WORK FORM			
Document Title	Document Description	Version No.	CO No.
QPO-001	**Quality Policy and Objectives**	***0***	***N/A***

Quality Policy

At Momentum Health, our highest priority is making safe and effective technology available to our patients and users, while transforming the standard of care for management of spinal deformities with our 3D imaging platform.

To achieve this, Momentum Health leadership encourages quality-focused culture & systems within the organization and ensures that patient and consumer safety is at the center of all decisions being made. Some of the measures that show our commitment to Quality are:

- Momentum Health complies with applicable regulatory requirements while ensuring that customer requirements are met.
- Management is committed towards implementation and maintenance of effective Quality Management System and design & development practices.
- All employees, including third-party resources, have appropriate education, training, and expertise to carry out their job duties in accordance with internal quality procedures.

Quality Objectives

For period: May-2024 until next Management Review

1. **Product Safety and Performance**: Ensure that all medical devices manufactured and distributed by the company meet safety and performance specifications, as defined by relevant regulatory standards. Implement thorough risk management processes to identify, assess, and mitigate potential hazards associated with the use of the devices.
    - Measured by: Number of reported adverse events or incidents related to device use.

Responsible person: Evan Dimentberg, COO

2. **Regulatory Compliance**: Achieve and maintain compliance with Health Canada & FDA regulations, including ISO 13485 and 21 CFR requirements, as well as any other applicable regulations in the target markets. This includes

maintaining accurate documentation, conducting regular audits, and staying updated on evolving regulatory changes.

- Measured by: Audits/inspections conducted and their outcomes. No failed audits.

Responsible person: Evan Dimentberg, COO

3. **Customer Satisfaction:** Establish and maintain a robust feedback system to monitor customer satisfaction and gather insights into product performance and user experience. Continuously improve products based on customer feedback and address any complaints or issues promptly and effectively.

- Measured by: Customer satisfaction surveys or feedback ratings.

Responsible person: Evan Dimentberg, COO

4. **Process Efficiency and Control:** Implement efficient and well-documented processes for design, development, manufacturing, and distribution of medical devices. Regularly review and optimize these processes to minimize errors and enhance overall operational efficiency.

- Measured by: Number of Nonconformities or CAPA open in the last 6 months.

Responsible person: Evan Dimentberg, COO

5. **Employee Training and Competence**: Provide comprehensive training programs for all employees involved in the design, manufacturing, testing, and distribution of medical devices. Ensure that employees have the necessary skills, knowledge, and qualifications to perform their tasks effectively and in accordance with regulatory requirement.

- Measured by: Training completion rate must be >90%

Responsible person: Evan Dimentberg, COO