



Wickham Laboratories

Microbiology Services - Medical Devices

Wickham Laboratories Ltd is an independent contract analytical Laboratory established for over 40 years. The microbiological testing service has been successfully examining products for over 30 years. Located in rural Hampshire, our experienced microbiology team offers a high degree of knowledge and expertise.

Using in-house, clients own methods or standard procedures, the department provides a rapid, cost effective service for all your quality control requirements.

Our mission is to provide our clients with an independent, confidential and professional service. Our customers look to Wickham Laboratories as being experts in our field, confident that testing is being performed with precision and speed. We take pride in having a reputation for high quality standards.



GCP **GMP** **GLP** **FDA**
Compliant Laboratory Compliant Laboratory Compliant Laboratory Audited Laboratory

the right choice

Outsourcing – Why?

Wickham Laboratories have a large microbiology facility separated into designated laboratory areas, with a staff in excess of 30 people we are able to cope with both large and small projects in a timely manner.

Our microbiology staff have experience of a wide range of medical device types and the different methods used to test them.

Our approach is to listen and understand your outsourcing requirements. We will translate this into an effective plan in order to deliver a solution to your testing needs.

Contact Lenses, surgical instruments, hip replacement joints, breast implants, wheelchair covers, catheters, inhalation devices, syringes, surgical gloves, plastic ware are just a few of the products tested by our staff.

We are able to undertake development work to confirm proof of concept, as well as the routine requirements of bioburden and sterility testing.



Legislation

Our services meet the stringent requirements of the regulators with our reports supporting claims for CE marking at various notified bodies.

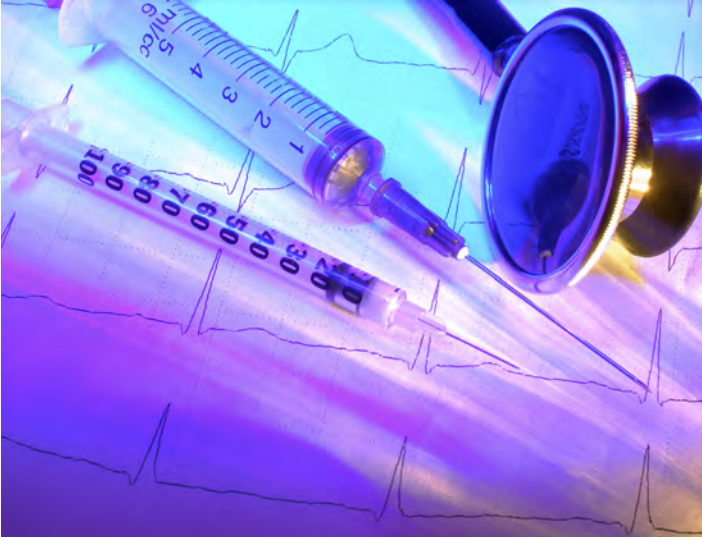
We are conversant with the microbiological requirements of:-

BS EN ISO 11135-1:2007 Sterilisation of health care products- Ethylene oxide- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.

BS EN ISO 11737-1 to 3:2000 Sterilisation of medical devices- microbiological methods

BS EN ISO 11137

BS EN 1174 series



Medical Device services

Bioburden Determination

BS EN ISO 11737-1

Sterilisation of medical devices.

Microbiological methods.

- Determination of recovery efficiency of the method.
- Membrane filtration bioburden methods.
- Industry standard.
- Validation and Routine testing

Microbiological Monitoring of Clean Rooms

We are able to offer a consultancy service to help with the setting up and microbiological monitoring of clean rooms to comply with ISO 14644 and the orange guide.

- Risk assessment
- Commissioning
- Routine monitoring

Using Settle plates, Contact plates and active air samples as appropriate.

“With considerable experience in experimental design we have assisted many companies to explore antimicrobial activity in a variety of medical devices using for example silver ion technology”



Sterility Testing

Dedicated facilities with two flexible film isolators.

Sterility testing for regulatory compliance using Ph Eur, USP, FDA or BS EN ISO 11737-2.

Validation of the test system to ensure recovery of low levels of microorganisms.

Sterility testing by direct inoculation method.

Sterility testing of fluid pathway.



Cytotoxicity Testing ISO 10993 Part 5

We offer two methods depending upon the medical device.

Cytotoxicity testing by extraction, this method is suitable for most medical devices which may be tested as a composite (part piece) or individual components.

Cytotoxicity by agar overlay, suitable for testing transparent materials such as contact lenses or flat clear plastic parts.

Detection of Bacterial Endotoxin (LAL testing)

We offer all three methods for the detection of bacterial endotoxin.

- Classic gel clot method
- Kinetic chromogenic method
- Turbidimetric method.





Additional Services

Process validation

We have supported claims for process validation where proof of reduction of bioburden is required. By providing an artificial bioburden with or without simulated soiling, processes designed for the reduction of bioburden can be investigated.

Results & Reporting

Results are reported either by conventional or electronic formats. Depending on the customer's needs the data can be faxed, phoned, e-mailed or provided as a hard copy. We provide assurance to our clients through proactive communication.

Individual samples and results may be discussed with the staff who analysed them. Very rarely will a microbiologist be unable to talk directly to you!

Consultancy Support & Advice.

In addition to laboratory services mentioned, Wickham Laboratories Ltd offers support and consultancy for;

- Clean rooms
- Water systems
- Microbiological issues



Wickham Laboratories Ltd endeavour to exceed customer's expectations. We provide a professional service tailored to your requirements.

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