer Data and Prof. Valmed’s non-public software, technical documentation, security information and pricing.

“Content” means Input and Output collectively. “Input” means a query and information submitted to the Service by or for an Authorized User. “Output” means the Service’s response, including the associated source references.

“Customer Data” means Content and other information provided by or for the Customer or its Authorized Users, including Personal Data, but excludes Aggregated Data that meets the requirements of these Terms.

“Order Form” means an ordering document, including schedules or appendices, accepted by both Parties that specifies the Service, Authorized Users, price, term or other agreed conditions.

“Personal Data” and “data concerning health” have the meanings given in Regulation (EU) 2016/679 (GDPR). “Pseudonymized Data” remains Personal Data unless it independently meets the requirements for Anonymized Data.

“Service” means the Prof. Valmed® medical device software supplied under the booked plan.

“Usage Data” means technical records about use of the Service, including account identifiers, query timestamps and token counts, but not the medical content of Inputs or Outputs.

IV. USAGE.

Subject to payment of the agreed Fees and compliance with these Terms, Prof. Valmed grants the Customer a non-exclusive, non-transferable and non-sublicensable right for its Authorized Users to access and use the Service during the agreed Subscription Term and within the booked scope. Each account is personal; accounts, credentials and included token allowances may not be shared or pooled except as expressly agreed. Prof. Valmed may suspend or terminate access only as provided in these Terms or mandatory law.

Only persons within the user groups specified in the applicable IfU, with the medical training and professional qualifications required there, may use the Service. The Customer shall verify and administer eligibility and ensure that Users can access and follow the current IfU. The Service is not intended for patients or laypersons. Users shall comply with the IfU, including its contraindications, safety instructions and incident reporting procedure.

API access and use within another system require a separate agreed integration. The integrating organisation is responsible for its own implementation, authentication and verification of professional users, secure handling of credentials, transmission of a unique user identifier and profession for each request, compliant presentation of device information, source references, warnings and the current IfU, and fulfilment of the API Integration Guide. It shall not alter the medical content of Outputs. Productive use is prohibited until the specified acceptance test has been passed and its completed protocol returned to Prof. Valmed. Prof. Valmed supplies the API and relevant documentation; integration work in the partner system is not included unless separately agreed.

Credential sharing, unauthorized scraping, systematic extraction of the database or source corpus, reverse engineering except where mandatory law permits, circumvention of technical limits, and unauthorized automated bulk use are prohibited. Use above an included token allowance is chargeable under Section VII and does not alone constitute misuse. Prof. Valmed may restrict affected access where misuse is reasonably suspected, with notice and an opportunity to remedy where practicable and appropriate to the risk.

The Customer shall submit Personal Data, in particular health data, only where its submission and processing are lawful, necessary and covered by the applicable privacy arrangements and, where required, a DPA. The Customer shall not submit direct patient identifiers unless the applicable product instructions and contractual data protection arrangements expressly permit this.

V. CHANGES AND ADJUSTMENTS.

Prof. Valmed may maintain, update and adapt the Service for security, safety, regulatory compliance, correction of defects and continuing performance. Changes to the certified medical device, its intended purpose or risk controls are implemented through the applicable quality and regulatory processes. Prof. Valmed will give reasonable notice of material changes affecting contractual use, except where urgent safety or security needs require earlier action.

Prof. Valmed does not promise uninterrupted availability or error-free Outputs. This does not limit its obligation to provide the Service in accordance with the agreed scope, the applicable IfU and mandatory law. Scheduled maintenance and support arrangements are governed by any applicable Order Form or service agreement.

VI. CONTENT AND FEEDBACK.

The Customer retains such rights as it has in its Input. Prof. Valmed and its licensors retain all rights in the Service, software, models, curated database, documentation, source selection and other proprietary materials. Subject to third-party rights and the source licences identified with an Output, the Customer may use Outputs for its own permitted professional purposes during and after the Subscription Term. No transfer of ownership in the Service or its database is implied.

The Customer grants Prof. Valmed the non-exclusive rights necessary to process Content and Usage Data to provide and secure the Service, authenticate Users, provide support, measure and bill usage, monitor quality, investigate incidents and meet medical-device and other legal obligations, subject to the DPA, confidentiality and applicable law. This clause is not an independent basis to process Personal Data for unrelated purposes.

To the extent the Customer is legally entitled to do so, it authorizes Prof. Valmed to process Customer Data to create Anonymized Data and Aggregated Data. Where Prof. Valmed acts as a processor, any processing of Personal Data for anonymization and subsequent independent use must be expressly covered by documented controller instructions in the DPA or another valid arrangement and by an applicable legal basis. Pseudonymized Data remains subject to those requirements. No Personal Data or Pseudonymized Data may be sold or disclosed under the commercial rights below.

