Instructions for Use

Prof. Valmed® (Integration Variant), access via the Prof. Valmed API

To use the medical device correctly, read and follow these instructions for use. If you have questions about their content or the use of the product, contact profvalmed@profvalmed.com.

These instructions for use are addressed to the clinical users of Prof. Valmed® when the product is accessed through a partner system (Integration Variant). Technical information for the integrating organisation is provided separately in the API Integration Guide.

This document intentionally contains no screenshots: the visual presentation is determined by the partner system and is outside the control of the manufacturer.

Instead, Section 5 defines the information elements that accompany every response independently of the presentation. Their correct implementation is verified in the acceptance test (Section 13) before productive use.

In this document, the manufacturer symbol in accordance with ISO 15223-1 and the CE marking with the number of the notified body are used (Section 1). Within the partner system, all information elements are provided as plain text.

Abbreviations:

API (Application Programming Interface),

eIFU (electronic Instructions for Use), MDR (Regulation (EU) 2017/745 on medical devices),

SRN (Single Registration Number of the manufacturer),

UDI-DI / UDI-PI (Unique Device Identifier, Device Identifier / Production Identifier).

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Document Identification

Document no. / Title	Prof. Valmed® Instructions for Use, Integration Variant
Version	03
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Purpose	Instructions for use pursuant to MDR Annex I Chapter III Section 23.4, provided in electronic form in accordance with Implementing Regulation (EU) 2021/2226.

Revision history

Version	Date	Change
01	2026-08-20	Initial version for UDI-DI: 04262455490058
02	2026-09-01	Update für UDI-DI: 04262455490072
03	November 2026	Update for UDI-DI: 04262455490096; emergency exclusion removed, personal data and data concerning health added, contraindications aligned with the web-based variant (Section 6)

1 Device identification and manufacturer

Product name	Prof. Valmed® CE 0483
Variant name	Integration variant
Basic UDI-DI	426245549PROFVALMED1KU
UDI-DI	04262455490096

As the product is software provided as a service, the information required on a label is provided electronically in this document and via the device information endpoint (Section 10), in human-readable plain text. Version and issue date of these instructions for use are stated in the document information table above.

2 Intended purpose

The software Prof. Valmed® processes natural language questions and inputs and generates natural language answers. It is intended to be used for the purpose of providing healthcare professionals and medical personnel with recommendations for diagnosis or therapy of human disease. Responses are generated exclusively from validated medical data selected and curated under human supervision within the proprietary Prof. Valmed® database; the sources are made available with each response.

The Integration Variant is a deployment form of Prof. Valmed®. Intended purpose, medical functionality and the underlying validated database are identical to the web-based variant. The difference is the access path: queries and responses are exchanged via the Prof. Valmed API and presented within the user interface of an integrating partner system.

Clinical benefit: rapid access to validated, source-referenced medical information in support of clinical decision-making. The final clinical decision always remains with the healthcare professional.

3 Intended users and use environment

- Intended users: physicians, healthcare professionals and medical personnel involved in the diagnosis, treatment and monitoring of diseases.
- Use environment: professional healthcare environments (e.g. hospitals, practices) through a partner system that has integrated the Prof. Valmed API and successfully completed the acceptance test (Section 13).
- The Integration Variant is not intended for use by patients or other laypersons. The integrating partner verifies the professional status of each user (Section 9).
- Patient population: the software provides information related to human diseases in general; it has no direct patient contact and administers no therapy.

4 Description and principle of operation

The Integration Variant has no Prof. Valmed user interface. The partner system transmits the user query to the Prof. Valmed API and displays the response. Independent of the presentation, the underlying mechanisms are identical to the web-based variant:

- **Curated knowledge base:** responses are generated exclusively from the proprietary Prof. Valmed® database of validated medical literature and guidelines, selected and curated under

human supervision. The database has its own version (the second component of the version string, e.g. 2.1.0_2.1.0).

