

Biocompatibility Test

With the rapid development of Chinese medical device manufacturing industry, more and more Chinese medical device manufacturers are eagerly to seek support for getting medical devices to United States, Europe and other markets, to sales their competitive products. STC makes the investment to build new test building, provide medical device testing services, and issue domestic and international qualified test report (FDA / CFDA / EU / MHLW).



We can perform product testing following ISO 10993 standards in Dongguan preclinical lab and customize our test method according to your requirement.



Phase 1 Service

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| • In vitro cytotoxicity study | Standard: ISO 10993-5:2009 | Tests for in vitro cytotoxicity |
| • Irritation study | Standard: ISO 10993-10:2010 | Tests for irritation and skin sensitization |
| • Skin sensitization study | Standard: ISO 10993-10:2010 | Tests for irritation and skin sensitization |
| • Hemolysis study | Standard: ISO 10993-4:2002 | Selection of tests for interactions with blood |
| • Implantation study | Standard: ISO 10993-4:2007 | Tests for local effects after implantation |
| • Acute systemic toxicity study | Standard: ISO 10993-11:2006 | Tests for systemic toxicity |
| • Ethylene oxide sterilization residuals study | Standard: ISO 10993-7:2008 | Tests for Ethylene oxide sterilization residuals |

Phase 2 Service

Testing items:

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|-----------------------------------|-------------------------------|--|
| • Tests for genotoxicity | • Functional and safety study | • Chemical characterization of materials |
| • Tests for carcinogenicity | • Other blood tests | • Sub Chronic and Chronic toxicity study |
| • Tests for reproductive toxicity | • Biodegradation test | |

Involved standards:

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|---------------------|---|
| • ISO 10993-3:2003 | Tests for genotoxicity, carcinogenicity and reproductive toxicity |
| • ISO 10993-11:2006 | Tests for systemic toxicity |
| • ISO 10993-4:2002 | Selection of tests for interactions with blood |
| • ISO 10993-18:2009 | Chemical characterization of materials |

Here's a sampling of products that we can test in the future:

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|------------------------|--------------------------|--------------------------|--------------------|
| • Implant | • Cell products | • Endoscopic equipment | • Suture materials |
| • Stent | • Disposable instruments | • Natural products | • Uterine devices |
| • Orthopedics products | • Reusable instrument | • Cardiovascular devices | • Wound Dressings |

Further information and enquiry are welcomed. Please contact our Chemical, Food and Pharmaceutical Products Division:

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For more information, please scan the QR code below to add STC on Wechat or Sina Weibo.

