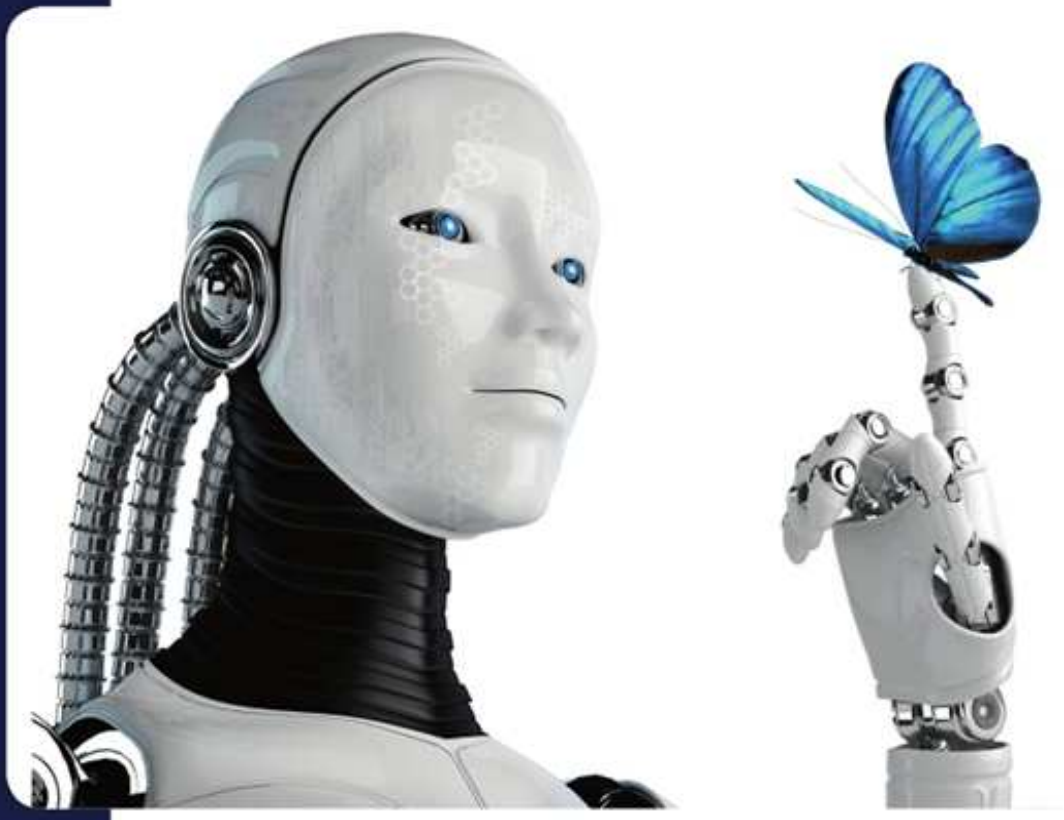
Newsletter
May, 2018

ICR



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Hot Issue

- Participated in KIMES 2018 International Medical Equipment Exhibition
- ICR Polska RED Seminar
- MOU agreement with DGMIF
- 2018 Research Equipment Joint Application Support Project
- ISO 22000:2005 Revision
- Changes of ISO 22000:2018
- Wireless Power Transfer Technology
- March 2018 Guide for the EMCD [2014/30/EU Directive for EMC]

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Participated in KIMES 2018 International Medical Equipment Exhibition

KIMES is the largest medical and hospital equipment exhibition in Korea, with 1,313 companies from 34 countries including 649 companies in Korea, 117 companies in the US, 165 companies in China, 90 companies in Germany, and 53 companies in Japan.

By participating in KIMES 2018, which shows the direction to go with the latest information related to the medical industry, ICR has gained a glimpse of the trend of the medical market and the medical devices that domestic and overseas manufacturers are aiming for.

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Participated in KIMES 2018 International Medical Equipment Exhibition

ICR was able to see **the medical market trend** and **the future** according to the fourth industrial revolution era by participating in KIMES.

