

Quality Policy

Innovative Health Sciences LLC is committed to providing safe, effective, and conforming medical devices that meet customer needs and applicable regulatory and statutory requirements. IHS is committed to maintaining and continually improving the effectiveness of our Quality Management System.

Our commitment to quality is demonstrated through the following principles:

- **Quality Management System and Continual Improvement:** IHS committed to continually improving the suitability, adequacy, and effectiveness of our Quality Management System and business processes through defined quality objectives and monitor their achievement.
- **Regulatory Compliance and Product Conformity:** Establishing, applying, maintaining, and continually improving the effectiveness of the Quality Management System according to ISO 13485:2016, FDA, EU Medical Device Regulation (MDR) 2017/745, MDSAP Country regulations, and other applicable country requirements.
- **Customer Satisfaction:** IHS committed to product quality and customer satisfaction by understanding and addressing the needs and expectations of our customers and other relevant interested parties, and by building strong, long-term relationships that support their success.
- **Patient Safety and Risk Management:** IHS prioritizes patient and user safety through a systematic, risk-based approach throughout the product lifecycle, including risk management in accordance with ISO 14971, quality assurance of medical devices, addressing nonconformities, implementing CAPA, and reporting any incidents in a timely manner within the compliance of applicable country regulations.
- **Supplier and External Provider Management:** We are committed to selecting, qualifying, monitoring, and evaluating suppliers and external providers based on their ability to meet specified quality and regulatory requirements, including appropriate oversight of critical suppliers and contract manufacturers.
- **Process and Product Quality:** Continually upgrading the Quality Management System, business processes, and well-defined measurements in all stages of manufacturing, including order receipt, production, inspection, testing, shipping, and post-shipment activities.

The framework for setting quality objectives is defined in the Quality Manual.

The Management Representative is responsible for communicating the Quality Policy to all people working for or on behalf of the organization and making it available to the public.

Reviewed and approved by:



09 / 15 / 2026

Andy Sealfon, Chairman & CEO

Date



09 / 21 / 2026

Tejasree Yenigalla, Quality Lead

Date