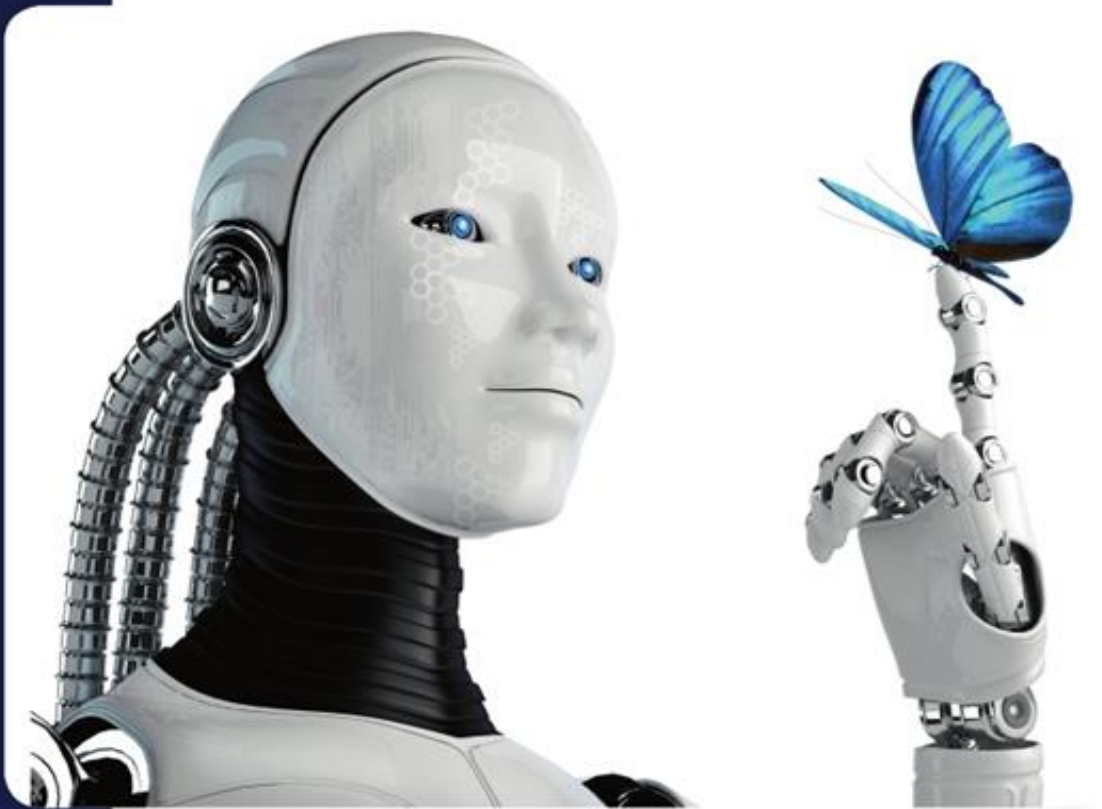


# Newsletter

## August, 2021



# ICR



# Hot Issue

1. MFDS (Ministry of Food and Drug Safety)  
Designation of a medical device testing and inspection body
2. Introduction of battery heater durability tester
3. Participation of PTB Proficiency Testing Scheme
4. Market Trends for ESG Assessment



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



제 18 호

## 의료기기 시험·검사기관 지정서

기관 명칭 : 주식회사 아이씨알  
소재지 : 경기도 김포시 양촌읍 황금3로7번길 112  
대표자 : 김덕용  
업무 범위 : 검사명령검사, 품질검사, 수거검사, 허가인증 신청 및 신고 검사  
분야 : 의료기기  
[의료기기] 진료용 일반장비, 수술용 장치 (마취기 및 레이저 장해 방어용 기구 제외), 진단용 장치 (방사선 용품 제외), 의료용 자극발생  
품 목 : 기계기구 등 4개 품목군의 품목  
[체외진단의료기기(기구, 기계, 장치, 소프트웨어에 한함)] 검체전처리 기기 품목군의 품목  
시험·검사 항목 : 안전성 및 성능 시험항목  
유효기간 : 2021. 6. 23. ~ 2024. 6. 22.

위 기관을 「식품·의약품분야 시험·검사 등에 관한 법률」 제6조 제1항 및 같은 법 시행규칙 제2조제4항에 따라 위와 같이 의료기기 시험·검사기관으로 지정합니다.