Based on this, we will provide technical support services for the elements required by the company. We also promise to **resolve technical barriers** based on the mutual recognition principle of mutual recognition between countries and to make more efforts to provide

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ICR Polska RED Seminar

ICR Polska offered about RED seminar in Korea. 10 companies and 17 particapants joined for this.

ICR Polska introduced **RED work procedure, module definition, essential requirements and harmonized standards**.

And also, ICR Polska introduced about **how to get Conformity of Certification** from Notified Body.

ICR Polska explained the chaing of upcoming standards, market trend and reviewing standards testing method.

ICR Polska is not just giving you an EC type-examination. we can offer the **seminar, training, consulting** and anything from your request.

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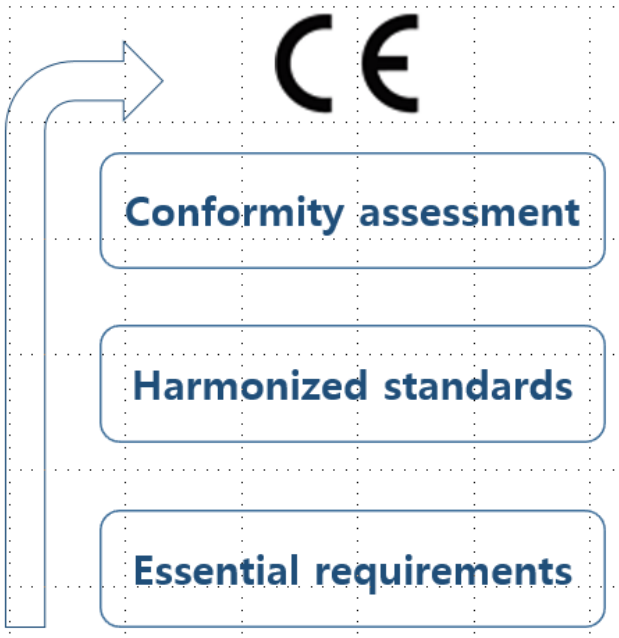
ICR Polska RED Seminar

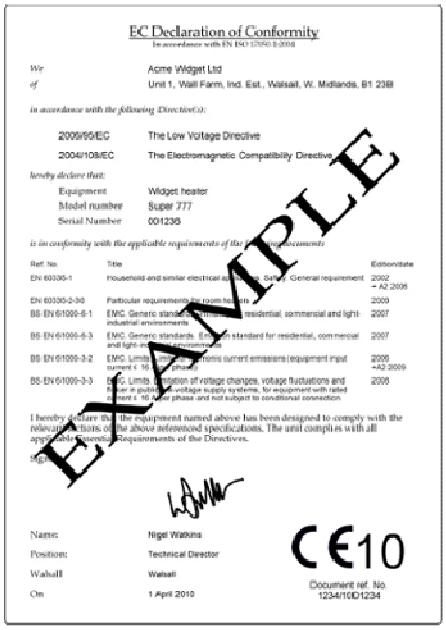
RED DOC Work Procedure

To declare RED DOC yourself then, you must to fullfil Harmonized Standards

*** HS (Health & Safety, EMC, Radio and Specific)**



option A
Self-declaration


EC Declaration of Conformity

We — Acme Widget Ltd
of — Unit 1, Wall Farm, Ind. Est., Walsall, W. Midlands, B1 2SB

In accordance with the following Directive(s):

2006/95/EC — The Low Voltage Directive
2004/108/EC — The Electromagnetic Compatibility Directive

hereby declare that:

Equipment — Widget heater
Model number — Super 777
Serial Number — 001236

Is in conformity with the applicable requirements of the following documents:

Ref. No.	Title	Edition/date
EN 60335-1	Household and similar electrical ap... Part 1: General requirement	2002 + A2 2006
EN 60335-2-36	Particular requirements for room heaters	2003
BS EN 61000-6-1	EMC: Generic standards ... residential, commercial and light-industrial environments	2007
BS EN 61000-6-3	EMC: Generic standards ... standard for residential, commercial and light-industrial environments	2007
BS EN 61000-3-2	EMC: Limits ... harmonic current emissions (equipment input current ≤ 16 A per phase)	2006 +A2 2009
BS EN 61000-3-3	EMC: Limits ... fluctuation off voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection	2008

I hereby declare that the equipment named above has been designed to comply with the relevant sections of the above referenced specifications. The unit complies with all applicable Essential Requirements of the Directives.

