

FOEDUS LEGAL STATUS

FOEDUS Cross-Border Organ Exchange Platform

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1. LEGAL ENTITY INFORMATION

1.1 Operating Entity

Name: FOEDUS z.s.

Legal Form: Czech Non-profit Organization (z.s. - zapsaný spolek)

Registration: Czech Republic

Registered Office: Ruska Street 85, 100 00 Prague 10, Czech Republic

Legal Representative: Franz Immer

1.2 Business Purpose

FOEDUS z.s. operates as a non-profit organization facilitating international organ exchange coordination among European countries through a secure digital platform.

2. REGULATORY COMPLIANCE FRAMEWORK

2.1 Data Protection Compliance

European Union Regulations

- **General Data Protection Regulation (GDPR)** - Regulation (EU) 2016/679
- **Regulation (EU) 2018/1725** - Protection of natural persons with regard to processing of personal data by Union institutions
- Full compliance maintained through comprehensive privacy controls and user rights framework

Czech Republic National Laws

- **Act No. 110/2019 Coll.** - Personal Data Processing Act
- **Act No. 181/2014 Coll.** - Cyber Security Act
- Compliance overseen by Czech Personal Data Protection Authority (ÚOOÚ)

2.2 Healthcare and Medical Device Compliance

European Medical Framework

- **Medical Device Regulation (MDR)** - Regulation (EU) 2017/745 (where applicable)
- **Clinical Trials Regulation** - Regulation (EU) No 536/2014 (for research activities)
- **Cross-Border Healthcare Directive** - Directive 2011/24/EU

Professional Medical Standards

- Compliance with European medical ethics guidelines
- Adherence to national transplant organization protocols
- International organ exchange agreement requirements

2.3 Cybersecurity and Technical Compliance

- **NIS Directive** - Network and Information Security requirements

- **Czech Cyber Security Act** compliance
- ISO 27001 security management principles implementation

3. OPERATIONAL LEGAL STATUS

3.1 Service Classification

- **Platform Type:** Business-to-Business (B2B) healthcare coordination system
- **User Base:** Licensed medical professionals and authorized healthcare institutions
- **Geographic Scope:** European Union and associated countries
- **Service Model:** Software as a Service (SaaS) with specialized healthcare focus

3.2 Licensing and Authorization

- Operating under Czech Republic non-profit organization registration
- No specific medical device licensing required (coordination platform only)
- Compliance with professional medical service provider requirements
- Authorization for cross-border healthcare data processing

4. DATA PROCESSING LEGAL BASIS

4.1 GDPR Legal Basis

- **Article 6(1)(f)** - Legitimate interests for healthcare coordination
- **Article 9(2)(h)** - Healthcare purposes and medical diagnosis
- **Article 9(2)(i)** - Public interest in public health sector

4.2 Data Processing Agreements

- **AWS Cognito Data Processing Agreement** - Ensures GDPR compliance for authentication services
- Third-party processor agreements maintain European data residency requirements
- User consent mechanisms for voluntary data provision

5. LIABILITY AND INSURANCE FRAMEWORK

5.1 Professional Liability

- Platform operates as coordination tool only
- No medical advice or treatment recommendations provided
- Professional medical decisions remain responsibility of licensed healthcare providers
- Clear disclaimers regarding medical decision-making authority

5.2 Technical Liability Limitations

- Standard software service limitations apply
- Force majeure protections for technical infrastructure failures
- User responsibility for data accuracy and professional compliance
- Third-party service provider liability limitations (AWS infrastructure)

6. INTELLECTUAL PROPERTY STATUS

6.1 Platform Ownership

- FOEDUS z.s. retains full ownership of platform software and design
- Proprietary algorithms and system architecture protected

- User-generated content ownership retained by users with platform usage license

6.2 Third-Party Components

- AWS cloud infrastructure services under commercial licensing
- Open-source components used in compliance with respective licenses
- No conflicts with existing intellectual property rights

7. CROSS-BORDER OPERATIONAL COMPLIANCE

7.1 International Data Transfers

- **European data residency maintained** through AWS European infrastructure
- Standard Contractual Clauses (SCCs) implementation where required
- No data transfers outside European Economic Area without appropriate safeguards

7.2 Multi-Jurisdictional Compliance

- Recognition of varying national transplant regulations
- Compliance framework adaptable to different European legal requirements
- User responsibility for local regulatory compliance

8. CONTRACTUAL FRAMEWORK

8.1 User Agreements

- **Terms of Use** - Comprehensive user obligations and platform rules
- **Privacy Policy** - GDPR-compliant data processing transparency
- Professional use limitations and compliance requirements

8.2 Service Provider Agreements

- AWS cloud services agreement with European data processing terms
- Technical support and development services contracts
- Third-party integration agreements with appropriate data protection clauses

9. DISPUTE RESOLUTION MECHANISM

9.1 Governing Law

- **Primary Jurisdiction:** Czech Republic law
- **Competent Courts:** Prague, Czech Republic
- Alternative dispute resolution mechanisms available

9.2 Regulatory Authority Contacts

- **Data Protection:** Czech Personal Data Protection Authority (posta@uoou.cz)
- **Healthcare:** Relevant national transplant authority in user's jurisdiction
- **Technical Issues:** JIRA ticketing system and direct support channels

10. COMPLIANCE MONITORING AND UPDATES

10.1 Regular Compliance Reviews

- Annual legal compliance assessments

- Annual privacy and security audits
- Ongoing regulatory change monitoring and implementation

10.2 Legal Update Procedures

- Systematic monitoring of regulatory changes in healthcare and data protection
- User notification procedures for significant legal or policy changes
- Terms and Privacy Policy update mechanisms with appropriate notice periods

11. EMERGENCY AND INCIDENT RESPONSE

11.1 Data Breach Response

- 72-hour notification to supervisory authorities as required by GDPR
- User notification procedures for high-risk breaches
- Comprehensive incident documentation and remediation processes

11.2 Service Continuity

- Business continuity planning for critical healthcare coordination services
- Emergency contact procedures for time-sensitive organ exchange activities
- Backup systems and disaster recovery protocols

12. CONTACT INFORMATION

12.1 Legal and Compliance Contacts

Primary Legal Contact:

FOEDUS z.s.

Email: info@foedus-eoeo.eu

Data Protection Officer:

Martin Kostal, DERS s.r.o.

Address: Polakova 737/1, 500 02 Hradec Kralove, Czech Republic

Email: kostal@ders.cz

Technical Development Partner:

DERS s.r.o.

Project Owner: Jiri Stohr

13. DECLARATION OF COMPLIANCE

This Legal Status document confirms that FOEDUS platform operations are conducted in full compliance with applicable European Union and Czech Republic legal requirements for healthcare data processing, cross-border medical coordination services, and digital platform operations.

The platform maintains appropriate legal, technical, and organizational measures to ensure ongoing compliance with all relevant regulatory frameworks while supporting critical healthcare coordination activities across European borders.

Document Authority: FOEDUS z.s. Legal and Compliance Framework

Next Review Date: 1.2.2027