

## **Regulatory & Compliance Statement**

STEM4CELLS Sp. z o.o. ("STEM4CELLS", "we", "our", or "the Company") is committed to conducting its activities in accordance with applicable laws, ethical standards, and internationally recognized principles governing biotechnology, regenerative medicine, stem cell technologies, scientific research, data protection, and business integrity. This statement outlines our commitment to regulatory compliance and responsible scientific communication.

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### **Commitment to Compliance**

STEM4CELLS conducts its activities in accordance with applicable national and European Union legislation relevant to its business operations.

Our compliance framework is designed to promote:

- scientific integrity;
- ethical research practices;
- regulatory transparency;
- data protection;
- quality management;
- responsible innovation;
- patient and animal safety where applicable.

Compliance is an ongoing process and is continuously reviewed as legislation and industry standards evolve.

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### **Research and Development**

STEM4CELLS develops and supports scientific research in the fields of biotechnology, regenerative medicine, immunology, and cell-based technologies.

Research activities are performed in accordance with applicable legal, ethical, and institutional requirements.

Where applicable, research is conducted under appropriate approvals, institutional oversight, and scientific governance procedures.

Descriptions of research projects on this Website are intended solely for informational purposes and should not be interpreted as evidence of regulatory approval or clinical validation.

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### **Regulatory Status of Products and Technologies**

Unless expressly stated otherwise, information published on this Website does not indicate that any product, technology, procedure, or service has been approved, certified, registered, licensed, or authorized by any governmental or regulatory authority. References to scientific concepts, laboratory methods, investigational technologies, or research outcomes should not be interpreted as:

- authorization for clinical use;
- approval for commercial distribution;

- confirmation of therapeutic efficacy;
- evidence of regulatory clearance.

Availability of products or services may vary depending on jurisdiction and applicable legislation.

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### **Compliance with European Legislation**

Where applicable to our activities, STEM4CELLS aims to operate in accordance with relevant European Union legislation, including but not limited to:

- Regulation (EU) 2016/679 (General Data Protection Regulation – GDPR);
- applicable national data protection laws;
- Regulation (EU) 2017/745 on Medical Devices (where applicable);
- Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (where applicable);
- applicable legislation governing biotechnology research, laboratory activities, and biological materials.

Compliance obligations depend upon the nature of specific products, services, collaborations, and research activities.

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### **Good Scientific Practice**

STEM4CELLS supports internationally recognized principles of responsible research, including:

- scientific accuracy;
- transparency;
- reproducibility;
- ethical conduct;
- proper documentation;
- independent verification where appropriate;
- respect for intellectual property.

Scientific conclusions may evolve as new evidence becomes available.

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### **Ethical Standards**

We are committed to conducting our activities responsibly and ethically.

Our principles include:

- integrity in research;
  - honesty in scientific communication;
  - respect for applicable ethical review processes;
  - compliance with institutional requirements;
  - responsible handling of biological materials;
  - respect for human and animal welfare where applicable.
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### **Data Protection**

STEM4CELLS processes personal data in accordance with applicable data protection legislation.

Personal information is processed only where there is an appropriate legal basis and appropriate technical and organizational safeguards.

Further information regarding personal data processing is available in our Privacy Policy and Cookie Policy.

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### **Quality and Continuous Improvement**

STEM4CELLS continually seeks to improve its internal processes, documentation, scientific standards, and operational practices.

Quality management includes ongoing evaluation of:

- internal procedures;
  - documentation practices;
  - regulatory developments;
  - risk management processes;
  - employee awareness and training.
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### **Intellectual Property**

STEM4CELLS respects intellectual property rights and expects the same from its partners, collaborators, suppliers, and Website users.

Scientific publications, trademarks, logos, graphics, technical materials, and other intellectual property displayed on this Website remain protected under applicable copyright and intellectual property laws unless otherwise indicated.

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### **Third-Party Collaborations**

The Company may collaborate with universities, research institutes, laboratories, clinical organizations, commercial partners, or other scientific institutions.

Such collaborations do not imply endorsement of any third-party products, services, or scientific conclusions unless expressly stated.

Each collaborating organization remains independently responsible for its own regulatory obligations.

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### **International Activities**

Where STEM4CELLS participates in international collaborations, applicable legal and regulatory requirements may differ between jurisdictions.

The availability of technologies, products, services, or research collaborations may therefore vary according to local legislation.

Users are responsible for ensuring compliance with the laws applicable in their own jurisdiction.

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### **Website Content**

Information published on this Website is intended solely for informational, educational, and corporate communication purposes.

Nothing contained on this Website should be interpreted as:

- legal advice;
- regulatory advice;
- medical advice;
- veterinary advice;
- clinical guidance;
- professional consulting services.

Professional advice should always be obtained from appropriately qualified specialists.

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### **No Regulatory Guarantee**

While STEM4CELLS is committed to maintaining high regulatory standards, we cannot guarantee that future legislation, regulatory guidance, or scientific developments will not affect previously published information.

Regulatory requirements may change over time, and users should not rely exclusively on Website content when making legal, regulatory, scientific, medical, or commercial decisions.

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### **Changes to This Statement**

This Regulatory & Compliance Statement may be updated periodically to reflect changes in legislation, regulatory guidance, scientific developments, or Company practices.

The most recent version will always be available on this Website together with the effective date.

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### **Contact**

Questions regarding regulatory matters or compliance may be directed to:

**STEM4CELLS Sp. z o.o.**

Website: <https://stem4cells.com>

Email: [info@stem4cells.com](mailto:info@stem4cells.com)

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### **Acceptance**

By using this Website, you acknowledge that you have read and understood this Regulatory & Compliance Statement.

You further acknowledge that the information published on this Website is provided for general informational purposes and does not constitute regulatory, legal, medical, veterinary, or professional advice.