

Hot Issue

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- 3. Addition of electromagnetic testing standards in industrial environments



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MFDS (Ministry of Food and Drug Safety)Designation of a medical device testing and inspection body

식품의약품안전처 공고 제2021-275호

의료기기 시험·검사기관 신규 지정

「식품·의약품분야 시험·검사 등에 관한 법률」 제6조, 같은 법 시행규칙 제2조에 따라 의료기기 시험검사기관이 다음과 같이 지정되었기에 공고합니다.

가. 지정내역

기관명칭	주식회사 아이씨알
소재지	경기도 김포시 양촌읍 황금3로 7번길 112
대표자	김덕용
분야	의료기기
지정번호	제18호
업무범위	검사명령검사, 품질검사, 수거검사, 허가·인증 신청 및 신고 검사
품목	[의료기기] 진료용일반장비, 수술용장치(미취기 및 레이저장해방어용기구 제외), 진단용장치(방사선용품 제외), 의료용자극발생기계기구 [체외진단의료기기(기구, 기계, 장치, 소프트웨어에 한함)] 검체전처리기기
시험·검사항목	안전성 및 성능 시험항목
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	2021. 6. 23

On 23 June 2021, **the ICR** has been designated as a **medical device testing and inspection body by MFDS**



※ Items designated for testing and inspection

Medical device sector

- General Medical Equipment
- Surgical devices (excluding anesthesia machines and laser disability defense equipment)
- Diagnostic devices (excluding radiation supplies)
- Medical stimulation generating machinery

Invitro diagnostic medical devices

(instruments, machinery, devices, software only)

- Sample preprocessing machine

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Revision of ISO Certification

- As the ISO certification application form has been revised, the ICR homepage has been updated.
- The ISO certification application form can be downloaded through the path below.





- ISO certification applications' scope of the standard have been added.
 - ISO 9001:2015, ISO 14001:2015, ISO 45001:2018
 - Multi-site(ISO 9001:2015, ISO 14001:2015, ISO 45001:2018)
 - ISO 22000:2018
 - ISO 13485:2016
- The application that were completed by the client, shall be submitted with documentary which can be evidence of number of employees to ICR.
 - <u>Example of evidence</u>: employment insurance certificate or employment national pensions insurance premium

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Addition of electromagnetic testing standards in industrial environments

General

In February 2021, as the announcement of the electromagnetic compatibility test method (National Radio Research Agency Announcement No. 2021-10, 2021.2.8.) was revised, the existing KN 61000-6-2:2012 was abolished and revised to KS C 9610-6-2:2019.(This announcement is effective from the date three months have elapsed after its promulgation.)

Standards for IEC 61000-4-34:2005 have been added for voltage dip and voltage interruptions testing part of electromagnetic immunity testing methods in industrial environments.

Addition of electromagnetic testing standards in industrial environments

KN 61000-6-2:2012						
Name of immunity test	Test specifications		Units	Basic standards	Performance criterion	
Voltage dips	(1) I	% residual voltage cycle	KN 61000 4 11	В	
	40 12	70 30	% residual voltage Cycle	KN 01000-4-11	С	
Voltage interruptions	0 300		% residual voltage cycle	KN 61000-4-11	С	

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KS C 9610-6-2:2019							
Name of immunity test	Test specifications		Units	Basic standards	Performance criterion		
Voltage dips	0 1		% residual voltage cycle	KN 61000-4-11	В		
	40 12	70 30	% residual voltage cycle	IEC 61000-4-34	С		
Voltage interruptions	0 300		% residual voltage cycle	KN 61000-4-11 IEC 61000-4-34	С		

KS C 9610-4-11

- This is the standard for voltage dip, voltage interruptions, and voltage variations immunity test methods.
- This standard applies to electrical and electronic equipment having a rated input current **not exceeding 16 A** per phase, for connection to 50 Hz or 60 Hz a.c. networks.

Addition of electromagnetic testing standards in industrial environments

IEC 61000-4-34

- This is the standard for voltage dip, voltage interruptions, and voltage variations immunity test methods.
- This standard applies to electrical and electronic equipment having a rated input current exceeding 16 A per phase, for connection to 50 Hz or 60 Hz a.c. networks.

Test Equipment





< SAG Generator >

< Variac >

Addition of electromagnetic testing standards in industrial environments

Test photo



< SAG Generator >





- The ICR can KS C 9610-4-11 tests and tests on the newly added IEC 61000-4-34 to provide electromagnetic compatibility assessments.
- We can test using Variac if the wiring method is single-phase, or SAG generator if the wiring method is three-phase or higher.

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Announcement of revision of broadcasting communication standards



No. 2021-45 (June 9, 2021)

In the enactment, revision, and abolition of broadcasting and communication standards, the main contents are announced as follows in order to inform the public, industry and related organizations in advance in accordance with Article 14 of the [¬]Broadcasting and Communication Standardization Guidelines_J.

Standard number and standard name to be revised

technical field	standard number	standard name	division
radio communication (wireless)	KS X 3123	Radio equipment conformity assessment test method	amendment

Purpose of revision

Prepare test methods for new introduction of 6 GHz band Wi-Fi among "wireless devices for wireless stations that can be opened without notification", simplify the test procedure for field strength wireless devices including 6 GHz band Wi-Fi devices, and To improve relevant test methods to prepare reasonable test methods.



Announcement of revision of broadcasting communication standards

Major revisions

- ► (Annex F) Application of antenna gain and test terminals of radio equipment
- "Cyclic Delay Diversity" device for multiple input/output devices with two or more antennas add
- ► (Annex G) Specific low power wireless equipment for wireless access systems (WAS) including wireless LAN and revision of test methods for each item of wireless LAN conformity evaluation of specific small power wireless devices for wireless data communication systems
- New test method for 'Listen before talk' introduced in 6GHz wireless LAN technical standard
- Improvements such as test procedures to shorten the test time of wireless LAN devices such as MU-MIMO
- ► (Annex J) Revision of the radiation test method for each radio equipment conformity evaluation item among radio equipment using a frequency of 20 GHz or higher in accordance with Article 25 No. 4 of the Enforcement Decree of the Radio Act
- Realization of set value of resolution bandwidth of spectrum analyzer when measuring peak power and Addition of correction factor correction method
- Uniform sweep time for each test item

Announcement of revision of broadcasting communication standards



- ► (Annex L) Revision of test methods for electric field strength and magnetic field strength radio equipment
- Improvement of test frequency selection method based on frequency band when measuring electric field and magnetic field strength
- If it is difficult to measure 10m because the output of the wireless device in the 30 ~ 1,000MHz band is small, a method of measuring 3m and correcting has been added

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