

## THE EFTY GROUP

The **Ergonomics Factory Group ("EFTY Group")** comprises two legal entities:

- (1) Ergonomics Factory Sàrl ("EFTY")**, Rue du Voisinand 8, 1095 Lutry, Switzerland. UID: CHE 285.744.392
- (2) KDA User and Market Research GmbH ("KDA")**, Bruchstraße 5, 60594 Frankfurt am Main, Germany. HRB 39686. VAT ID: DE 811842866

The contracting entity for any given project is identified in the applicable proposal, Service Agreement or Statement of Work ("SOW"). Both entities are bound by these Terms and Conditions (T&C) unless a clause expressly states otherwise.

## ACCEPTANCE

By signing a proposal or SOW, or by instructing the EFTY Group to commence work, the Client accepts these T&C in full. Any conflicting Client terms apply only if accepted in writing by an authorized EFTY Group representative. Where mandatory consumer protection law applies, it takes precedence.

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## 1. Proposals & Agreements

Proposals describe the scope, timeline and cost of services. They are non-binding until both parties confirm agreement in writing - which includes signed documents and email confirmation by an authorized representative.

The SOW or Service Agreement defines the exact scope of services. Where a conflict exists between a proposal and a signed Service Agreement / SOW, the signed Service Agreement / SOW prevails. Where a conflict exists between these T&C and a signed Quality Agreement or signed Service Agreement / SOW, the following order of precedence applies:

1. Signed Quality Agreement
2. Signed Service Agreement / SOW
3. These Terms & Conditions

All proposal content - including methodologies, pricing and regulatory strategies - is confidential from the moment of receipt and may not be shared with third parties without prior written consent.

## 2. Standards

The standards applied to any project depend on the product type, intended use and regulatory pathway. Applicable frameworks include, but are not limited to:

- **Quality & Risk:** ISO 13485 · ISO 14971 · AAMI TIR57 · AAMI TIR59
- **Human Factors & Usability:** IEC 62366 · AAMI HE74/HE75 · FDA HF Guidance (2016)
- **Software & Safety:** IEC 62304 · IEC 60601 · ISO 9241
- **Regulatory:** EU MDR (2017/745) · EU IVDR (2017/746) · FDA 21 CFR 820
- **Research & Ethics:** For all projects involving third-party participants, we adhere to **ISO 20252** and the **EphMRA Code of Conduct**.

These obligations also apply to all engaged subcontractors.

## 3. Changes to Scope

Any change to the agreed scope requires a written **Change Order** confirmed by both parties before the changed work begins. The EFTY Group will not commence additional work, incur additional costs or modify deliverables without a confirmed Change Order. Revised timelines and fees apply only as documented in that Change Order.

## 4. Service Delivery

The EFTY Group delivers services to recognized professional, scientific and technical standards.

Our work supports the Client's decision-making; we do not make product, safety, commercial or regulatory decisions on the Client's behalf.

**Impracticability.** If a project proves impractical for methodological, organizational, ethical or regulatory reasons, we will notify the Client in writing and may terminate in accordance with Section 13.

**Client cooperation.** Where delivery depends on Client input - materials, approvals, documentation or access - required inputs and timelines are agreed separately. Delays caused by missing Client input shift our timelines by an equivalent period at no liability to us.

**Regulatory deliverables** may include, depending on project scope:

- HFE Plan
- Usability Failure Mode and Effects Analysis
- Formative Evaluation Protocol & Report
- Summative Evaluation Protocol & Report
- Usability Engineering File
- HF / UE Report
- Use-Related Risk Analysis (ISO 14971)
- Software UI Risk Analysis (IEC 62304)
- IFU & Labelling
- MDR/IVDR Technical Documentation
- FDA HF Submission Documentation
- PMS & PMCF Documentation.

We do not guarantee regulatory approval by any authority.

**Subcontractors.** We may engage subcontractors in any jurisdiction. All subcontractors are bound by confidentiality, quality and data protection obligations equivalent to those in these T&C, including Data Processing Agreements where required under GDPR Art. 28(4). Where the Client specifies a subcontractor, the EFTY Group accepts no liability for that subcontractor's performance.

