eurofins | Medical Device Testing



Bioburden Testing

No regulatory submission can be complete without bioburden testing. Eurofins Medical Device Testing's global network of >20 laboratories can provide the expertise to keep your submission on track with our Bioburden Testing services.

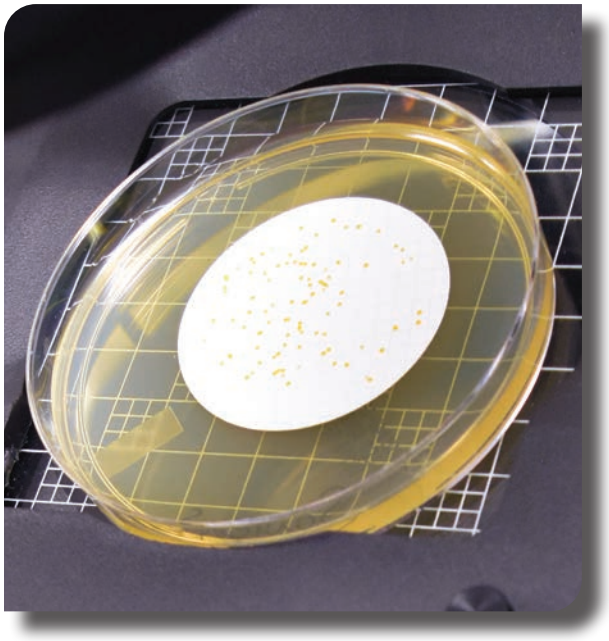
Bioburden testing allows device manufacturers to determine the microbial load on their product. A client's non-sterile product is introduced to a process that provides the opportunity for recovering microorganisms present on or in the product. This process includes product specific disassembly/dissecting, one or more rinsing steps, potential membrane filtration of the rinsing fluid, and transfer of the membrane filters to growth media for microorganisms. After incubation at the chosen conditions, the microorganisms are counted in colony forming units (CFU/filter) for calculation of the bioburden.

Eurofins Medical Device Testing's network of labs has a complete understanding of the Bioburden Testing execution process. Our expertise, along with our full suite of product types necessary for testing, will ensure you receive complete and accurate results for your regulatory submission.

Eurofins Medical Device Testing facilities are best equipped, authority approved, and experienced in Bioburden Testing. With our full service offering, Eurofins Medical Device Testing will ensure accurate results for your regulatory submission.

Choose Eurofins Medical Device Testing to help you:

- Ensure a level of cleanliness by determining the presence or absence of bioburden on your sterile or non-sterile medical device, according to requirements of ISO 11737-1, ISO 11737-2, and ISO 11137-2.
- Understand the worst-case master product for your bioburden testing.



- Complete your sterilization validation using VDmax or other methods compatible with your device.
- Confirm your validation meets all regulatory requirements for USP 61 & ISO 11737-2.
- Execute your routine sterilization dose audits for all product families.
- Determine the quantity of samples needed to complete bioburden testing on your medical device.
- Overcome challenges based on your medical device's material composition and configuration.