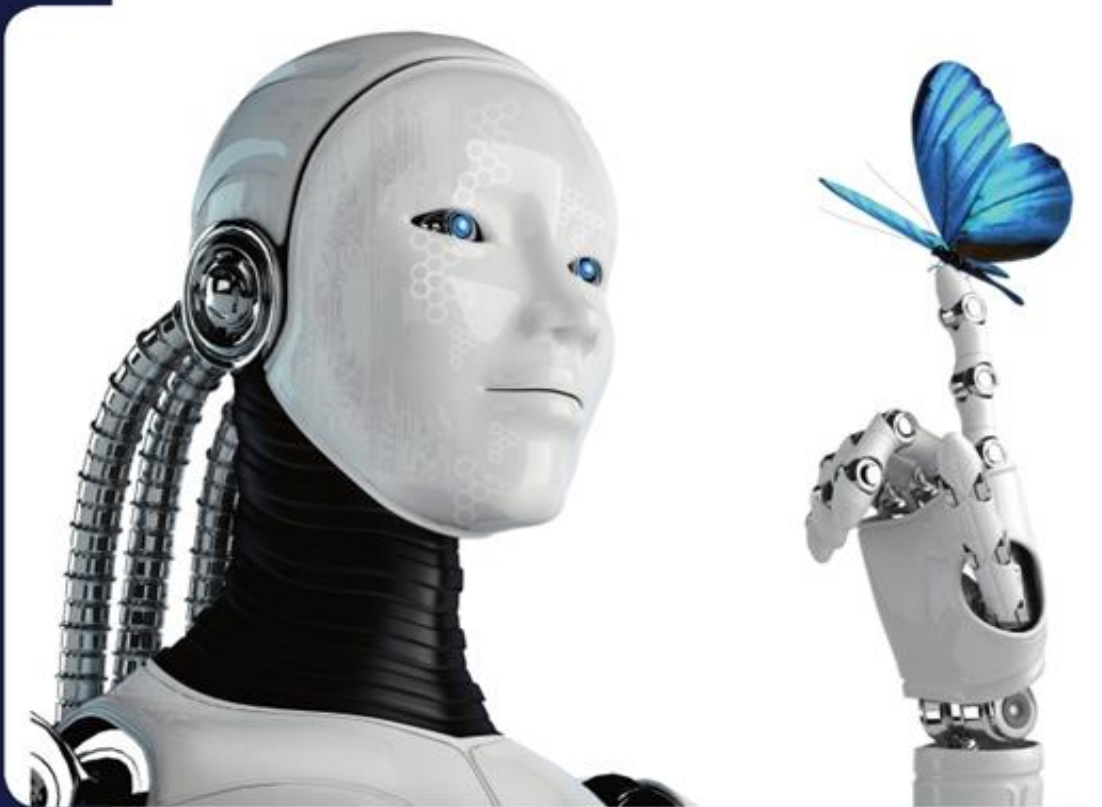


Newsletter

November, 2020



ICR



Hot Issue

1. ISO 13485 Accreditation Scope Extension
2. Designated as a high-efficiency testing institution and Extension of Efficiency management Scope
3. Extension of KOLAS Scope
4. Brexit – UKCA marking



ISO 13485 Accreditation Scope Extension



- Recently, **ICR** was assessed by the Korea Accreditation Board (KAB) to expand the scope of accreditation **the Medical Devices Quality Management System (ISO 13485)**.
- According to the results of the audit, the expansion of accreditation scope was approved **on Oct 15, 2020**.
- The expanded **scope of accreditation** is as follows.

In vitro Diagonostic Medical Devices (IVD)	DI, DII, DIII
Parts or services	GI, GII, GIII, GIV, GV, GVI, GVII, GVIII

- The certificate issued in accordance with the above can be found on the ICR website (<http://www.icrqa.com>)-**ICR** About-Accreditation.

Inquiries

System Certification Div. / Kim, Chae-Lin
T.02-6351-9001 / kcl@icrqa.com

ISO 13485 Accreditation Scope Extension



KOREA ACCREDITATION BOARD



Medical Device Quality Management System Certification Body CERTIFICATE OF ACCREDITATION

Korea Accreditation Board(KAB) has accredited

ICR

112, Hwanggeum 3-ro 7beon-gil Yangchon-eup, Gimpo-si, Gyeonggi-do, Republic of Korea

Complying with ISO/IEC 17021-1:2015 and KAB-AR-MD9:2017 in following conditions for providing medical device quality management system certification in accordance with ISO 13485:2016

- Accreditation No. : KAB-MC-02
- Initial Accreditation Date : May 1, 2020
- Validity : May 1, 2020 ~ December 11, 2021
- Name of Representative : Kim Deok-yong
- Legal Entity Registration No. : 105-86-35114
- Issue Date : October 15, 2020

• Scope of Accreditation :

