

GENERAL TERMS AND CONDITIONS OF SIFo GMBH (SIFo)

This document contains the General Terms and Conditions of SIFo. Please select the relevant subject matter:

**A.
DIGITAL CONTENT**

**B.
ANALYSIS SERVICES**

SIFo GmbH
Bärenweg 11
6140 Telfs
Austria
Tel: +43 676 359 29 90
E-Mail: office@sifo-medical.com
Web: <https://www.sifo-medical.com/>

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A.

GENERAL TERMS AND CONDITIONS OF SIFo GMBH (SIFo) FOR DIGITAL CONTENT VERSION AUGUST 2025

§ 1 SCOPE OF APPLICATION

1.1 These General Terms and Conditions (hereinafter: "GTC") apply to all transactions between SIFo and its customers concerning the provision of digital content. Any general terms and conditions of the customer that deviate from these GTC or from amendments and supplements confirmed in writing by SIFo are hereby expressly excluded. Deviations from these GTC may only be agreed upon in writing.

1.2 SIFo's offer to provide digital content is directed exclusively at entrepreneurs (B2B). SIFo does not enter into contracts with consumers (B2C). The customer shall confirm upon conclusion of the contract that it is acting as an entrepreneur.

1.3 These GTC shall also apply to all future contracts with the customer concerning the provision of digital content until new GTC are issued by SIFo, even if such contracts are concluded without express reference to these GTC. The version in force at the time of conclusion of the contract shall be determinative in each case.

§ 2

CONCLUSION OF CONTRACT

2.1 SIFo offers its customers digital content on its website at www.sifo-medical.com ("Website"), in particular concerning test method validation in medical device technology. A detailed description of the digital content and the applicable prices are set out directly on the Website.

2.2 A binding contract for the provision of digital content against payment is concluded on the Website at www.sifo-medical.com by clicking the button "Pay Now". Upon advance payment (cf. § 3.2), the customer receives online access to the digital content and must, for this purpose, create a personal user account through which the customer may access the digital content. The customer is permitted to use access to the digital content solely for personal use within its own business. The digital content shall be made available to the customer for an indefinite period. The customer undertakes not to reproduce, process, or make available to third parties (including affiliated companies of the customer) any digital content provided by SIFo.

2.3 The customer is solely responsible for ensuring that it has the necessary hardware, software, and a sufficient internet connection to retrieve the digital content via its user account, and for selecting a secure password for its user account.

2.4 Without the prior written consent of SIFo, the customer is not entitled to transfer any rights or obligations arising from the contractual relationship with SIFo to any third party.

2.6 Unless expressly agreed otherwise in writing, SIFo does not grant the customer any contractual right of withdrawal from the contract.

§ 3

REMUNERATION AND PAYMENT

3.1 The amount of the remuneration for the provision of digital content shall be indicated at the time of ordering and shall, in case of doubt, be understood as exclusive of value added tax. Upon conclusion of the contract, the customer confirms its awareness and acceptance of the remuneration.

3.2 Payment of the remuneration shall be made in advance and constitutes a prerequisite for the provision of the digital content. The available payment methods are indicated directly on the Website.

3.3 Following receipt of payment, SIFo shall issue the customer with a proper invoice for the remuneration.

3.4 SIFo is entitled to transmit invoices to the customer in electronic form. The customer expressly consents to the receipt of invoices in electronic form.

§ 4

COPYRIGHT AND LICENCE TO USE

4.1 All digital content provided by SIFo constitutes works protected by copyright. The exclusive right of use in respect of such works vests in SIFo.

4.2 Unless expressly agreed otherwise, SIFo grants its customers only a simple, non-exclusive licence to use the works and no exclusive rights of use. The licence granted to the customer is limited to the personal use of the content within the customer's own business. A licence granted in favour of the customer shall be deemed to have been granted only upon full payment of the agreed remuneration therefor.

§ 5

WARRANTY AND LIABILITY

5.1 SIFo warrants that the digital content shall be available for retrieval via the customer's user account and shall conform to the agreed service description. The digital content is prepared to the best of SIFo's knowledge and belief and in accordance with the current state of the art in the relevant subject area.

5.2 SIFo cannot assume any warranty or liability for circumstances outside its sphere of control. This includes, in particular, cases of force majeure, natural disasters, power outages, or internet failures.

5.3 A notice of defect must contain a specific, detailed description of the defect (e.g. an error message when retrieving digital content). Adequate documentation of the defect must be provided within four weeks of its occurrence. If a complaint is lodged validly and in a timely manner, the customer shall initially be entitled only to subsequent performance (remedy of the defect). Claims for price reduction or rescission of the contract shall be available to the customer only if SIFo's attempts to remedy the defect have failed even after a period of one month.

