Biocompatibility Study for Medical Device

SGS provides series of testing service items in biocompatibility assessment based on ISO 10993-1 ANNEX A (as the following Table).

Biocompatibility Categorization for Medical Device

Medical Device Categorization by			Testing items														
Nature of body contact		Contact duration A: limited (≤ 24h) B: prolonged (> 24 h to 30 C: Long term (permanent) (> 30 d)	Physical and chemical properties Chemical information	Cytotoxicity	Sensitization	Irritation or Intracutaneous reactivity	Material-Mediated Pyrogenicity	Acute systemic toxicity	Subacute toxicity	Subchronic toxicity	Chronic toxicity	implantation	Hemocompatibility	Genotoxicity	Carcinogenicity	Reproductive/developmental toxicity	Biodegradability
Category	Contact																
Surface device	Intact skin	A	X	E	E	E											
		B	X	E	E	E											
		C	X	E	E	E											
	Mucosal membrane	A	X	E	E	E											
		B	X	E	E	E	F	E	E			E					
		C	X	E	E	E	F	E	E	E	E	E		E			
	Breached or compromised surface	A	X	E	E	E	E	E									
		B	X	E	E	E	E	E	E			E					
		C	X	E	E	E	E	E	E	E	E	E		E	E		
External communicating medical device	Blood path,indirect	A	X	E	E	E	E	E					E				
		B	X	E	E	E	E	E	E				E				
		C	X	E	E	E	E	E	E	E	E	E	E	E	E		
	Tissue/ bone/ dentin	A	X	E	E	E	E	E									
		B	X	E	E	E	E	E	E			E		E			
		C	X	E	E	E	E	E	E	E	E	E		E	E		
	Circulating blood	A	X	E	E	E	E	E					E	E			
		B	X	E	E	E	E	E	E				E	E			
		C	X	E	E	E	E	E	E	E	E	E	E	E	E		
Implant device	Tissue/bone	A	X	E	E	E	E	E									
		B	X	E	E	E	E	E	E			E		E			
		C	X	E	E	E	E	E	E	E	E	E		E	E		
	Blood	A	X	E	E	E	E	E				E	E	E			
		B	X	E	E	E	E	E	E			E	E	E			
		C	X	E	E	E	E	E	E	E	E	E	E	E	E		

X：X means prerequisite information needed for a risk assessment.

This table is only used as reference for establishment ofevaluation procedure, not a checklist

E：E means endpoints to be evaluated in the risk assessment indicated in both ISO 10993-1:2018 and US FDA published "Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing in the Risk Management Process" for ISO 10993-1 on Sep. 4th, 2020.

F：Additional US FDA recommended endpoints for consideration indicated in US FDA published "Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing in the Risk Management Process" for ISO 10993-1 on Sep. 4th, 2020.

Extractables & Leachables Testing

During the service cycle of medical devices, raw materials of the products, isomer or polymer generation during manufacturing process, additives, even the substances from manufacturing equipments will be released and into human body. Therefore, study and risk assessment for extractables and leachables of medical devices will become important. SGS provides comprehensive services for ISO 10993-17 & -18 by various analysis method, such as GC/MS, HS-GC/MS, Q-TOF-LC/MS, ICP/MS, IC, etc.:

- Customized R&D service for extractables and leachables
- Composition and distribution of extractables (including organic and inorganic fractions)
- Qualitative and quantitative study for extractables
- Development and validation for analysis methodology of leachables in finished products
- Consultation and evaluation service for specific projects

Reprocessing of Reusable Medical Devices

With the remarkably advanced materials and technology in medical devices, the complexity in product design has been increased, which involves the increasingly complicated efforts in reprocessing for reusable medical devices. Based on FDA's "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" guidance and other guidelines including AAMI TIR30, SGS provides relevant testing and validation services for such medical devices, assisting the clients to conform with the review requirements and principles in submitting application for 510 (k), PMAs, HDE, and IDE.