- **Retrieval and generation:** for each query, the relevant passages are retrieved from the database and processed into a natural-language answer by a language-model based pipeline. The system does not answer from open internet content.
- **Source referencing:** every response carries references to the underlying sources. The references are part of the medical information and are always displayed (Section 5).
- **No autonomous action:** the software provides information and recommendations for consideration by the professional user. It does not trigger, order or execute any diagnostic or therapeutic measure.

5 Information provided with each response

Regardless of how the partner system presents the content, the following elements accompany every response and are displayed to the user:

Element	Meaning for the user
Source references	The validated sources on which the response is based. Review them before acting on a response.
Timestamp	Date and time at which the response was generated.
Output ID	Unique identifier of the individual response (session/response ID). Quote it in support requests, complaints and incident reports; it enables exact traceability.
Version and data status	Software version and database version (format software_database, e.g. 2.1.0_2.1.0). The database version indicates the knowledge status of the underlying medical content.
Instructions for use	A clearly labelled link to the current version of these instructions for use, for example "Instructions for Use (provided electronically instead of on paper)". A general attribution such as "Powered by Prof. Valmed®" may be shown in addition but does not replace that label.

If one of these elements is missing in the partner presentation, do not rely on the response and inform the operator of the partner system.

6 Contraindications and limitations of use

- Not intended for use by patients or laypersons.
- Not suitable for questions in dentistry.
- Not suitable for questions in veterinary medicine.
- Not to be used for non-medical issues.
- Not to be used as the sole basis for diagnosis or therapy decisions.
- The knowledge status of a response corresponds to the displayed database version. Content published after that status is not reflected.
- Responses are provided in the language configured for the partner system (e.g. German). Other languages are not covered.

Personal data and data concerning health

Personal data, including information relating to identified or identifiable natural persons and data concerning health, may be provided as input to Prof. Valmed®, provided that an appropriate legal basis exists and all applicable data protection requirements are complied with, including any applicable data processing agreement and contractual data protection arrangements.

7 Warnings and safety information

- Prof. Valmed® provides decision support only. It does not replace the professional judgement of the treating physician or healthcare professional. The final clinical decision remains with the user.
- Always review the cited sources before acting on a response.
- The quality of a response depends on the quality and completeness of the query. Formulate queries precisely and provide the clinically relevant context.
- If a response appears implausible, incomplete or contradictory to established knowledge, do not act on it and report it (Section 14).

8 Residual risks and undesirable effects

The product has no physical contact with patients; no physical side effects exist. The relevant residual risk is that a response may be incomplete, ambiguous or not applicable to the individual case. This risk is mitigated by the exclusive use of the validated database, mandatory source referencing, and use by qualified professionals who verify the information against the cited sources and their own judgement. Any serious incident that occurs in relation to the device shall be reported as described in Section 14.

9 Obligations of the integrating partner

The integrating partner operates the user-facing presentation layer. For safe and compliant use, the partner shall:

- display the information elements of Section 5 with every response, without modification, truncation or re-ranking of the source references;
- make these instructions for use accessible via the clearly labelled link and present the warnings of Sections 6 and 7 to end users in an easily accessible manner;
- ensure that only verified healthcare professionals access the product, and transmit a unique user identifier (X-User) and the medical profession of the user (X-Profession) with every request; both are required for regulatory reasons;
- not modify the medical content of responses;
- make the UDI and device information accessible to users (Section 10);
- report malfunctions, degradation of performance and suspected incidents to the manufacturer without delay (Section 14).

The complete set of technical obligations is defined in the API Integration Guide and verified in the acceptance test (Section 13).