5.4 Claims for damages in cases of minor negligence are mutually excluded; this exclusion shall not apply to personal injury. The customer bears the burden of proving that any damage is attributable to fault on the part of SIFo. Claims for damages by the customer may only be brought before a court within six months of the customer becoming aware of the damage and the party responsible, but in any event no later than three years after the causative event. Consequential damages and loss of profit, in particular in the event of delayed or defective performance, are excluded from liability. SIFo shall not be liable for damage suffered by the customer as a result of the customer's failure to observe the substantive explanations contained in the digital content. To the extent that SIFo's liability is excluded or limited, this shall also apply to the personal liability of SIFo's employees, agents, and vicarious agents.

§ 6

DATA PROTECTION

6.1 In the context of concluding the contract, SIFo stores and processes the customer's first and last name or company name, value added tax identification number, salutation, address (postal address, e-mail address, telephone number), contact persons at the customer's premises, digital content ordered, the remuneration and payment status, as well as any correspondence with the customer (collectively hereinafter: "personal data"). Such personal data shall – unless the customer has provided express consent beyond this – be processed solely for the purpose of contractual performance and the provision of the digital content. These data are collected lawfully pursuant to Art. 6(1)(b) of the General Data Protection

Regulation (hereinafter: “GDPR”), as they are necessary for the performance of the contract between SIFo and the customer. Without the provision of such personal data, the ongoing provision of digital content cannot therefore take place. The collected data shall be deleted when the customer deletes its user account and no other legal basis for continued use exists (in particular, express consent of the customer, statutory retention periods, or outstanding warranty or liability periods). The specific contract shall be stored for the purpose of contract performance and as evidence of the conclusion of the contract.

6.2 Personal data of the customer shall be disclosed only to the extent necessary for the performance of this contract, in particular to the following recipients:

- **Stripe:** SIFo uses the payment service provider Stripe for payment processing (provided in Europe by: Stripe Payments Europe, Limited (SPEL), 1 Grand Canal Street Lower, Grand Canal Dock, Dublin, D02 H210, Ireland). In particular, the following data may be transmitted to Stripe:
 - Full name
 - E-mail address
 - Contact number
 - Billing and shipping address
 - Payment method information (e.g. credit or debit card number, bank account details, or the payment card image selected by the customer)
 - Merchant and location details
 - Purchase amount and date
 - Information about the purchased item

Further information on Stripe’s data protection practices is available at: <https://stripe.com/at/privacy>

- **Odoo:** SIFo uses the services of Odoo (Odoo SA, Rue du Laid Burniat 5, 1348 Louvain-la-Neuve, Belgium) for the provision of the Website. Odoo collects and processes the data referred to in § 6.1 on behalf of SIFo in order to provide the services subscribed to by SIFo, in particular the Website. Odoo’s customer service staff and engineers may access such information to a limited and reasonable extent in order to resolve any issues with the Website. Further information on Odoo’s data protection practices is available at: <https://www.odoo.com/privacy>

6.3 The customer, if a natural person, has the right at any time to request information from SIFo regarding which data SIFo has collected about it. If the collected data is or becomes incorrect, the customer may request rectification of the data. Where the legal requirements are met, the customer also has the right to erasure (Art. 17 GDPR), the right to restriction of processing (Arts. 18 et seq. GDPR), and the right to data portability (Art. 20 GDPR). An English version of the GDPR is available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679>

6.4 Customers may contact SIFo at the following address for any questions regarding the processing of their data: office@sifo-medical.com

6.5 If the customer is a natural person and believes that SIFo is processing its personal data in breach of applicable law, the customer is free to lodge a complaint with the Austrian Data Protection Authority (Datenschutzbehörde), Barichgasse 40–42, A-1030 Vienna, or with the national supervisory authority of the customer’s country of residence.

§ 7

FINAL PROVISIONS

7.1 All agreements containing amendments, supplements, or specifications to these GTC, as well as any special representations and commitments, must be made in writing. This shall also apply to any agreement to waive this formal requirement. If made by employees of SIFo, such agreements shall be binding only if the authorised governing bodies of SIFo have given their written consent. All notices and declarations by the customer relating to this contractual relationship must be made in writing.

7.2 The language of the contract is German. The German version of these GTC shall be the authoritative version.

7.3 The contractual relationship between SIFo and the customer shall be governed by the laws of the Republic of Austria, to the exclusion of the United Nations Convention on Contracts for the International Sale of Goods (CISG / Vienna Convention), and to the exclusion of the conflict of law rules of private international law and the Rome I Regulation.

