

Good Laboratory Practice for Medical Devices(as of April 18, 2022)

No.	Good Laboratory Practice Test facilities inspected			Genotoxicity-Carcinogenicity-Reproductive and Developmental toxicity test								Haemocompatibility test			Cytotoxicity test			Implantation test			Identification and Quantification of degradation products			Irritation and Skin sensitization test								Systemic Toxicity test			Toxicokinetics		Others	
	Test Facility	Date of Submission	Genotoxicity		Carcinogenicity	Reproductive and Developmental toxicity					In vivo	Ex vivo	In vitro	Extract	Direct Contact	Indirect Contact	in Subcutaneous tissue	in muscle	in bone	Degradation		Irritation(include Intracutaneous)						Skin sensitization	Repeated Exposure Systemic Toxicity		Pyrogen test		Toxicokinetics	Immuno toxicology	Others			
			In vivo	In vitro		Segment I, ICH I(Fertility and Early Embryonic Development, Segment III, ICH II)	Pre-and Postnatal Study (Segment III, ICH II)	Embryo-Fetal Development Study(Segment II, ICH III); Rodent	Embryo-Fetal Development Study(Segment II, ICH III); non-Rodent	from Polymers										from Ceramics	from Metals and Alloys	Skin Irritation	Intracutaneous	Eye Irritation	Oral mucous membrane irritation	Penile Irritation	Rectal Irritation	Vaginal Irritation	LLNA	GPMT	Acute Systemic Toxicity	Subchronic (Subacute) Systemic Toxicity	Chronic Systemic Toxicity	Endotoxin	Pyrogen			
1	Korea Testing & Research Institute, Hwasun 12-63, Sandan-gil, Hwasun-eup, Hwasun-gun, Jeollanam-do, Korea (Zip code : 58141)	'18.12.19	O	O							O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O					
2	Korea Testing Laboratory Medical Industry Venture Center, 1397, Bugwon-ro, Heungeop-myeon, Wonju-si, Gangwon-do, Korea, Zip code : 26495	'18.12.28	O	O							O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O					
3	Nonclinical Research Institute, Chemon Inc. 240, Nampyeong-ro, Yangji-myeon, Cheoin-gu, Yongin-si, Gyeonggi-do, Korea, Zip code : 17162	'19.01.09	O	O							O									O	O	O	O	O	O	O	O	O	O	O	O	O	O	O				
4	Daegu-Gyeongbuk Medical Innovation Foundation(DGMIF) Medical Device Development Center DGMIF Medical Device Development Center, 80, Cheombok-ro, Dong-gu, Daegu, Korea (Zip code : 41061)	'19.03.27	O								O									O							O											
5	Korea Conformity Laboratories, Bio Technology Division 8, Gaetbeol-ro 145beon-gil, Yeonsu-gu, Incheon, Korea (Zip code : 21999)	'19.04.26	O	O							O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O					
6	Osong Medical Innovation Foundation 123 Osongsaeangmyung-ro, Osong-eub, Heungsdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea (Zip code : 28160)	'19.06.18	O								O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O					
7	Korea Testing Certification Institute, Bio Health Center 57, Yangcheong 3-gil, Ochang-eup, Cheongwon-gu, Cheongju-si, Chungcheongbuk-do, Korea (Zip code : 28115)	'19.10.29	O								O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O					
8	Korea Testing & Research Institute Bld #3, 98, Goyukwon-ro, Gwacheon-si, Gyeonggi-do, Korea (Zip code : 13810)	'20.02.10									O																											
9	DTACRO CO.,Ltd. 46, Yurim-ro 154beon-gil, Cheonan-gu, Yongin-si, Gyeonggi-do, Korea (Zip code : 17042)	'20.3.18																		O		O														O		
10	Seoul National University Dental Hospital Dental Life Science Research Institute, Dental Materials & Devices Evaluation Center 101, Daejak-ro, Jongno-gu, Seoul, Korea (Zip code : 03080)	'20.8.28										O		O																								
11	Seoul National University Hospital, Biomedical Research Institute 101, Daehak-ro, Jongno-gu, Seoul, Korea (Zip code : 03080)	'20.11.11	O	O							O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O					
12	Korea Institute of Toxicology, KRICT 141, Gajeong-ro, Yuseong-gu, Daejeon, 34114, Republic of Korea	'21.4.23	O								O																											

※ The above translation into Korean does not convey or represent any kind of an endorsement by OECD