

1. 의료기기 안전관리 체계 선진화

2. 혁신 의료기기 안전관리

3. 생활 밀착형 의료기기 안전관리

4. 국내외 의료기기 안전관리 기술 협력 방안

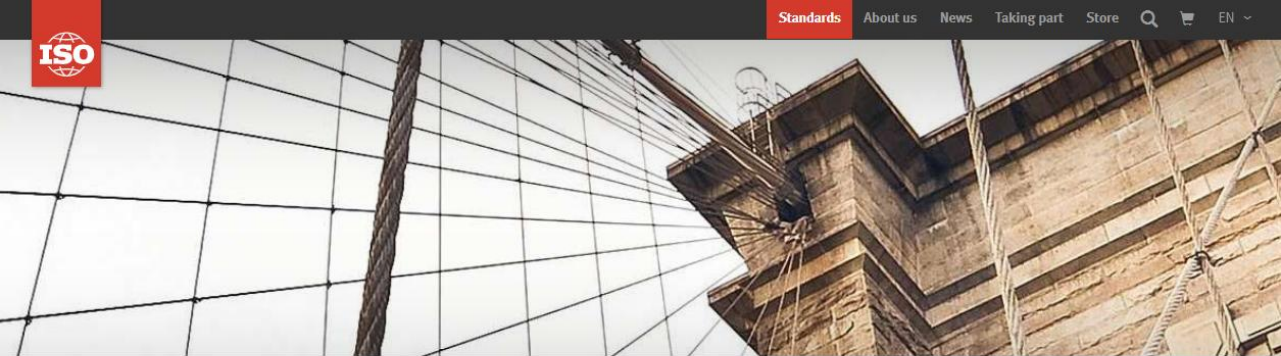
5. In vivo연구의 In vitro 대안 평가법 개발 평가법: OECD 동물 대체 실험법

생물학적 안전성에 대한 biological evaluation report (BEF) 표준화, ISO 10993-1 개정

6. 생체모사 물질 기반 의료기기 비임상/임상 평가법

7. 생물학적 안전성 시험법 표준물질 개발

8. 의료기기 함유 성분에 대한 위험관리: 유럽 MDR 기준, FDA USP



STANDARDS

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ISO STANDARDS ARE INTERNATIONALLY AGREED BY EXPERTS

Think of them as a formula that describes the best way of doing something.

LIST OF TECHNICAL COMMITTEES

FILTER BY TECHNICAL SECTOR: [ALL SECTORS \(249\)](#)

REFERENCE <input type="button" value="v"/>	TITLE	ISOTC WORKING AREA	PUBLISHED STANDARDS	STANDARDS UNDER DEVELOPMENT
ISO/IEC JTC 1	Information technology	Working area	3248	552
ISO/TC 1	Screw threads	Working area	26	0
ISO/TC 2	Fasteners	Working area	193	28
ISO/TC 4	Rolling bearings	Working area	77	16
ISO/TC 5	Ferrous metal pipes and metallic fittings	Working area	58	7
ISO/TC 6	Paper, board and pulps	Working area	189	28
ISO/TC 8	Ships and marine technology	Working area	356	120
ISO/TC 10	Technical product documentation	Working area	154	13
ISO/TC 11	Boilers and pressure vessels <small>[STANDBY]</small>	Working area	2	0
ISO/TC 12	Quantities and units	Working area	14	3
ISO/TC 14	Shafts for machinery and accessories	Working area	8	3
ISO/TC 17	Steel	Working area	311	37
ISO/TC 18	Zinc and zinc alloys <small>[STANDBY]</small>	Working area	10	0
ISO/TC 19	Preferred numbers <small>[STANDBY]</small>	Working area	3	0
ISO/TC 20	Aircraft and space vehicles	Working area	677	108
ISO/TC 21	Equipment for fire protection and fire fighting	Working area	100	22
ISO/TC 22	Road vehicles	Working area	934	270
ISO/TC 23	Tractors and machinery for agriculture and forestry	Working area	377	97
ISO/TC 24	Particle characterization including sieving	Working area	68	14
ISO/TC 25	Cast irons and pig irons	Working area	17	3

2. Testing Selection

Contact duration
A - limited (~ 24 hr)
B - prolonged (24 hr ~ 30 d)
C - permanent (30 d ~)

Medical device categorization by		Biological effect											
Nature of body contact		Contact duration	Cytotoxicity 세포독성	Sensitization 감작성	Intracutaneous Reactivity 피내반응	Acute Systemic Toxicity 전신독성	Material-Mediated Pyrogenicity 발열성	Subchronic Toxicity 아만성독성	Genotoxicity 유전독성	Implantation 이식	Haemocompatibility 혈액적합성	Chronic Toxicity 만성독성	Carcinogenicity 발암성
Category	Contact												
Implant device	Tissue / Bone	A											
		B											
		C	●	●	●	●	◇	●	●	●	-	◇	◇
	Blood	A											
		B											
		C											

● = ISO 10993-1:

◇ = Additional FDA recommended endpoints for consideration

ISO Standard

Category	ISO Standard	Europe	FDA	Type
Sample Preparation	ISO 10993-12	●	●	-
Cytotoxicity 세포독성	ISO 10993-5	●	●	In vitro
Sensitization 감작성	ISO 10993-10	●	●	In vivo
Irritation or Intracutaneous Reactivity 자극 또는 피내반응	ISO 10993-10	●	●	In vitro and In vivo
Acute Systemic Toxicity 전신독성	ISO 10993-1	●	●	In vivo
Material-Mediated Pyrogenicity 발열성	ISO 10993-11		◇	In vitro and In vivo
Subschronic Toxicity 아만성 독성	ISO 10993-11	●	●	In vitro and In vivo
Genotoxicity 유전독성	ISO 10993-3	●	●	In vitro and In vivo
Implantation 이식	ISO 10993-6	●	●	In vivo
Haemocompatibility 혈액적합성	ISO 10993-4	-	-	In vitro and In vivo
Chronic Toxicity 만성독성	ISO 10993-11		◇	In vitro and In vivo
Carcinogenicity 발암성	ISO 10993-3		◇	In vitro and In vivo