Newsletter
June, 2020

ICR

Address :3611, Hagun-ri, Yangchon-eup, Gimpo-si, Gyeonggi-do , South Korea (10048)

Company Id No : 110111-243147
Tax & VAT Id No : 105-86-35114

Tel : (+82)2-6351-9001~5 / Fax : (+82)2-6351-9007
Home page : www.icrqa.com

Hot Issue

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Accreditation Certificate Reissued by KOREAN REGISTER

KOREAN REGISTER

APPROVAL CERTIFICATE FOR TEST LABORATORY

Certificate No. : PCT37514-TL001 **Initial Approval :** 15th June, 2017
Scope of Services : Electrical Testing and Vibration Testing

Test Laboratory : ICR

#112, Hwanggeum 3-ro 7beon-gil, Hagun-ri, Yangchon-eup, Gimp-si, Gyeonggi-do, Rep. of Korea

Approval Condition: See "Appendix 1 & 2 "

THIS IS TO CERTIFY that the Test Laboratory of the above-mentioned including testing facilities, quality control and general standards of testing procedures has been audited by this Society and found to be in compliance with the requirement of this Society's Rules and / or of the recognized standards as follows and entered in the "List of Approved Test Laboratories".

Circular 8.58 Instruction for the approval of test laboratory and KS Q ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories.

This Certificate is valid until 14th June, 2023
Issued at Busan, Korea on 13th May, 2020

KOREAN REGISTER

General Manager of
Marine & Ocean Equipment Team

Note : 1. This certificate will be valid subject to complying with the approval conditions described on the certificate and/or on the Rules of this Society.
2. This certificate will be invalid from the expiry date aforementioned unless the extension or renewal has been granted to the applicant or the manufacturer.
3. Any significant modifications or changes in design or construction to the above product without approval from this Society will render this certificate invalid.
4. Should the specified rules, regulations or standards be amended during the validity of this certificate, the product is to be re-approved by this Society in accordance with the requirements as amended.

Form AC-5A (2017.09)

On May 13, 2020, the accreditation certificate is reissued by **KOREAN REGISTER**.

Approved as KAB ISO 13485:2016

▣ ICR received an audit of ISO 13485:2016(Medical Device Quality Management System) from **KAB accreditation body** on Dec 26-27, 2019.

▣ As a result of the audit, ICR has been accredited with the **authority to issue the ISO 13485:2016 Medical Device Quality Management System Certificate** from Accreditation (**KAB**) on MAY 01st, 2020.

▣ Consequently, ICR can provide certification audit service for ISO 13485:2016. For more information, please refer to ICR homepage notes.

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

Approved as KAB ISO 13485:2016

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

A Non-active Medical Devices
- General non-active, non-implantable medical devices
- Non-active implants
- Devices for wound care
- Non-active dental devices and accessories
- Devices for wound care

B Active Medical Devices (Non- implantable)
- General active medical devices
- Devices for imaging
- Monitoring devices
- Devices for radiation therapy and thermo therapy
- Active (non-implantable) medical devices other than specified above

E Sterilization Method for Medical Devices
- Ethylene oxide gas sterilization (EOG)
- Moist heat
- Aseptic processing
- Radiation sterilization
- Sterilization method other than specified above

Korea Accreditaion Board

Yun Sang-jae, CEO

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Occupational Safety and Health Act Modifying in 2020

▣ Occupational Safety and Health Act was modified in 28 years as of **January 16, 2020**.

▣ Occupational Safety and Health Act was modified for worker's safety including tightening regulations on dangerous work and expanding the scope of workers.

▣ Details is refer to below.

Expanding the protection of the law

- Expand from **"employee"** to **"workers who provide labor"**.

Expanding the responsible parties for Industrial accidents prevention

- Implementing safety and health measures according to **number of workers and merchants, cost of construction**

Restricting of contracts for **harm and dangers wokr** in company

- **Restricting of contracts in company and working** about using harm and danger material

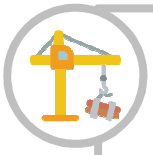
☎ Inquiries

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

Occupational Safety and Health Act Modifying in 2020

Strengthening the **scope of responsibility and level of punishment** for contractor

- **Expanding the scope of places** where contractors should take safety and health measures
- **Increasing level of punishment** for breach of health and safety measures



Strengthening the **Safety and Health management system** in the construction industry

- **Expanding the selection** of safety managers and safety and health coordinator in the construction idustry
- **Only registered people** can install and dismantle tower cranes.

