

## SAFETY & COMPLIANCE

Since our inception, Medical Indicators has been dedicated to manufacturing clinically-accurate, single-use thermometers that exceed even the highest quality and infection control standards. We continually adapt and improve our processes in order to maintain the effectiveness of our quality control systems and increase product development.

### PRODUCT COMPLIANCE

All of our thermometers are non-hazardous, non-toxic, hypoallergenic, 100% hygienic, glass and mercury-free, and not made with natural rubber latex; are manufactured in our U.S. FDA-registered and ISO-certified facility; are UKCA and CE Certified meeting all EU standards for health, safety, and environmental protection; and meet all ASTM standards of accuracy for both domestic and international requirements.

### OUR FACILITY

At Medical Indicators, we have developed an integrated quality system based on the requirements of the ISO 13485 Quality System Standard and the FDA's Quality System Regulation to meet Good Manufacturing Practices (GMP). Our facility is registered with the FDA and as such, complies with all of the latest requirements for medical devices. We also implement quarterly testing of our production facilities, as well as routine testing of all of our products, and we are assessed annually from an authorized representative to ensure our conformance to these standards.

### SAFETY

To ensure the safety of our thermometers, we test both our standard and sterilized thermometers for bioburdens via two forms of testing: sterility testing (for sterile products) and bioburden testing (for standard products).

The sterility rate on our sterile thermometers is 0. The bioburden rate on our standard thermometers is <1cfu, meaning that our standard thermometers have a population of <1 viable micro-organism, which is the equivalent of a 0 sterility rate.

### CERTIFICATIONS

- FDA Registered (No. 2246308)
- ISO Certified (No. 13485)
- CE Certified (No. 01943)
- UKCA Certified (No. 761223)
- ASTM E 1299
- ASTM E 825