Signed

Name: Nigel Watkins
Position: Technical Director
Walsall
On: 1 April 2010

CE10

Document ref. No. 1234/10/D1234

EXAMPLE

PCA Polskie Centrum Akredytacji Certyfikacja Wyrobów AC 197

PCA Polskie Centrum Akredytacji Certyfikacja Systemów Zarządzania AC 200

Notyfikacja CE 2703

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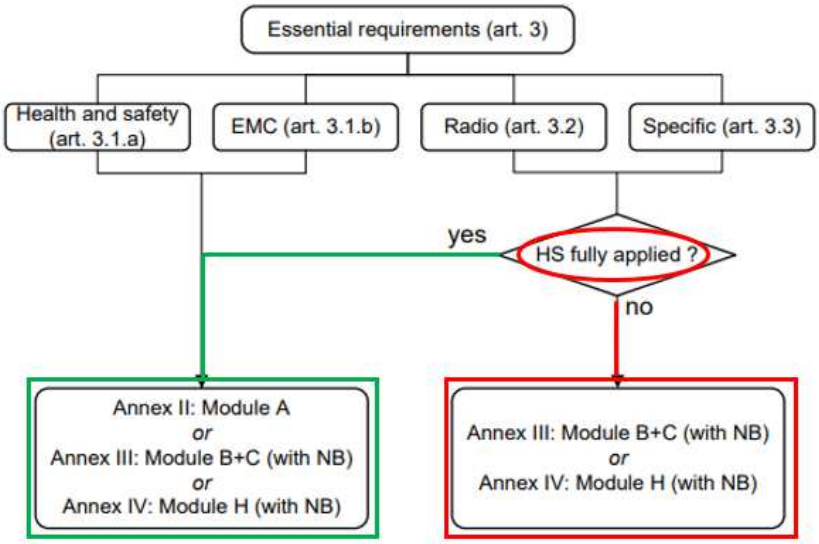
ICR Polska RED Seminar

RED COC Work Procedure

To declare RED COC then, you can choose between Harmonized Standards and Non Harmonized Standards



option B
Notified body


EC-TYPE EXAMINATION CERTIFICATE

No ICR Polska/2/2018

* HS : Harmonized Standard
* YES : Safety, SAR, EMC, RF TEST requires
* NO : RF TEST only can but, needs to be certified by N.B

PCA Polskie Centrum Akredytacji Certyfikacja Wyrobów AC 197
PCA Polskie Centrum Akredytacji Certyfikacja Systemów Zarządzania AC 200
Notyfikacja CE 2703

