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English version

International Certification: ISO 9001:2025 (Quality Austria No. 21807/0)

0. General Introduction and Purpose of the Document

The Italian Society of Health Services (SISS) hereby formalizes the standardized corporate Informed Consent Form for Physical Medicine and Rehabilitation services. This document complies with the information and transparency requirements imposed by healthcare legislation, ensuring that patients are fully aware of the delivery methods, expected benefits, contraindications, and potential temporary risks associated with both manual and instrumental therapies offered at the center.

1. Regulatory Framework of Reference

The adoption and mandatory administration of this informed consent form takes place in strict compliance with current legislation:

Law 221/2017 (Rules on informed consent and advance directives for treatment) - Art. 1: Enshrines the right to life, health, dignity, and self-determination of the person, establishing that no health treatment can be initiated or continued without the free and informed consent of the interested party.

Law 24/2017 (Gelli-Bianco Law) - Art. 15: Establishes the traceability of healthcare activities and correlates correct and complete user information with the management and prevention of clinical risk in the rehabilitation setting.

EU Regulation 2016/679 (GDPR) - Articles 6 and 9: Regulates the lawfulness and special protections for the processing of sensitive data relating to health and physical condition collected during the physiotherapy anamnesis.

International Standard ISO 9001:2025: Requirements for service control and documented information to ensure customer satisfaction and continuous improvement of processes (Quality Austria Certificate No. 21807/0).

2. Information Note on SISS Rehabilitation Services

Before giving consent, the patient is invited to read the technical characteristics and warnings relating to the services provided by the center's team.

2.1 Physiotherapy and Manual Rehabilitation

Manual therapy services include: **Motor rehabilitation, Orthopedic rehabilitation, Neurological rehabilitation, Sports rehabilitation, Massage therapy, Postural gymnastics, Lymphatic drainage and Kinesio taping**.

Expected Benefits: Recovery of functional autonomy, reduction of painful symptoms, improvement of neuromotor coordination, restoration of correct postural patterns and increase in joint range of motion.

Transient Side Effects: Possible onset of localized muscle soreness, tiredness or mild reactive pain responses within 24-48 hours following the session.

Absolute/Relative Contraindications: Acute infectious inflammatory states, non-consolidated fractures, malignant neoplasms in the area to be treated, deep vein thrombosis (particularly for massage therapy and lymphatic drainage).

2.2 Physical and Instrumental Therapies (Electromedical)

Instrumental services include: **Tecar therapy, Laser therapy, TENS, Hilotherapy, Electrostimulation, Cryo T-Shock, Ionophoresis, Diadynamics, Ultrasound, Magnetotherapy, Shock waves and Pressotherapy**

Expected Benefits: Anti-inflammatory, tissue biostimulating, deep analgesic, muscle relaxant, vascular draining and acceleration of bone or tendon repair processes.

Transient Side Effects: Risk of mild skin erythema, localized thermal reactions, transient increase in pain after the first applications (especially for shock waves) or superficial micro-bruises.

Critical Contraindications: Presence of **cardiac pacemakers** or implantable defibrillators, **pregnancy**, presence of intra-articular metal synthesis devices or prostheses in the area of energy emission (contraindication for ultrasound, tecar, magnetotherapy and shock waves), active neoplasms, epilepsy, alterations in skin sensitivity to temperature or pain.

3. Unified Informed Consent Form MFR

Medical Record / Record ID: _____ Date Completed: ____/____/____

Patient's Name and Surname: _____

Born on: ____/____/____ Tax Code: _____

SERVICES BEING PROVIDED AT THE CENTER (Select the relevant fields):

☐ PHYSIOTHERAPY AND MANUAL REHABILITATION (Motor rehabilitation, Orthopedic, neurological, sports rehabilitation, Massage therapy, Postural gymnastics, Lymphatic drainage, Kinesio taping)

☐ PHYSICAL AND INSTRUMENTAL THERAPIES (Tecar therapy, Laser therapy, TENS, Hilterapia , Electrostimulation, Cryo T-Shock, Ionophoresis, Diadynamics , Ultrasound, Magnetotherapy, Shock waves, Pressotherapy)

The undersigned declares that he/ she has been informed clearly and comprehensibly by the SISS staff regarding the prepared rehabilitation treatment plan.

SAFETY DATA SHEET (Mandatory for the patient)

Report the presence of one or more of the following physiological or pathological conditions:

- Do you have a cardiac pacemaker, ICD or nerve stimulators? ☐ YES ☐ NO

- Are you pregnant, confirmed or suspected? (For women) ☐ YES ☐ NO

- Do you have any metal implants, prostheses or synthesis devices in the treatment area? ☐ YES ☐ NO

- Are you suffering from any current or previous tumor pathologies (neoplasms)? ☐ YES ☐ NO

- Do you suffer from epilepsy, thrombophlebitis or sensory alterations? ☐ YES ☐ NO

HEALTH CONSENT STATEMENT

The undersigned certifies that he/she has understood the therapeutic indications, benefits, contraindications, and risks associated with the manual and instrumental treatments described above. He/she has had the opportunity to ask questions and receive comprehensive answers from the Medical Director, Dr. Francesco Trabattoni, or the designated professional. Therefore:

☐ AGREE ☐ DOES NOT AGREE

Freely to carry out the cycle of Physical Medicine and Rehabilitation treatments.

Signature of the Patient (or Legal Representative): _____

Signature of the Doctor or Physiotherapist in Charge: _____