- Cleaning Validation
- Disinfection Validation
- Sterilization Verification

Biocompatibility evaluation of breathing gas pathways in healthcare applications, ISO 18562)

It is clearly mentioned in ISO 10993-1:2018 that for breathing circuit components in indirect contact with patients, the ISO 18562 standard should be used for biocompatibility assessment; although the materials used in breathing circuit related products are used for general purposes , The possibility of causing risks is low, but once it is used in respiratory medical-related equipment, its safety needs to be considered to assess whether patients will be exposed to chemicals that may cause harm when they continue to use respiratory medical equipment. SGS can provide the following related services for the ISO 18562 standard:

- Toxicological risk assessment (TRA) of condensed water extract
- Particulate matter released by respirator products (ISO 18562-2)
- Analysis of volatile compounds (VOCs) released by respirator products (ISO 18562-3)
- Analysis of extracts in condensed water (ISO 18562-4)

Microbiological Testing Service

SGS has been the domestic leading testing services laboratory for microbiological QC testing. SGS acquires microbiological experts with profound experience, providing consultation and testing services in microbiology.

- Microbial limits tests USP<61><62>
- Sterility tests USP<71>
- Microbial endotoxins ; LAL test
- Sampling and analysis of water for pharmaceutical purposes
- Environment monitoring
- Mycoplasma test
- Antimicrobial test
- Microbiologic barrier

Sterilization Validation Service

SGS's experts in sterilization technology provide medical device sector with the most comprehensive consultation and planning for sterilization validation, improving sterilizing criteria and operating procedures of the product based on client's requirements.

- Sterilization validation for moisture test sterilization (ISO 17665) and EO sterilization (ISO 11135)
- Bioburden
- Recovery
- Bacteriostasis/ Fungistasis
- Biological indicators, BIs
- Sterility Test
- Ethylene oxide (EO) or ethylene chlorohydrin (ECH) residual test

Package Validation & Transportation Test

SGS provides comprehensive packaging testing for medical devices, and quality testing services for transportation

- Package study ISO 11607
- Accelerated Aging study ASTM F1980
- Burst test for packaging ASTM F1140
- Creep test for packaging ASTM F1140
- Dye penetration study ASTM F 1929
- Microbial ranking(ASTM F1608), Microbial barrier testing (DIN 58953-6)"
- Seal peel test for packaging, ASTM F88
- Bubble test for packaging ASTM F2096
- Transportation test for ASTM D4169, ISTA

GET IN TOUCH WITH THE BEST SERVICES IN SGS TAIWAN

WWW.SGS.COM

營養與健康事業群 Health and Nutrition
健康產業服務 Health Industry Services

Taipei
No.38, Wu Chyuan 7th Rd., New Taipei Industrial Park, Wu Ku District,
New Taipei City, Taiwan (R.O.C.) 24890

Selene Ma e: selene.ma@sgs.com Tel: + 886 2 2299 3279 # 7319
Mobile: + 886 933 200 704

Bruce Hung e: bruce.Hung@sgs.com Tel: + 886 2 2299 3279 # 7314
Mobile: + 886 955 676 509

Taichung
No. 9, Gongyequ 14th Rd., Xitun Dist., Taichung City 40755 , Taiwan (R.O.C.)

Cesar Yang e: cesar.yang@sgs.com Tel: + 886 4 2359 1515 # 1502
Mobile: + 886 963 302 867
Fax: + 886 4 2359 2949

Kaohsiung
No. 61, Kaifa Rd., Nanzi Processing Export Zone, Nanzi Dist., Kaohsiung City 811637 , Taiwan (R.O.C.)

Jim Lin e: jim.lin@sgs.com Tel: + 886 7 301 2121 # 4802
Mobile: + 886 929 526 278
Fax: + 886 7 301 0860

SGS-HIS-MD01-A4-EN-21-V1

WHEN YOU NEED TO BE SURE

SGS

MEDICAL DEVICE SERVICE

SGS