October 30, 2025

FrontAct Co., Ltd. Obtains ISO 13485:2016 Certification for Its Medical Device Quality Management System
— Strengthening the Global Quality Assurance Framework for the "MELTz® Hand Rehabilitation System" and Accelerating Business Expansion —

FrontAct Co., Ltd. (Head Office: Chuo-ku, Tokyo; Representative Director, President, and Chief Executive Officer: Takehiko Nomura) is pleased to announce that it has obtained certification for ISO 13485:2016, the international standard for quality management systems for medical devices, as of October 27, 2025.

1. Background and Purpose of ISO 13485 Certification

FrontAct Co., Ltd. was established on April 1, 2024, and at the same time, it acquired the medical business from MELTIN MMI Co., Ltd. On July 1, 2025, the company became a subsidiary of Sawai Group Holdings Co., Ltd.

FrontAct's flagship product, the MELTz® Hand Rehabilitation System, is an active extension / bending and stretching rotation exercise equipment developed to support upper-limb functional recovery in patients with conditions such as stroke.

Obtaining ISO 13485 certification confirms that every process related to MELTz®—from design and development through manufacturing, marketing, and post-market service—is managed under a quality management system (QMS) that complies with internationally recognized regulatory requirements for medical devices. Through this certification, FrontAct has established a robust framework to continuously deliver high-quality, safe, and reliable medical devices, further enhancing its credibility and competitiveness in both domestic and global healthcare markets.

2. Certification Overview

Certification Standard	ISO 13485:2016 – Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
Scope of Certification	Design, development, manufacturing, and marketing of the MELTz® Hand Rehabilitation System
Certified Product	MELTz® Hand Rehabilitation System (Active Extension/Flexion Rotational Exercise Device)

3. About the MELTz® Hand Rehabilitation System

The MELTz® Hand Rehabilitation System is a robotic rehabilitation device that utilizes advanced bio-signal (myoelectricity) processing technology to detect the user's intention to move their hand and provides motor assistance in accordance with that intent. This synchronized support is designed to promote re-learning in the brain during rehabilitation.

- **Generic name:** Active extension / bending and stretching rotation exercise equipment
- **Commercial name:** MELTz® Hand Rehabilitation System
- **Classification:** Class II controlled medical device (controlled medical devices requiring special maintenance)
- **Intended use / effect:** To maintain, develop, or restore upper-limb muscle strength
- **Medical device certification date:** May 18, 2022
- **Insurance coverage:** Registered as an "exercise-volume-increasing device" eligible for additional reimbursement under Japan's medical fee schedule

FrontAct currently markets MELTz® primarily to convalescent rehabilitation hospitals and plans to introduce a compact, portable model to further expand accessibility.

About FrontAct Co., Ltd.

Guided by its mission to create innovation through cutting-edge technology and take bold action ("Act") at the forefront ("Front") beyond conventional treatments with pharmaceuticals and medical devices, FrontAct aims to deliver innovative healthcare solutions that empower people to pursue diverse and fulfilling ways of living.

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