7.4 The exclusive place of jurisdiction for all disputes shall be the court of competent subject-matter jurisdiction in Innsbruck, Austria. SIFo reserves the right, however, to bring proceedings against the customer before the courts of the customer's registered office.

7.5 Should any individual provision of these GTC be or become wholly or partially invalid or unenforceable, the validity of the remaining provisions shall not be affected. In such case, the invalid provision shall be replaced by a legally valid provision that corresponds to, or most closely approximates, the economic purpose of the invalid provision or the presumed intention of the contracting parties. The same shall apply if any provision proves to be unenforceable for practical reasons.

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B.

GENERAL TERMS AND CONDITIONS

OF SIFo GMBH (SIFo)

FOR ANALYSIS SERVICES

VERSION AUGUST 2025

§ 1

SCOPE OF APPLICATION

1.1 These General Terms and Conditions (hereinafter: "GTC") apply to digital analysis services for medical devices provided by SIFo. Any general terms and conditions of the customer that deviate from these GTC or from amendments or supplements confirmed in writing by SIFo are hereby expressly excluded. Deviations from these GTC may only be agreed upon in writing.

1.2 SIFo's offer is directed exclusively at other entrepreneurs (B2B). Orders from consumers (B2C) are not accepted. The customer shall confirm during the ordering process that it is acting as an entrepreneur.

1.3 These GTC shall also apply to all future contracts with the customer until new GTC are issued by SIFo, even if such contracts are concluded without express reference to these GTC. The version in force at the time of conclusion of the contract shall be determinative in each case.

§ 2

CONCLUSION OF CONTRACT

2.1 SIFo offers its customers the opportunity in its web shop at www.sifo-medical.com to purchase credits for the use of analysis services for medical devices pursuant to § 3.

2.2 The customer may purchase credits for analysis services in SIFo's web shop by selecting the desired credits and clicking the button "Order with obligation to pay". Upon receipt of payment, the purchased credits shall be credited to the customer's user account and may be used for analysis services at any time.

2.3 The credits are valid for a period of three (3) years from the date of purchase and are non-refundable. An extension of the validity period is only possible with the express consent of SIFo.

2.3 Without the prior written consent of SIFo, the customer is not entitled to transfer credits to third parties.

§ 3

PROVISION OF ANALYSIS SERVICES

3.1 The analysis services offered by SIFo enable a supported risk analysis for medical devices. A detailed description of the analysis services and the applicable prices can be found directly in SIFo's web shop at www.sifo-medical.com. SIFo's analysis services are performed by means of an AI analysis tool developed by SIFo.

3.2 The customer may access SIFo's analysis services at any time in the internal user area of SIFo's web shop by using credits. The analysis services are provided exclusively online via SIFo's web shop. To use the services, the customer must have a valid user account and sufficient credits.

3.2 In order for the analysis services to be successfully performed, the customer must upload the required data or respond to the prescribed questionnaire. The customer is solely responsible for the completeness and accuracy of the data and responses submitted to SIFo for analysis. Once an analysis has been commissioned, no further changes to the data or responses may be made. To supplement or amend data or responses, a new analysis must be initiated. SIFo is not required to carry out any plausibility check of the data or responses provided. The customer acknowledges that the risk analysis may yield both positive and negative results.

3.3 The customer undertakes to provide SIFo with data for analysis only that does not constitute personal data within the meaning of Art. 4(1) of the General Data Protection Regulation (GDPR). If the customer wishes to have personal data analysed, such data must be properly anonymised by the customer on its own responsibility prior to submission to SIFo.

3.4 SIFo is entitled to modify the scope, content, or structure of the analyses at any time, insofar as this serves to improve the offering or is required for regulatory reasons.

§ 4

PRICES AND PAYMENT

4.1 The prices for credits for analysis services are set out in SIFo's web shop. All prices shall, in case of doubt, be understood as exclusive of value added tax.

4.2 Payment for credits shall be made in advance and constitutes a prerequisite for the use of analysis services. The available payment methods are indicated directly in SIFo's web shop.

4.3 SIFo shall issue the customer with a proper invoice.

4.4 SIFo is entitled to transmit invoices to the customer in electronic form. The customer expressly consents to the receipt of invoices in electronic form.

§ 5

WARRANTY

5.1 SIFo warrants that the analysis services, at the time of use by the customer, comply with the standard ISO 14971:2019 and are free of defects. The analysis services are suitable for the described use.

5.2 Warranty claims shall become statute-barred six months from the date of use of an analysis. Warranty claims may only be asserted by the respective customer itself.