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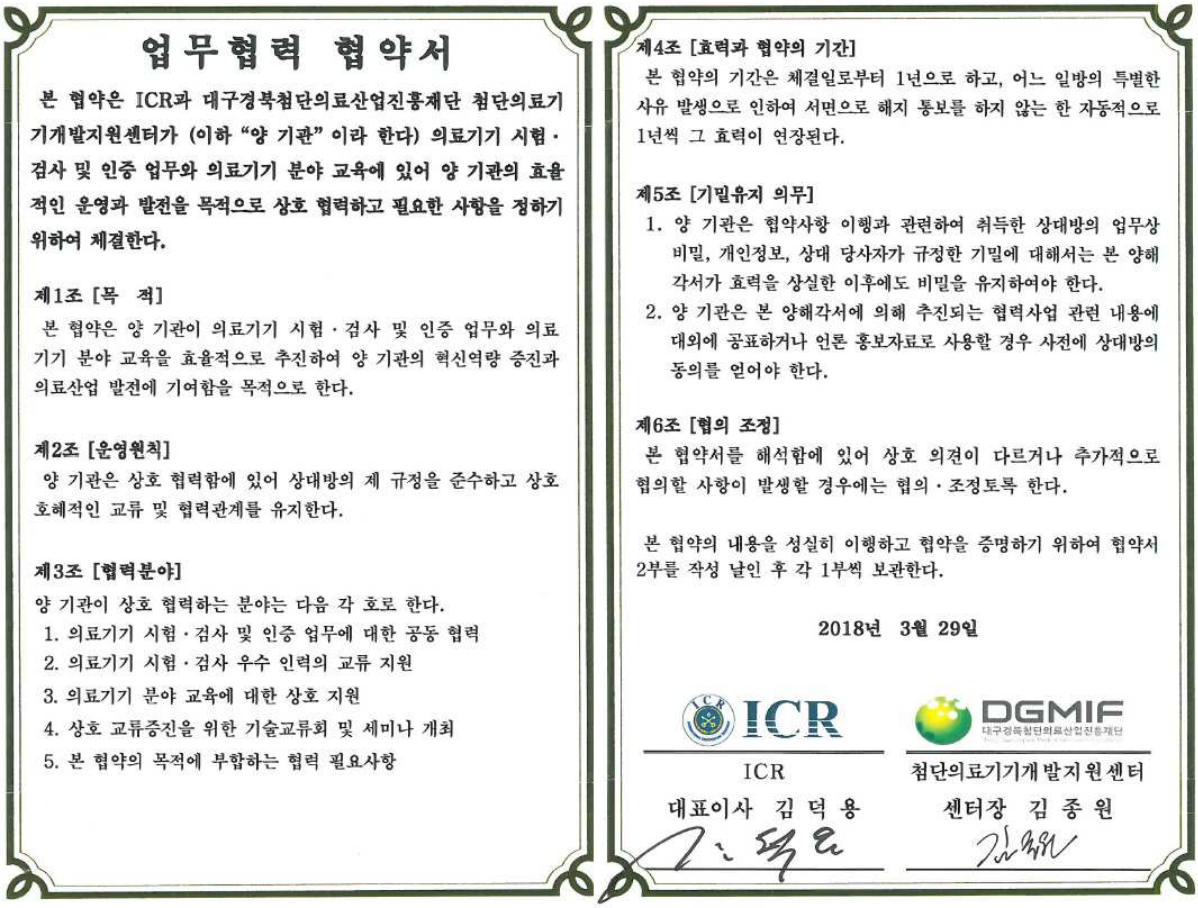
MOU agreement with DGMIF



업 무 협 력 협 약 서

본 협약은 ICR과 대구경북첨단의료산업진흥재단 첨단의료기기개발지원센터가 (이하 "양 기관" 이라 한다) 의료기기 시험·검사 및 인증 업무와 의료기기 분야 교육에 있어 양 기관의 효율적인 운영과 발전을 목적으로 상호 협력하고 필요한 사항을 정하기 위하여 체결한다.

제1조 [목 적]

본 협약은 양 기관이 의료기기 시험·검사 및 인증 업무와 의료기기 분야 교육을 효율적으로 추진하여 양 기관의 혁신역량 증진과 의료산업 발전에 기여함을 목적으로 한다.

제2조 [운영원칙]

양 기관은 상호 협력함에 있어 상대방의 제 규정을 준수하고 상호 호혜적인 교류 및 협력관계를 유지한다.

제3조 [협력분야]

양 기관이 상호 협력하는 분야는 다음 각 호로 한다.

1. 의료기기 시험·검사 및 인증 업무에 대한 공동 협력
2. 의료기기 시험·검사 우수 인력의 교류 지원
3. 의료기기 분야 교육에 대한 상호 지원
4. 상호 교류증진을 위한 기술교류회 및 세미나 개최
5. 본 협약의 목적에 부합하는 협력 필요사항

제4조 [효력과 협약의 기간]

본 협약의 기간은 체결일로부터 1년으로 하고, 어느 일방의 특별한 사유 발생으로 인하여 서면으로 해지 통보를 하지 않는 한 자동적으로 1년씩 그 효력이 연장된다.

