

Packaging Testing and Validation from Medical Engineering Technologies

MET has invested in new hydrogen trace gas technology to allow us to conduct the most sensitive product and packaging leak tests. In the test impermeable packs are filled with a mixture of 5% hydrogen in nitrogen. Hydrogen has a very low natural abundance and very low viscosity. This makes it very useful as an extremely sensitive method of both quantifying and locating leaks.

Medical device manufacturers are required to demonstrate that their packs maintain product sterility throughout the shelf life period. MET is equipped to provide a wide variety of pack strength and integrity tests, including validation of sterile barriers and packaging systems according to ISO 11607. 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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