5.3 In the event of a defect in the analysis, SIFo shall be entitled to remedy the defect by way of subsequent performance through a new analysis (replacement delivery). The customer shall grant SIFo the necessary time and opportunity to carry out subsequent performance; failing this, SIFo shall be released from its warranty obligations. The customer shall cooperate in the subsequent performance to the extent necessary.

5.4 No warranty claim shall exist in respect of minor defects.

5.5 The customer shall be entitled to rescind the contract only if the defect is not minor and subsequent performance by SIFo fails, is in particular impossible, or if SIFo does not manage to remedy the defect within a reasonable period of at least two weeks, refuses to do so, or culpably delays remedying the defect.

5.6 SIFo does not warrant compliance with any special regulations applicable in the country of destination.

§ 6

LIABILITY AND DAMAGES

6.1 SIFo shall be liable for analysis services only in cases of intentional or negligent causation of damage. Claims for damages in cases of minor negligence are mutually excluded; this exclusion shall not apply to personal injury. The customer bears the burden of proving gross negligence or wilful misconduct in the causation of damage. Liability shall be limited to typical and foreseeable contractual damage. Liability for loss of profit, indirect damages, delays, or data loss is excluded.

6.2 The customer bears the burden of proving in each case that the damage is attributable to fault on the part of SIFo.

6.3 Claims for damages by the customer may only be brought before a court within six months of the customer becoming aware of the damage and the party responsible, but in any event no later than three years after the performance of the analysis service.

6.4 SIFo assumes no liability for misinterpretations by the customer of the analysis results or for any measures taken by the customer on the basis thereof. Interpretation and conclusions are at the customer's sole risk.

§ 7

INTELLECTUAL PROPERTY

All content, analyses, and tools of SIFo are protected by copyright. The customer receives a simple, non-transferable licence to use the analysis results. SIFo is entitled to use the analyses itself for internal evaluation and statistical purposes.

§ 8

DATA PROTECTION

8.1 In the context of concluding the contract, SIFo stores and processes the customer's first and last name or company name, value added tax identification number, salutation, address (postal address, e-mail address, telephone number), contact persons at the customer's premises, purchased credits, payment status, the data and responses uploaded by the customer, and the analysis services performed (collectively hereinafter: "personal data"). Such personal data shall – unless the customer has provided express consent beyond this – be processed solely for the purpose of contractual performance and the provision of the analysis services. These data are collected lawfully pursuant to Art. 6(1)(b) of the General Data Protection Regulation (hereinafter: "GDPR"), as they are necessary for the performance of the contract between SIFo and the customer. Without the provision of such personal data, the performance of the analysis services cannot therefore take place. Following completion of the analysis services and expiry of the warranty period (six months pursuant to § 5) and the absolute limitation period for damages claims (three years after performance of the analysis service pursuant to § 6), the collected data shall be deleted, unless any other legal basis for continued use exists (in particular, express consent of the customer or statutory retention periods). Disclosure of personal data of the customer shall occur only to the extent strictly necessary for the performance of this contract. The specific contract shall be stored for the purpose of performing the delivery and as evidence of the conclusion of the contract.

8.2 The customer, if a natural person, has the right to request information from SIFo regarding which data SIFo has collected about it. If the collected data is or becomes incorrect, the customer may request rectification of the data. Where the legal requirements are met, the customer also has the right to erasure (Art. 17 GDPR), the right to restriction of processing (Arts. 18 et seq. GDPR), and the right to data portability (Art. 20 GDPR). An English version of the GDPR is available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679>

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Protection Authority (Datenschutzbehörde), Barichgasse 40–42, A-1030 Vienna, or with the national supervisory authority of the customer's country of residence.

§ 9

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9.2 The language of the contract is German. The German version of these GTC shall be the authoritative version.

9.3 The contractual relationship between SIFo and the customer shall be governed by the laws of the Republic of Austria, to the exclusion of the United Nations Convention on Contracts for the International Sale of Goods (CISG / Vienna Convention), and to the exclusion of the conflict of law rules of private international law and the Rome I Regulation.

9.4 The exclusive place of jurisdiction for all disputes shall be the court of competent subject-matter jurisdiction in Innsbruck, Austria. SIFo reserves the right, however, to bring proceedings against the customer before the courts of the customer's registered office.

9.5 Should any individual provision of these GTC be or become wholly or partially invalid or unenforceable, the validity of the remaining provisions shall not be affected. In such case, the invalid provision shall be replaced by a legally valid provision that corresponds to, or most closely approximates, the economic purpose of the invalid provision or the presumed intention of the contracting parties. The same shall apply if any provision proves to be unenforceable for practical reasons.

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