## 5. Client Responsibilities & Participant Protection

### 5.1 Client Responsibilities

The Client is solely responsible for:

- Product safety, performance and regulatory classification
- Completeness and accuracy of all technical documentation (IFU, labelling, risk files)
- Conducting all required safety testing prior to participant exposure
- Regulatory compliance in all target markets
- Accuracy of the intended use definition
- Pre-study verification that no unmitigated participant safety risks remain
- Compliance with all applicable export, import and customs regulations

The EFTY Group is not obligated to verify Client-provided documentation unless verification is explicitly commissioned in the Service Agreement / SOW.

### 5.2 Informed Consent

The EFTY Group obtains informed consent from all study participants in accordance with applicable ethical, regulatory and legal requirements. The Client ensures that any product, prototype or software provided for study use is safe for participant exposure and accompanied by complete, accurate documentation.

### 5.3 Right to Halt

The EFTY Group may immediately halt, reject or postpone any study if:

- Participant safety is at risk
- The product shows unexpected defects
- Documentation is incomplete or misleading
- Regulatory or data protection requirements cannot be met

Participant safety always takes precedence.

## 5.4 Indemnification

The Client indemnifies EFTY Group against all claims arising from:

- Participant injury, side effects or adverse reactions
- Device or software failure
- Electrical, mechanical or toxic hazards
- Errors in IFU or documentation
- Inadequate safety testing

This includes claims by participants, regulators, insurers, healthcare providers or third parties.

## 5.5 Liability for Harm

EFTY Group is liable for participant harm **only** if caused by our **gross negligence or wilful misconduct**.

**However**, nothing in these T&C limits liability for **personal injury or death caused by any degree of our negligence**, as required by mandatory law (e.g., German § 309 No. 7 BGB, Swiss Art. 100 OR).

## 6. Fees & Payment

All prices are net and exclusive of applicable taxes.

### 6.1 Standard Schedule

Unless agreed otherwise:

- 1/3 upon contract signature
- 1/3 upon project start
- 1/3 upon delivery

### 6.2 New or High-Risk Clients

For new clients or those with  $\geq 2$  late payments (high-risk clients):

- 2/3 upon signature
- 1/3 upon delivery

### 6.3 Terms

- Payment due within **30 days** of invoice
- Late payments accrue statutory interest
- Services may be suspended until full payment is received
- Disputed invoices must be notified in writing within **10 business days**; undisputed amounts remain payable

## 7. Intellectual Property & Usage Rights

### 7.1 Ownership

All deliverables (reports, analyses, models, strategies, methodologies, etc.) remain EFTY Group's exclusive property unless otherwise agreed in writing.

### 7.2 Usage Rights

Upon **full payment**, the Client receives a **non-exclusive, non-transferable right** to use deliverables **internally** as defined in the SOW. This does not include sublicensing, public disclosure, or use in legal/regulatory proceedings beyond the agreed scope.

### 7.3 Raw Materials

Raw data, tools, templates and internal methods always remain our property.

### 7.4 Non-Payment

If payment is overdue:

- No usage rights are granted
- All deliverables remain our property
- Client must, upon request, return or delete all materials
- Continued use constitutes copyright infringement

We will issue a **14-day cure notice** before seeking injunctive relief.

## 8. Confidentiality

Both parties treat all project-related information as confidential for **10 years** after project completion.

**Exceptions** apply only if information is:

- Publicly available through no fault of the recipient
- Previously known or independently developed without reference to the disclosed information
- Lawfully received from a third party without restriction
- Required to be disclosed by law (with prior notice where possible)

Proposal content is confidential from receipt and may not be shared without written consent.

## 9. Data Protection

We process personal data in compliance with GDPR, Swiss revDSG, German BDSG, HIPAA (where applicable), and other relevant laws.

Where we process data on your behalf, a **Data Processing Agreement (DPA)** under GDPR Art. 28 is executed before processing begins.

Health and other special category data are handled per GDPR Art. 9 and equivalent standards.

Full details are in our Privacy Policy: [www.efty.group/privacy](http://www.efty.group/privacy)

Sub processors are contractually bound to equivalent data protection obligations.

## 10. Use of Results

Deliverables are for the Client's **internal use only**. Without written consent, the Client may not:

- Publish or publicly share results
- Disclose results to third parties beyond the Service Agreement / SOW scope
- Use EFTY Group's name in marketing, advertising or competitive comparisons
- Cite results in legal, regulatory or administrative proceedings outside the agreed purpose

Attribution is required if results are quoted with permission. Misuse causing harm entitles EFTY Group to damages and indemnification.

