

# Safety & Compliance



Since our inception more than 35 years ago, Medical Indicators has been dedicated to manufacturing clinically-accurate, single-use thermometers that exceed even the highest levels of 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.

## Our Products

All of Medical Indicators' thermometers are non-hazardous, non-toxic, latex, glass and mercury-free; are manufactured in our U.S. FDA-registered and ISO-certified facility; are UKCA certified meeting all UK standards. 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. 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 TempaDot only and we are assessed annually from a notified body to ensure our conformance to these standards.

## Our Commitment to Safety

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

The sterility rate on our sterile thermometers is 0. The bioburden rate on our non-sterile thermometers is <1cfu, meaning that our non-sterile thermometers have a population of <1 viable micro-organism, which is the equivalent of a 0 sterility rate. Therefore, both our sterile and non-sterile thermometers are equally safe.

## Our Certifications

- FDA Registration No. 2246308
- ISO-13485
- CE Certificate No. 01943
- UKCA Certificate No. 761223

