MEDICAL ENGINEERING TECHNOLOGIES

TECHNICAL AND SCIENTIFIC SOLUTIONS

# Medical Device Biological Safety Testing Services

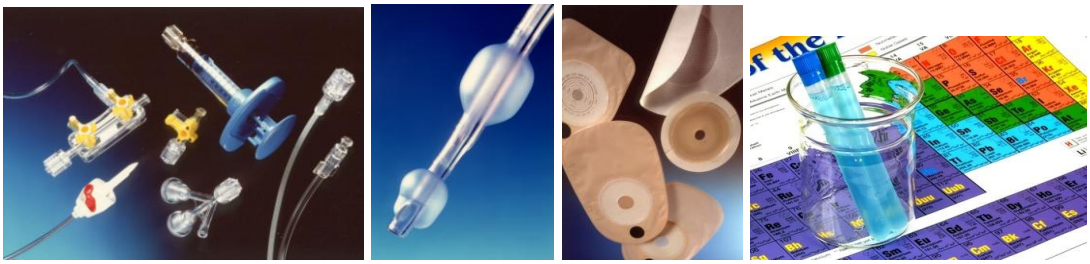
An essential part of the development cycle for medical devices is the establishment of material and product biocompatibility or biological safety. MET can classify your device and establish a route to market for both CE marking and FDA submissions. We will set out to minimise your test programs and time scales, whilst providing robust support for your technical files and submissions.

Chemical analysis is often used initially to characterise materials. This can be followed by cytotoxicity, a low cost, rapid and sensitive test. Success in these stages leads to further testing from ISO 10993:2003 *Biological evaluation of medical devices.* With more complex products, further functional testing or even clinical trials may be required.

Sections 13 and 14 of ISO 10993 also discuss the evaluation and quantification of biodegradation products.

Chemical testing requirements are described in the ISO standard and USP 661.

We can help plan your project, contact us on 0845 458 8924 to discuss your needs.



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# Medical Device Biocompatibility Testing

| Body Contact | | Contact Duration | Testing Required | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Cytotoxicity | Sensitisation | Irritation | Acute Toxicity | Subchronic Toxicity | Genotoxicity | Implant | Haemocompatibility | Chronic Toxicity | Carcinogenicity |
| Surface Devices | Skin | <= 24hours | x | x | x | | | | | | | |
| | | 1- 30 days | x | x | x | | | | | | | |
| | | >30 days | x | x | x | | | | | | | |
| | Mucosal Membrane | <= 24hours | x | x | x | | | | | | | |
| | | 1- 30 days | x | x | x | ∇ | ∇ | | ∇ | | | |
| | | >30 days | x | x | x | ∇ | x | x | ∇ | | ∇ | |
| | Breached or compromised surfaces | <= 24hours | x | x | x | ∇ | | | | | | |
| | | 1- 30 days | x | x | x | ∇ | ∇ | | ∇ | | | |
| | | >30 days | x | x | x | ∇ | x | x | ∇ | | ∇ | |
| Externally Communicating Devices | Blood path indirect | <= 24hours | x | x | x | x | | | | x | | |
| | | 1- 30 days | x | x | x | x | ∇ | | | x | | |
| | | >30 days | x | x | ∇ | x | x | x | ∇ | x | ∇ | ∇ |
| | Tissue, Bone, Dentin | <= 24hours | x | x | x | ∇ | | | | | | |
| | | 1- 30 days | x | x | x | x | x | x | x | | | |
| | | >30 days | x | x | x | x | x | x | x | | ∇ | ∇ |
| | Circulation blood | <= 24hours | x | x | x | x | | ∇ | | x | | |
| | | 1- 30 days | x | x | x | x | x | x | x | x | | |
| | | >30 days | x | x | x | x | x | x | x | x | ∇ | ∇ |
| Implant Devices | Tissue, Bone | <= 24hours | x | x | x | ∇ | | | | | | |
| | | 1- 30 days | x | x | x | x | x | x | x | | | |
| | | >30 days | x | x | x | x | x | x | x | | ∇ | ∇ |
| | Blood | <= 24hours | x | x | x | x | x | | x | x | | |
| | | 1- 30 days | x | x | x | x | x | x | x | x | | |
| | | >30 days | x | x | x | x | x | x | x | x | ∇ | ∇ |
| Sample Requirements | $cm^2$ | | 60 | 360 | 120 | 120 | 336 | 600 | TBD | 192 | TBD | TBD |
| | | Contact Duration | Cytotoxicity | Sensitisation | Irritation | Acute Toxicity | Subchronic Toxicity | Genotoxicity | Implant | Haemocompatibility | Chronic Toxicity | Carcinogenicity |

Please use this chart only as an indication of testing that may be needed. Specific requirements apply to many products in addition. Tests marked 'x' are to be considered for ISO 10993. Tests marked '∇' are additional tests to be considered for the FDA. Reproductive or developmental testing should also be considered for certain devices. The FDA usually require GLP.

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