2021년 6월 23일

식품의약품안전처장



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

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



## ※ 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

### ■ In vitro diagnostic medical devices

(instruments, machinery, devices, software only)

- Sample preprocessing machine

 **Inquiries**

Electronic Safety Center / Kim, Young-Bin  
T.010-5522-2974 / [kyb@icrqa.com](mailto:kyb@icrqa.com)

# Introduction of battery heater durability tester



## ■ TRENDS

- Currently, most **electric vehicles use lithium-ion batteries**. The problem is that when the temperature drops in the middle of winter, electrolytes harden, which greatly shortens the driving distance of electric vehicles and takes a long time to charge them.
- To address this problem, a battery heater system is being developed that makes the battery at its optimal temperature.

## ■ Battery Heater Durability Tester

- In line with the customer's request, **ICR introduced the battery heater durability tester in June and has been operating the service since July.**



Specification	
1) Coolant temperature	(-30 ~ 90) °C (1.0°C/min)
2) Flow	5 ~ 120 LPM
3) Pressure measurement	(0 ~ 10) Bar(Inlet, Outlet Measure )
4) Environmental chamber	(-40 ~ 150) °C
ES related standard test possible (Multi-valve, COD heater, 20kw or less battery heater test, etc.)	

**Inquiries**

Mobility Center / Lee, Han-Kook  
T.010-5522-1825 / lhk9876@icrqa.com

# Participation of PTB Proficiency Testing Scheme



- **Participation with an Ex Proficiency Testing Scheme** is essential for the compliance of the requirements of ISO/IEC 17025 and IECEx regarding the need of the Ex laboratories to perform interlaboratory comparisons.
- The **Physikalisch-Technische Bundesanstalt (PTB)** located in Germany is the national metrology institute providing scientific and technical services. PTB conducts Ex proficiency testing scheme and provides 2 program every 2 years.
- About 77 Ex laboratories around the world, including ICR, come to participate in **Test Round 2021**.

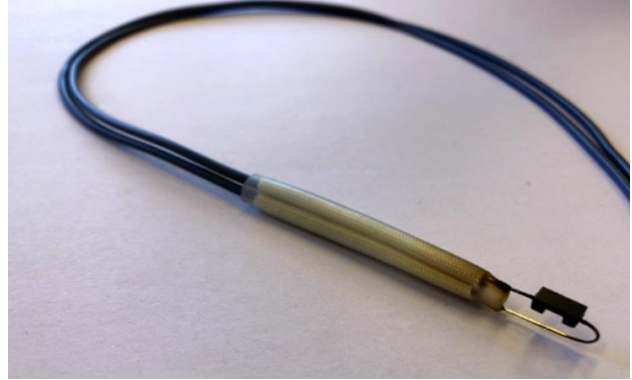
- ▶ Test Round 2021  
"Flameproof Joints"  
(IEC 60079-1, Ed. 7.0)



# Participation of PTB Proficiency Testing Scheme



- ▶ Test Round 2021  
"Small Component  
Temperature"  
(IEC 60079-0, Ed. 7)



- ▣ **ICR** has participated in a number of **IECEx PTB proficiency testing programs (intrinsic safety, flameproof, etc.)** to meet requirements as Ex laboratories and to establish the effectiveness of the applied testing methods.
- ▣ With continuous participation in the PTB proficiency testing program, including Test Round 2021, ICR will ensure the validity of the results of the Ex testing and provide reliability to customers.

 **Inquiries**

Industrial Safety Center / Yang Dae-song  
T.02-6351-9001 / [yds@icrqa.com](mailto:yds@icrqa.com)

# Market Trends for ESG Assessment



## ■ What is ESG?

When making investment decisions, this evaluate the sustainability of the company with environmental, social and governance criteria.

## ■ ESG Market Trends

Companies that have invested in pension funds and reported high earnings in the UK, Germany and Sweden have been revealed to be strong in ESG, and the culture is spreading to many companies.

In Korea, the Financial Services Commission requires an ESG notice for all listed companies with more than 2 trillion won in assets from 2025. ESG is no longer an option.

## ■ EGS Evaluation Model

For the objectivity of the ESG evaluation indicators, the indicators are currently being established, and the grades given to each company according to the ESG evaluation



# Market Trends for ESG Assessment



will be applied to various aspects such as financial institution credit, supplier selection criteria, and investment indicators in the stock market .

## ■ Relevance of ESG Evaluation Model and ISO Management System Certification

In the ESG evaluation model, certification of 'ISO 14001 Environmental Management System, ISO 45001 Occupational Health and Safety Management System, and ISO 37001 Anti-Bribery Management System' accounts for a large proportion.

- ICR will continuously monitor international and domestic trends on ESG and **promote business agreements with ESG evaluation agencies** in order to preoccupy companies that require ISO certification by responding quickly to market trends for ESG.

 **Inquiries**

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