

CERTIFICATE OF ACCREDITATION

Korea Testing and Research Institute

Accreditation No. : KT011

Corporation Registration No. : 134122-0007297

Address of Laboratory : 98, Gyoyukwon-ro, Gwacheon-si, Gyeonggi-do, Korea
68, Gajaeul-ro, Seo-gu, Incheon, Korea
15, Jongga-ro, Jung-gu, Ulsan, Korea
42-27, Jungbu-daero 2517beon-gil, Yangji-myeon, Cheoin-gu,
Yongin-si, Gyeonggi-do, Korea
5, Myeongji ocean city 9-ro, Gangseo-gu, Busan, Korea
12-63, Sandan-gil, Hwasun-eup, Hwasun-gun, Jeollanam-do, Korea
122-11, Seongseo4chacheomdan-ro, Dalseo-gu, Daegu, Korea

date of Initial Accreditation : December 10, 1994

Duration : April 28, 2014 ~ April 27, 2018

Scope of Accreditation : Attached Annex

Date of issue : August 7, 2017

This testing laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025 : 2005. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint ISO-ILAC-IAF Communique dated 8 January 2009).



Jung Dong Hee

Administrator

Korea Laboratory Accreditation Scheme

Korea Laboratory Accreditation Scheme

No. KT011

Address of Laboratory : 12-63, Sandan-gil, Hwasun-eup, Hwasun-gun, Jeollanam-do, Korea

09. Biological Test

09.002 Microbiological Test

Test Method	Standard designation	Test range or Limits of detection
ISO 10993-3 : 2014	Biological evaluation of medical device - Tests for genotoxicity, carcinogenicity and reproductive toxicity 5.2.2 a) Gene mutations in bacteria (Bacterial reverse mutation assay)	Negative

09.004 On-shore zoology

Test Method	Standard designation	Test range
Notice of Ministry of Food and Drug Safety (MFDS's No.2014-115)	Part 4 : Selection of tests for interactions with blood,	0.01 %
	Part 6 : Tests for local effects after implantation,	Negative
	Part 9 : Tests for irritation and skin sensitization	Negative
	Part 10 : Tests for systemic toxicity	Negative
The Japanese Pharmacopoeia 17th (JP XVII)	7.03 Test for Rubber Closure for Aqueous Infusions (5) acute systemic toxicity (6) hemolysis test	Negative
	4.04 Pyrogen Test	Negative
The Korea Pharmacopoeia 11 (KP XI)	General Tests 15. Pyrogen Test	Negative
ISO 10993-3 : 2014	Biological evaluation of medical device - Tests for genotoxicity, carcinogenicity and reproductive toxicity 5.2.3 Step 5) Micronucleus test in rodents (Mammalian erythrocyte micronucleus test)	Negative

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09.004 On-shore zoology

Test Method	Standard designation	Test range
ISO 10993-4 : 2004	Biological evaluation of medical devices- Part 4: Selection of tests for interactions with blood, Annex c Evaluation of haemolytic properties of medical devices and their components, 6. haemolysis testing	0.01 %
ASTM F756-13	Standard Practice for Assessment of Hemolytic Properties of Materials	0.01 %
ISO 10993-6 : 2007	Biological evaluation of medical devices- Part 6: Tests for local effects after implantation	Negative
ISO 10993-10 : 2010	Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization	Negative
ISO 10993-11 : 2006	Biological evaluation of medical devices- Part 11: Tests for systemic toxicity	Negative
ISO 9394 : 2012	Ophthalmic optics - Contact lenses and contact lens care products - Determination of biocompatibility by ocular study with rabbit eyes	Negative
USP 36 : 2013	<151>Pyrogen test <88>Biological reactivity test, in vivo	Negative
OECD 442B : 2010	Skin Sensitization Local Lymph Node Assay: BrdU-ELISA	1.6
ASTM F2148-07	Standard Practice for Evaluation of Delayed Contact Hypersensitivity Using the Murine Local Lymph Node Assay (LLNA)	Negative

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09.008 Cell culture and GMO

Test Method	Standard designation	Test range
ISO 10993-3 : 2014	Biological evaluation of medical device - Tests for genotoxicity, carcinogenicity and reproductive toxicity 5.2.2 b) Cytogenic evaluation test of chromosomal damage with mammalian cells(Chromosome aberration test)	Qualitative