

Packaging and Process Validation from Medical Engineering Technologies

Recent guidance from the FDA accepts a range of physical testing in lieu of microbiological testing for package integrity as well as product and package stability studies. All of these physical testing requirements are conducted by MET's test laboratory team at MET. We are equipped to provide a wide variety of pack strength and integrity tests. Validation for sterile barriers and packaging systems according to ISO 11607:1 is also available. Test programmes include: accelerated ageing; studies of pack integrity and seal strength; environmental conditioning; and shipping simulation.

Our experts are also on hand to provide machine validations as described in ISO 11607-2:2006 Packaging for terminally sterilized medical devices. Testing equipment is brought to your site to carry out machine validations.

For ongoing QA requirements MET offer a unique low-cost burst test machine as well as a variety of other test equipment. Details of our medical device testing equipment and services are available at www.medical-engineering.co.uk

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