제5조 [기밀유지 의무]

1. 양 기관은 협약사항 이행과 관련하여 취득한 상대방의 업무상 비밀, 개인정보, 상대 당사자가 규정한 기밀에 대해서는 본 양해각서가 효력을 상실한 이후에도 비밀을 유지하여야 한다.
2. 양 기관은 본 양해각서에 의해 추진되는 협력사업 관련 내용에 대외에 공표하거나 언론 홍보자료로 사용할 경우 사전에 상대방의 동의를 얻어야 한다.

제6조 [협의 조정]

본 협약서를 해석함에 있어 상호 의견이 다르거나 추가적으로 협의할 사항이 발생할 경우에는 협의·조정토록 한다.

본 협약의 내용을 성실히 이행하고 협약을 증명하기 위하여 협약서 2부를 작성 날인 후 각 1부씩 보관한다.

2018년 3월 29일

ICR	첨단의료기기개발지원센터
ICR	
대표이사 김 덕 용	센터장 김 종 원

March 29, 2018

"ICR" and "Ministry of Food and Drug Safety (MFDS) designated testing institute Daegu-Gyeongbuk Medical Innovation Foundation (DGMIF) conducted MOU agreement for mutual cooperation.

MOU agreement with DGMIF

DGMIF acquired **KOLAS international accredited testing body certification** for **52 standards** of electromagnetic compatibility in July last year.

In December, DGMIF acquired **6 kinds of medical equipment** (surgical apparatus, diagnostic apparatus, medical stimulation apparatus, in vitro diagnostic apparatus, Etc.), we have been appointed as **the authorized testing and inspection institution** for medical devices in Korea.

It is expected that the **MOU** agreement will strengthen the capacity of test and inspection business through establishment of exchange and cooperation network of excellent manpower, technical exchanges and holding seminars.

In particular, through this agreement, ICR will be able to solve problems related to licensing of medicines, and the Medical Equipment Center will be able to respond to matters related to overseas certification.

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2018 Research Equipment Joint Application Support Project

We have been selected as the main organ for the "**2018 Research Equipment Joint Application Support Project**". Participating organizations in this project can utilize our research equipment. The government **subsidizes part of the equipment fee.**

The amount of the support is **60 ~ 70% of the equipment usage fee** and the equipment can be used at a lower amount.

I will inform you of the amount of support you can receive as a participating organization and how to apply for it.

중소기업 기술개발사업
종합관리시스템

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2018 Research Equipment Joint Application Support Project

1. Support Amount and Limit

1) Subsidy support criteria

◦ Government contributions :
Within 60 ~ 70% of total equipment usage fee

◦ Company burden fee :
More than 30 ~ 40% of total equipment usage fee

Classification	Government contributions	Company burden fee
A startup company (7 years or less)	Within 70% (Up to 3 ~ 70 million won)	More than 30% (cash)
General Business (Over 7 years)	Within 60% (Up to 3 ~ 70 million won)	More than 40% (cash)

2) Purchasing a voucher

◦ Vouchers (Government subsidy + corporate contribution) within government subsidies (up to 70 million won) can be purchased at any time.

◦ The voucher expires 90 days after the purchase date. (automatic refund application)

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2018 Research Equipment Joint Application Support Project

2. Application and Selection Procedure

1) Apply for participating organizations

◦ Apply online · Reception
Online address : http://www.smtech.go.kr

2) Participating Agency Selection Process

◦ Whether they are small and medium enterprises, research
equipment utilization plan check list, etc.
◦ Applicant buys vouchers online during the 2018 business
period.

3. Support business information and consultation

◦Phone: (02) 6351-9003 Fax: (02) 6351-9007

We have produced detailed manuals on how to use the business of the participating organizations, so if you are interested, please contact us and we will be happy to answer any questions you may have.