A Non-active Medical Devices	D In Vitro Diagnostic Medical Devices (IVD)	G Parts or services
A I General non-active, non-implantable medical devices	D I Reagents and reagent products, calibrators and control materials for Clinical Chemistry etc.	G I Raw material G VI Maintenance services
A II Non-active implants	D II In Vitro Diagnostic Instruments and software	G II Components G VII Transportation services
A III Devices for wound care	D III IVD medical devices other than specified above	G III Subassemblies G VIII Other services
A IV Non-active dental devices and accessories		G IV Calibration services*
A V Devices for wound care		G V Distribution services
B Active Medical Devices (Non-implantable)	E Sterilization Method for Medical Devices	
B I General active medical devices	E I Ethylene oxide gas sterilization (EOG)	
B II Devices for imaging	E II Moist heat	
B III Monitoring devices	E III Aseptic processing	
B IV Devices for radiation therapy and thermo therapy	E IV Radiation sterilization	
B V Active (non-implantable) medical devices other than specified above	E V Sterilization method other than specified above	

Korea Accreditation Board

Yun Sang-jae, CEO

Designated as a high-efficiency testing institution and Extension of Efficiency management Scope



산업통상자원부

산업통상자원부



수신 수신자 참조

(경유)

제목 효율관리 및 고효율 시험기관 지정신청 승인 통보(아이씨알)

1. 관련근거 : 에너지이용합리화법 제15조 및 제22조, 효율관리기자재 운용규정 제6조 및 고효율에너지기자재 보급촉진에 관한 규정 제12조
2. 주식회사 아이씨알(ICR)의 효율관리시험기관 및 고효율시험기관 지정 신청서에 대해 한국에너지공단을 통해 시험능력을 확인한 결과 적합하여 승인합니다.

- 효율관리기자재 중 지정 신청 승인 품목
 - 컨버터 내장형 LED 램프, 컨버터 외장형 LED 램프
- 고효율에너지기자재 중 지정 신청 승인 품목
 - 등기구, LED 램프. 끝.

산업통상자원부 장관인



수신자 주식회사 아이씨알(ICR), 한국에너지공단 이사장

ICR got recognition for **high-efficiency new extension** and extending the range of recognition for efficiency management from **Ministry of Trade, Industry and Energy** in 8th Oct, 2020.

Extension of KOLAS Scope



Korea Laboratory Accreditation Scheme

CERTIFICATE OF ACCREDITATION

ICR Co., Ltd.

Accreditation No. : KT652

Corporation Registration No. : 110111-2431479

Address of Laboratory : (Branch site)112, Hwanggeun 3-ro 7 beon-gil Yangchon-eup, Gimpo-si, Gyeonggi-do

Date of Initial Accreditation : January 16, 2015

Validity of Accreditation : January 04, 2019 ~ January 03, 2023

Scope of Accreditation : Attached Annex

Date of issue : September 10, 2020

This testing laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025 : 2017. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to Joint ISO-ILAC-IAF Communiqué).



LEE Seung Woo

Head

Korea Laboratory Accreditation Scheme

Korea Laboratory Accreditation Scheme(KOLAS) is a signatory to the ILAC Mutual Recognition Arrangement

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ICR has extended KOLAS scope for and of **03.009 and 03.005/03.007/03.0310/03.0313**, certificate of accreditation was issued by KOLAS on 10th September, 2020

Inquiries

Electric Safety Center / Yang, Young-Jun
T. 010-5522-3613/ yangyj@icrqa.com

Brexit – UKCA marking



- According to the **UK** has left the EU, **the UKCA (UK Conformity Assessed) marking** is a new UK product marking that will be used for goods being placed on the market in Great Britain (England, Wales and Scotland).



- The UKCA marking will not be recognized **in the EU market**. Products that require CE marking will still **need a CE marking** to be sold in the EU.
- The UK Government has confirmed that the UKCA mark will come into force on 1 Jan 2021, although CE marking will continue to be recognized in the UK until the end of 2021, as long as the UK and EU regulations remain aligned (exclude some products). However, **from the beginning of 2022** only products with UKCA marking will be accepted in Great Britain.

Brexit – UKCA marking

- Most products that are currently covered under regulations and directives for CE marking will fall under the scope of UKCA marking.

❖ Product areas covered by the UKCA marking

- Toy safety
- Simple pressure vessels
- Electromagnetic compatibility
- Lifts
- ATEX
- Radio equipment
- Pressure equipment
- Personal protective equipment
- Machinery
- Low voltage electrical equipment, etc.



❖ Product covered by the UKCA marking but have some special rules

- medical devices
- rail interoperability
- construction products
- civil explosives

 **Inquiries**

Industrial Safety Center / Yang Dae-Song
T.010-5522-4529 / yds@icrqa.com



www.icrqa.com

ICRO-31/R20161125 본 문서는 법률 제 14088호 저작권법의 보호대상이며, ICR의 지적 자산으로 불법 편집 및 복사를 금합니다.

Address :3611, Hagun-ri, Yangchon-eup, Gimpo-si,
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Home page : www.icrqa.com



www.icrqa.com

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