



## MET News – January 2016

### Global Excellence in Medical Device Testing

#### Accelerated Ageing Calculator

In order to assist clients in deciding the optimum temperature for accelerated stability studies, MET provides a [handy calculator](#). Most of our shelf life validations are conducted at 55°C, which for a base temperature of 25°C and a Q<sub>10</sub> of 2, delivers 1 year of natural (Real Time) ageing in 6.5 weeks. Our calculations are based on the information given in ASTM F 1980.



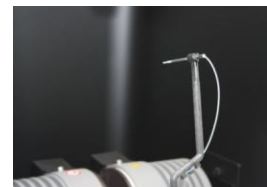
#### New Standard for Breathing Circuits



MET's laboratories offer a complete range of design validation testing for anaesthetic equipment. This includes the new biocompatibility standards for breathing circuits : **ISO 18562** *Biocompatibility evaluation of breathing gas pathways in healthcare applications*, comes in 4 sections. It is intended to provide more relevant assessment of the biological safety of the equipment, which is varied in construction, performance and patient contact. Following risk assessment, testing should be applied for particulate release, emission of volatile materials and the availability of leachates.

#### Extractables and Leachables

A wide range of chemical analyses are available from MET including E and L studies. For medical devices the primary concern is to identify what chemical could transfer from a device to a patient. In pharmaceuticals it is the packaging that is of interest. Can chemicals be transferred from the blister, vial, canister, tube etc to the material injected, ingested, inhaled, applied etcetera. In the food industry this transfer is known as migration.



#### IVD POC Progress



MET is participating in the EU funded (H2020) [SAPHLEY](#) project to develop an in-vitro diagnostic device to detect tumours by identifying RNA released into the blood. The intention is to get the *Self-amplified photonic biosensing platform for microRNA-based early diagnosis of diseases* to clinical trial. Our role at MET is to elucidate the regulatory and commercial pathways for the device. The project is lead by Jamie Garcia Ruperez of the [Universitat Politècnica de València](#),

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