Once Aggregated Data has been lawfully created and its anonymization has been verified, Prof. Valmed may use, combine, reproduce, publish, disclose, license, sell and otherwise commercialize it worldwide, including by supplying it to IQVIA and other analytics, research or commercial partners, without further payment to the Customer. To the extent any non-personal rights of the Customer in such Aggregated Data are needed for these acts, the Customer grants Prof. Valmed a perpetual, worldwide, transferable, sublicensable, non-exclusive, royalty-free licence for those purposes. Prof. Valmed shall not disclose identifiable Customer Data, Confidential Information, raw Inputs or raw Outputs under this paragraph.

Prof. Valmed shall apply documented controls appropriate to the data and the intended recipients, including suppression or generalization of small or rare cohorts and assessment of linkage and inference risks. If a dataset no longer meets the requirements for Aggregated Data, Prof. Valmed shall not disclose it under the preceding paragraph and shall take appropriate remedial action in respect of prior disclosures.

Prof. Valmed may use lawfully generated Anonymized Data and Aggregated Data for analytics, research, quality assurance and further development of the Service, subject to the applicable medical-device change-control processes. Use of identifiable or pseudonymized Content for independent model training or other purposes beyond the DPA requires a separate valid legal basis and, where applicable, a separate agreement.

Content and Personal Data shall be retained only for the periods and purposes set out in the applicable DPA and privacy information or required by law and regulatory obligations. Any longer retention of lawfully Anonymized Data or Aggregated Data is subject to the safeguards above. Feedback may be used to improve the Service without compensation, provided it does not contain Personal Data or third-party Confidential Information that Prof. Valmed is not entitled to use.

VII. FEES AND TOKEN-BASED BILLING.

VII.1 Plans and Token Allowances

(a) A “Token” is a unit of text processed by Prof. Valmed’s AI pipeline in the course of a query. Consumption comprises input and output Tokens across the pipeline steps attributable to the query, without double counting. Failed technical retries caused solely by Prof. Valmed are not charged again.

(b) The base fee, monthly included token allowance, token rate, Subscription Term and renewal terms for each Authorized User account are displayed before booking and recorded in the booking confirmation and account panel, or agreed in an Order Form. No token charge applies unless its rate was agreed before the relevant usage. Allowances are per account and are not pooled unless expressly agreed.

(c) A “Usage Period” is a calendar month. The included allowance resets monthly and unused Tokens expire without compensation. Where a Subscription Term begins or ends during a month, the allowance for that partial month is prorated by active calendar days; the agreed base fee remains unchanged.

VII.2 Additional Usage and Payment

(a) Tokens exceeding the included allowance, or all Tokens under a plan without an included allowance, are charged at the agreed token rate. There is no separate overage rate. Additional usage is calculated per account and invoiced monthly in arrears, irrespective of the Subscription Term, and payable within fourteen (14) days of receipt of the invoice unless otherwise agreed.

(b) Any base fee covers the entire Subscription Term, is invoiced in advance at its start and is due by the third working day of that term unless otherwise agreed. All prices are stated exclusive of applicable value added tax unless expressly stated otherwise. The agreed Order Form governs any different payment schedule.

(c) If payment is materially overdue despite a reminder and a reasonable period for payment, Prof. Valmed may suspend further access until payment is made, having regard to patient-safety and mandatory legal requirements. Accrued Fees remain payable. Prof. Valmed may require advance payment for further chargeable usage where there is a reasonable, documented credit risk, after giving notice.

VII.3 Measurement and Reports

(a) Prof. Valmed’s technical usage records form the basis of billing, subject to correction of errors. The Customer may request a usage report for any Usage Period within ninety (90) days after its end. This request period does not limit statutory rights to dispute an invoice.

VIII. TERM AND TERMINATION.

These Terms take effect on acceptance. A paid plan runs for the Subscription Term agreed at booking. Any automatic renewal, renewal term and ordinary termination notice must be shown before booking and recorded in the booking confirmation or Order Form. Without an agreed renewal, the plan ends at the expiry of its Subscription Term. Ordinary notice may be given for that expiry in accordance with the agreed renewal terms but cannot end the current Subscription Term early. Either Party may terminate for good cause in accordance with applicable law.

Prof. Valmed may terminate for good cause in particular in the case of serious or repeated misuse under Section IV or material non-payment. Where a breach can be remedied, the legally required prior notice or opportunity to remedy shall be given. Exceeding an included token allowance alone is not good cause. Prepaid base fees are not refunded solely due to non-use or ordinary termination at the end of the term; statutory remedies and the consequences of termination for good cause attributable to Prof. Valmed remain unaffected.