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ISO 22000:2005 Revision

ISO 22000:2005, **Food Safety Management System Standard** is on revision.

In 16th March 2018, **FDIS** version standard was issued, and the voting for the standard was finished in 25th April 2018.

The official standard(**ISO 22000:2018**) is schedule to be published in **June 2018**.

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Changes of ISO 22000:2018

Followings are main changes.

1) By adopting HLS(High Level Structure), organizations can establish the integrated management among various management system. Easily.

2) The standard now includes a different approach to understanding risk.

3) The standard clarifies the Plan-Do-Check-Act cycle, by having two separate cycles in the standard working together: one covering the management system and the other, covering the principles of HACCP.

4) A clear description is given of the differences between key terms such as: Critical Control Points (CCPs), Operational Prerequisite Programmes (OPRPs) and Prerequisite Programmes (PRPs).

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Wireless Power Transfer Technology

What is Wireless Power Transfer?

WPT is a transmit the power that is mainly using charging of battery.

WPT has 3 types such as Inductive, Resonant and EMF.

Below table is what you can do adapt and mention which standards need to be tested.

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Wireless Power Transfer Technology

	Inductive	Resonant	Electromagnetic Field
Effective distance	80 ~ 90 % efficiency in few mm	60 ~ 90 % efficiency In a meter	10 ~ 50 % effciency in several km
Hazards	Almost Clear (EMI Compliant)	Clear (No Standards yet)	High (Special purpose)
Techniques	Using magnetic field	Using resonant inductive coupling	Transfer the radio wave
Example			
Standards	KN17, RF EMC EN 303 417 EN 300 330-1 FCC Part. 15/18	CISPR25 New standard will be released	KN11 FCC Part. 18 EN 303 417 EMC

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March 2018 Guide for the EMCD [2014/30/EU Directive for EMC]

These guidelines are intended to be a manual for all parties directly or indirectly affected by the "new" Electromagnetic Compatibility Directive 2014/30/EU (EMCD).

《 INTRODUCTION 》

- This Guide should always be read in conjunction with the 'Blue G uide' on the implementation of EU product rules.

- The purpose of this Guide is to give guidance on certain matters and procedures of the EMCD.

- The new EMCD (Directive 2014/30/EU) repeals and replaces the old EMCD
  (Directive 2004/108/EC). It maintains the same objectives to guar antee the free
  movement of equipment and to create an acceptable electromag netic environment in the Union territory

- The main objective of the EMCD is thus to regulate the electrom agnetic compatibility
  of equipment. In order to achieve this objective, provisions have been put in place so that:
  equipment shall comply with the requirements of the EMCD whe n it is made
  available on the market and/or put into service when properly in stalled, maintained and used for its intended purpose

source (The Blue Guide): http://ec.europa.eu/growth/single-market/goods/index_en.htm

March 2018 Guide for the EMCD [2014/30/EU Directive for EMC]

the application of good engineering practice is required for fixed i nstallations,
with the possibility for the competent authorities of Member State s to request
evidence of compliance of the fixed installation, and, when approp riate, initiate an evaluation if non-compliances are established.

- After 2010, the Blue Guide was updated to the NLF. The NLF is a fl exible regulatory framework for the marketing of products.

- In 2014 a set of Directives (including the
new EMCD and the new LVD) were aligned according to the NLF. Also in 2014, theRadio Equipment Directive (RED) entered into forc e and is applicable as of 13 June
2016, subject to one year transitional period (ended on 12 June 20 17).

- The EMCD is applicable as of 20 April 2016.

- The main changes in the new EMCD (Directive 2014/30/EU), as co mpared to the old
EMCD (Directive 2004/108/EC), relate with the alignment with the new legislative
framework, Standardisation Regulation (EU) No 1025/2012 and Art icle 291 of the TFEU (Implementing Acts).

source (The Blue Guide): http://ec.europa.eu/growth/single-market/goods/index_en.htm

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