10 UDI and device information

In accordance with MDR Annex VI Part C Section 6.5.4(c), software without its own user interface transmits the UDI through an application programming interface. In accordance with Section 6.5.4(b) and (e), the UDI is displayed in the partner system in easily readable plain text, including the

Application Identifiers of the standard used by the issuing entity. The UDI and the device identification data of Section 1 can be retrieved at runtime via the device information endpoint (GET /api/device-info) and are displayed in the information area of the partner system in plain text. Until the endpoint is available, the identification data of Section 1 apply and are additionally provided with the contractual documentation.

11 Operating environment and IT requirements

- The product is provided as a service; no installation, calibration or maintenance by the user is required.
- Access requires the partner system and the network environment of the healthcare organisation. Integration of the partner system into the IT network of the healthcare organisation, including risk management of that network, is the responsibility of the operating organisation (see IEC 80001-1).
- Availability and maintenance windows are communicated by the manufacturer to the integrating partner and by the partner to the users.
- Minimum requirements (MDR Annex I Chapter III Section 23.4(ab)): access requires a current web browser or partner application capable of TLS 1.2 or higher, an internet connection to the manufacturer service, and the display of text-based responses. No dedicated hardware is required beyond the workstation used to operate the partner system.
- IT security measures: all communication with the Prof. Valmed API is encrypted in transit (TLS). Access to the interface is authenticated by an API key held by the integrating partner; the partner authenticates its users, verifies their professional status and protects the API key against unauthorised access. Detailed security requirements and the split of responsibilities are defined in the API Integration Guide.
- Displaying these instructions for use requires a current web browser with internet access; no additional software is needed.

12 Maintenance, updates and versioning

The software is updated centrally by the manufacturer; users do not install updates. Every release changes the displayed version (Section 5). Substantial changes are managed under the manufacturer's change control and, where required, notified to the Notified Body before deployment. The integrating partner is informed of releases via release notes; version and data status are always retrievable at runtime (Section 10), so no manual maintenance of version information is required in the partner system.

Decommissioning: if use of the Integration Variant is discontinued, no local uninstallation is required. The integrating partner deactivates the interface and the manufacturer revokes the access credentials; details are described in the API Integration Guide.

13 Technical integration and acceptance test

Technical integration details (authentication, mandatory headers, payload limits, session handling, streaming) are specified in the API Integration Guide and are not part of these instructions for use.

Prior to productive use, the integrating partner shall successfully complete the acceptance test according to the Test Specification API Integration and return the completed test protocol to Prof. Valmed GmbH.

Recurring questions are answered in the document "Prof. Valmed API Integration FAQ".

14 Incident reporting and support

Malfunctions, degradation of performance, implausible outputs and suspected incidents shall be reported to Prof. Valmed GmbH: profvalmed@profvalmed.com, stating the Output ID and timestamp of the affected response where available. In the case of a serious incident in relation to the device, users and/or the operating organisation shall additionally inform the competent authority of the Member State in which they are established (for Germany: BfArM).

15 Provision of these instructions for use

These instructions for use are provided in electronic form in accordance with Implementing Regulation (EU) 2021/2226. The current version is available per link by the device information endpoint (ifuUrl). Issue date and version are stated in this document. Previous versions remain available from the manufacturer.

A paper copy can be requested free of charge from profvalmed@profvalmed.com and will be provided within 7 calendar days, and in no event later than seven calendar days after receipt of the request, or at the time of delivery if requested when the product is ordered.

Language: these instructions for use are issued in the respective acceptable language. The applicable official language version for each target market is defined in the internal specification and is the reference against which the acceptance test verifies the document.

16 Validity

These instructions for use apply exclusively to the Integration Variant of Prof. Valmed®. The web-based variant is covered by its own instructions for use.

The revision history of this document is part of the document information at the beginning of this document.

Manufacturer 	Prof. Valmed - validated medical information GmbH, Fasanenweg 2, 63225 Langen, Deutschland; profvalmed@profvalmed.com; www.profvalmed.com
SRN	DE-MF-000043022
Device status	Medical device (MD), Class IIb under Regulation (EU) 2017/745 (MDR), Rule 11, Annex VIII

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