## 11. Warranty & Liability

### 11.1 Warranty

We warrant **professionally competent and methodologically sound** service delivery per the agreed standards and Service Agreement / SOW.

### 11.2 Limitations

We do not warrant:

- Regulatory approval
- Commercial or strategic utility of results
- Accuracy of outputs based on incomplete or incorrect Client-provided information

### 11.3 Liability

We are liable only for:

- Intentional or grossly negligent acts
- Personal injury or death (at any level of fault)
- Breach of essential contractual obligations

**Liability is capped at the net project fee.**

We exclude **indirect, consequential, or lost-profit damages.**

**U.S. Clients:** Consequential, incidental, special, punitive or exemplary damages — including lost profit, business interruption or reputational harm — are expressly excluded to the fullest extent permitted by law.

### 11.4 Defect Claims

Report defects within:

- **14 days** of delivery (obvious)
- **3 months** of discovery (non-obvious)

All claims expire **2 years** from delivery, unless mandatory law provides otherwise.

## 12. Delay & Force Majeure

Client-caused delays (e.g., late input) extend our deadlines accordingly. Neither party is liable for failure to perform due to **force majeure** (e.g., war, natural disaster, pandemic, strikes, cyberattack). Affected deadlines are extended for the event's duration. If force majeure lasts more than 60 days, either party may terminate per Section 13.

## 13. Termination

### 13.1 For Cause

Either party may terminate with **immediate effect** if the other:

- Materially breaches and fails to cure within **14 days** of notice

- Becomes insolvent or subject to insolvency proceedings

Upon Client cause: pro-rata refund for uncompleted work.

Upon EFTY cause: full payment for completed work.

### 13.2 For Convenience

Either party may terminate with **30 days' written notice**. Client pays for all completed work and reasonable demobilization costs.

### 13.3 Survival

Sections 5 (Participant Indemnity), 7 (IP), 8 (Confidentiality), 9 (Data Protection), 10 (Use of Results) and 11 (Liability) survive termination.

### 14. Dispute Resolution

1. **Negotiation:** Parties attempt resolution through senior representatives within **30 days** of dispute notice.
2. **Mediation:** If unresolved, parties may mediate before a mutually agreed mediator (costs shared).
3. **Proceedings: If mediation fails, disputes proceed per Section 15.**
4. **Interim Relief:** Either party may seek urgent injunctive relief without prior steps.

For international disputes, parties may agree to binding arbitration under **ICC or Swiss Rules** in **Lausanne, Frankfurt, or Singapore**.

### 15. Governing Law & Jurisdiction

Contracting Entity	Governing Law	Jurisdiction
KDA GmbH	German law (excl. CISG)	Frankfurt am Main courts
EFTY Sàrl	Swiss law (excl. CISG)	Lausanne courts (Canton Vaud)

For international clients, parties may agree on a neutral venue. Consumer rights under local law remain unaffected.

### 16. General Provisions

- **Amendments:** Require written agreement by authorized representatives.
- **Assignment:** Not permitted without prior written consent (except in bona fide mergers with successor's written acceptance of these T&C).
- **Severability:** Invalid clauses are modified or severed; the rest remains in force.
- **Entire Agreement:** These T&C, the Service Agreement / SOW and any Quality Agreement constitute the full agreement.
- **Notices:** Sent by email to [legal@efty.group](mailto:legal@efty.group) (with delivery confirmation) or registered post to the addresses above.
- **Language:** English prevails in case of translation discrepancies.

### 17. Glossary

- **Change Order** – Written amendment to scope, fee or timeline
- **DPA** – Data Processing Agreement (GDPR Art. 28)
- **Force Majeure** – Event beyond reasonable control preventing performance
- **Formative Study** – Development-phase usability study

- **EFTY** – Ergonomics Factory
- **HF** – Human Factors
- **HFE** – Human Factors Engineering
- **IFU** – Instructions for Use
- **PMS/PMCF** – Post-Market Surveillance / Clinical Follow-up
- **Quality Agreement** – Regulatory quality agreement (e.g., under ISO 13485, MDR)
- **SOW** – Statement of Work
- **Summative Study** – Final regulatory validation study
- **T&C** – Terms and Conditions
- **UE** – Usability Engineering
- **UEF** – Usability Engineering File
- **UI** – User Interface
- **Use Error** – Deviation from intended device use

For legal inquiries: [legal@efty.group](mailto:legal@efty.group)

EFTY Group entities are registered in Switzerland and Germany as listed on page 1.