



WELCH Fluorocarbon, Inc.
113 Crosby Road, Unit 10
Dover, NH 03820
Tel: 603. 742. 7070
Fax: 603. 742. 4806
www.welchfluorocarbon.com

Welch Fluorocarbon Announces ISO 13485:2016 Certification

March 8th, 2019 (Dover, NH) - [Welch Fluorocarbon](http://www.welchfluorocarbon.com) announces that the Company has received ISO 13485:2016 certification for its Quality Management System (QMS). This certification demonstrates Welch's continued commitment to consistently meet its customers' quality expectations.

Welch has over 33 years of experience and is a long-time leader in manufacturing custom thermoformed and heat-sealed products by utilizing, thin high-performance plastic films. Decades of experience have given the company a diverse manufacturing portfolio ranging from small proof of concept to large continuous production applications.

Kevin Wiley, CEO, for Welch commented, "We are very proud to have certified our QMS as compliant with ISO 13485:2016. Our team's focus on creating a "quality-first" culture led to the achievement of this milestone. "

ISO 13485:2016, "Medical devices - Quality management systems - Requirements for regulatory purposes" is an internationally recognized standard that specifies requirements for a quality management system that demonstrates its ability to provide medical devices and related components and services to its customers. "This certification represents an important step for our company, and reflects our rigorous approach to development." added Kevin Wiley.

While it remains a stand-alone document, ISO 13485 is based on ISO 9001 with additional requirements, including regulatory, that are specific to the medical device industry. Requirements include:

- Focus on risk management activities and design transfer activities during product development.
- Specific requirements for inspection and traceability for medical devices.
- Specific requirements for documentation and validation of processes for medical devices

Nicole Deblois, Quality Manager at Welch adds, "Welch's Quality Management System has matured over the years. As we continue to move forward as the industry leader of custom thermoformed components, we will continue to improve our quality system to meet the requirements of our medical device customers".