During a Subscription Term, the Customer may upgrade an account to a plan with a higher base fee for the same term. The upgrade takes effect upon Prof. Valmed's confirmation in text form and does not restart or extend the term. The additional base fee is the difference between the two plan base fees multiplied by the days remaining in the term divided by the total days in that term. A change to a plan with a different term requires separate agreement.

In the month of an upgrade, the allowance is the old monthly allowance prorated for days before the effective date plus the new monthly allowance prorated for the remaining days. All Tokens in that month count against the combined allowance chronologically. Chargeable Tokens before the upgrade are billed at the old token rate and from the effective date at the new rate. A downgrade during the term is unavailable; a lower plan may be booked for a subsequent term under the agreed renewal arrangements.

Upon expiry or termination, access ends and unpaid amounts become due according to the applicable payment terms. Data return or deletion, retention for legal and medical-device obligations, and permitted further use of lawfully created Aggregated Data are governed by Sections VI and X and the DPA.

IX. LIMITATIONS OF LIABILITY.

Prof. Valmed is liable without limitation for intent and gross negligence; for injury to life, body or health caused by a negligent breach of duty; under the Product Liability Act; and in other cases in which liability cannot lawfully be excluded or limited.

For slight negligence resulting in breach of a material contractual obligation, Prof. Valmed's liability for property damage and financial loss is limited to the foreseeable damage typical of this contract. Material obligations are those whose fulfilment enables proper performance of the contract and on which the Customer may regularly rely. Liability for slight negligence in breach of non-material obligations is excluded to the extent permitted by law. The foregoing also applies to legal representatives and vicarious agents.

Nothing in this Section changes the Service's intended purpose, the warnings in the IfU, mandatory medical-device obligations, or statutory remedies that cannot be restricted by these Terms. The Customer remains responsible for its own clinical decisions and for the operation of its integration environment.

X. DATA PROTECTION.

Each Party shall comply with applicable data protection law. Prof. Valmed's privacy information describes processing for which it is controller. Where Prof. Valmed processes Personal Data on behalf of the Customer, the Parties shall conclude a DPA before that processing begins; the DPA governs their respective obligations and documented instructions. In the event of conflict concerning such processing, the DPA prevails over these Terms.

The Customer is responsible for a lawful basis for submitting Personal Data and health data, for the accuracy of its instructions, and for information or authorisations it is required to provide. The Parties shall separately document any processing needed to create Aggregated Data for Prof. Valmed's independent purposes. Contractual rights to commercialize Aggregated Data do not dispense with the legal requirements governing the processing and anonymization that precede it.

XI. CONFIDENTIALITY.

Each Party shall use the other Party's Confidential Information only to perform or exercise rights under their agreements, protect it with reasonable care and disclose it only to personnel and service providers bound by appropriate confidentiality obligations. This duty does not apply to information that becomes public without breach, was lawfully known, is independently developed, or is lawfully received without a duty of confidence. Legally required disclosures are permitted after notice where lawful.

Lawfully created Aggregated Data meeting Section III does not constitute Customer Confidential Information. Prof. Valmed's use and sale of such data under Section VI therefore does not breach this Section. Identifiable Customer Data, patient information, raw Inputs and raw Outputs remain protected as applicable. Confidentiality continues for three (3) years after termination and for trade secrets as long as they remain protected by law.

XII. FORCE MAJEURE.

Neither Party is liable for delay caused by circumstances beyond its reasonable control, provided it promptly informs the other Party where practicable and takes reasonable steps to mitigate the effect. Payment obligations for Services already provided remain unaffected. Either Party may terminate an affected obligation if performance remains impossible for a sustained period and continuation cannot reasonably be expected.

XIII. FINAL PROVISIONS.

These Terms, the booking confirmation or Order Form, any applicable DPA and the controlling documents identified in Section II constitute the agreement for their respective subject matters. They do not supersede an individual agreement or a DPA by a general integration clause. Amendments and notices may be made in text form by email to the addresses designated by the Parties, except where a stricter form is required by law.

The Customer may not assign its contractual rights or obligations without Prof. Valmed's prior consent, except where mandatory law provides otherwise. Prof. Valmed may assign the contract as part of a transfer of the relevant business to an entity capable of performing it, after notice to the Customer and subject to its mandatory rights.

German law applies, excluding its conflict-of-law rules, subject to mandatory law. Frankfurt am Main is the exclusive place of jurisdiction only where a jurisdiction agreement is legally permissible; otherwise the statutory courts have jurisdiction. If a provision is ineffective, the remaining provisions remain effective and the statutory rules apply in its place.

Prof. Valmed® – validated medical information GmbH

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