Strengthening **chemical safety management**

- Person who import and manufacture MSDS materials should submit MSDS

Strengthening the level of punishment for workers' deaths in violation of safety and health measures

- **Strengthening the level of punishment**

▣ Various systems and law of Occupational Safety and Health Act will be established to protect workers in industrial sites

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TOUCH SCREEN ENDURANCE EQUIPMENT

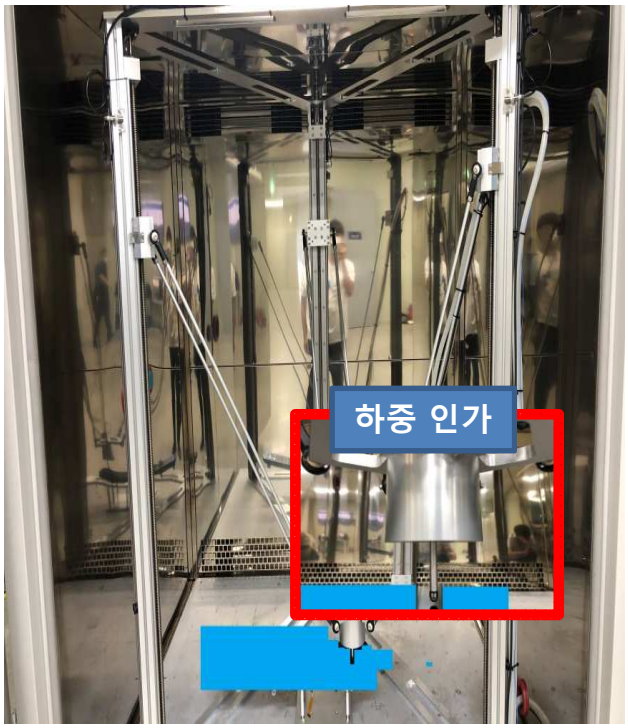
▣ TRENDS

▶ Advances in digital technology have improved the convenience of motorists, and in particular, integrated control such as navigation, audio, video, and temperature control is possible through touch display technology.

▶ In addition, the installation of large-sized displays is gradually expanding to new models of automobile manufacturers

▣ TOUCH SCREEN ENDURANCE EQUIPMENT

▶ To meet the needs of customers, **ICR** introduces and operates a **TOUCH SCREEN ENDURANCE EQUIPMENT**.



- Performance : Touch Screen Weight
- Chamber : -40 ~ 150 ℃
- Size : 1.5 m * 1.4 m * 1.8 m
- Touch Speed : 1 sec (Weight control)
- Max Weight : 6 N
- BMW, FORD, Benz, H/KMC, GM

☎ Inquiries

Mobility Center / Lee, Han-Kook

T.010-5522-1825 / lhk9876@icrqa.com

CE labeling requirements

- ▣ Minimum height = 5 mm.
- ▣ Must be affixed permanently and indelibly
- ▣ Placement on packaging and accompanying documents (if any).

4.5.1.4. Principles of affixing the CE marking

The CE marking must be affixed visibly, legibly and indelibly to the product or to its data plate. However, where this is not possible or not warranted on account of the nature of the product, it must be affixed to the packaging, if any, and/or to the accompanying documents. The CE marking may not, in principle, be affixed until the conformity assessment procedure has been completed to ensure that the product complies with all the provisions of the relevant Union harmonisation acts. This will usually be at the end of the production phase. This poses no problem if, for example, the CE marking is on a data plate that is not affixed to the product until after the final inspection. However, if (for example) the CE marking is affixed by stamping or casting, the marking can be affixed at any other stage of the production phase, provided that the conformity of the product is verified as part of the production process.

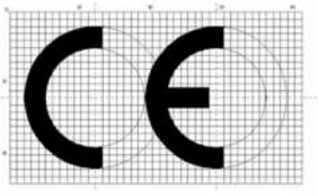
The requirement for visibility means that the CE marking must be easily accessible for all parties. It could, for instance, be affixed on the back or underside of a product. The requirement for visibility does not necessarily mean that the CE marking must be visible before opening a products' packaging because affixing the CE marking also to the packaging is only necessary in case this is explicitly required in the relevant Union acts. A minimum height of 5 mm is required to ensure that it is legible. However according to the several pieces of legislation ([220]) the minimum dimension of the CE marking may be waived for small devices or components.

The CE marking can take different forms (e.g. colour, solid/hollow) as long as it remains visible, legible and respects its proportions. It must also be indelible so that it cannot be removed under normal circumstances without leaving noticeable traces (for example some product standards provide for a rub test with water and petroleum spirits). Nevertheless, this does not mean that the CE marking must form an integral part of the product.

However in certain cases affixing of the CE marking to the product is impossible (for example on certain types of explosives) or not possible under reasonable technical or economic conditions. Furthermore there can be cases where the minimum dimensions for the affixing cannot be respected, or it cannot be ensured that the CE marking is visibly, legibly and indelibly affixed.

In such cases, the CE marking can be affixed to the packaging, if it exists, and/or to the accompanying document, where the Union harmonisation legislation concerned provides for such documents. The CE marking on the product may neither be omitted nor be moved to the packaging or accompanying documents on purely aesthetic grounds.

Regulation (EC) No 765/2008 and Decision 768/2008/EC lay down that the CE marking must have the dimensions, format and proportions defined in Annex II to Regulation (EC) No 765/2008 and be legible and clearly affixed. Regulation (EC) No 765/2008 and Decision No 768/2008/EC do not forbid any kind of design (e.g. 'hollow' design) as long as the above conditions are respected. However, electronic labelling only is not allowed.



☎ **Inquiries**

EMC&RF Test Center / Lee, Hong-Kyu

T.010-5522-2943 / hklee@icrqa.com

www.icrqa.com

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

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