1. PURPOSE

The purpose of this procedure is given by our company; (EU) 2017/745 regulation and EN ISO 13485 to explain how the use of the brands and certificates issued to organizations after the certification process will be carried out in accordance with EN ISO 17021-1, relevant regulations and Turkak Guide R10.06 requirements.

2. SCOPE

This procedure covers the certificates, CExxxx mark and Türkak- KAREV logo / brands issued under the EN ISO 13485 Medical Devices QMS and (EU) 2017/745 regulation Product Conformity Assessments.

3. RESPONSIBILITIES

-Technical Manager
-System Manager
-MDR Responsible

4. DEFINITION

Logo: The symbol that KAREV uses to introduce its own name.

Brand: It is the symbol used by KAREV to indicate the certification status of the companies it has certified. The brand is created by typing the certification area and the corresponding standard number under the logo.

CEXXXX Mark: All medical devices must carry the identification number of the notified body responsible for the implementation of the procedures specified in the CE marking (EU) 2017/745 regulation when they are introduced to the market. CE mark; it is not a quality symbol but a sign that the product attached to it meets all the requirements of the relevant regulation and is intended to ensure the free movement of goods between member states of the European Union. The numbers XXXX next to CE are the identification number of the notified body performing the process.

5. IMPLEMENTATION

Organizations that receive certificates from accredited certification bodies from TURKAK can use the TURKAK Accreditation Brand in stationery, advertising, promotion or similar materials. TURKAK Accreditation Brand should be used in relation to the brand of accredited certification body or certification program. (See: www.turkak.org.tr / Guides/ R10–06)

Only KAREV has the right to use the KAREV brand. Companies certified by KAREV should take measures to prevent the use of the KAREV brand, its customers, subcontractors or any third party given to them and should not transfer this right. KAREV has the right to change the conditions specified in this procedure without prior notice.

When KAREV wants to learn where the companies it has certified use the brand and certificate; must show all uses. KAREV; In case the customers use the brand and certificates in violation of this procedure, they are obliged to initiate the necessary corrective and preventive actions, suspend and withdraw the certificate and brand, disclose the violation to the public and initiate other legal actions.

Companys that are granted the right to use certificate, logos and/or brands; In case the certificate/agreement is suspended or withdraw by KAREV, the organization holding the certificate will stop using the certificate/logo/brand.

In case of unauthorized use of the KAREV brand by third parties, KAREV uses its right to initiate legal action.

5.1 KAREV Management System Certificate, Logo/Brand Usage

Certificates, logos and brands issued by KAREV; it can be accessed from KAREV's official website www.karevcert.com.

The company cannot use the System Certification symbol (logo) in the fields of activity and advertisements outside the scope of the certificate belonging to the management system.

The customer has the right to use certificates and/or logos on promotional materials, correspondence and advertisements, on condition that the scope and location conditions on the certificate are strictly adhered to. TURKAK logo cannot be used on vehicles, flags, buildings, business cards.

It cannot be used on the product at all. (Here, product can be a product that can be touched directly, or a product in a separate package, container, etc.). It can be used on the outer packaging used for the transportation of the products with a statement indicating that the certificate is not given to the product, but to the relevant Management System. It can be used in the company's publications for advertising purposes or on promotional brochures, with or without specifying that the certificate is given to the relevant Management System. It is possible to use with the necessary explanations on the second packaging (parcel, etc.). (For example, it was produced in the facilities of XXXX company with EN ISO 13485:2016 certificate.)

The management system certificate is valid for three years, provided that the interim audits are successful. Logos can be used as long as the certificate is valid. In case the company's certificate is revoked or KAREV's accreditation expires, companies are obliged to stop using the logo.

The customer must show the auditors the place where the logos are used during surveillance audits.

KAREV and accreditation agency logos are provided to customers in a ready-to-reproduce format. The following conditions apply regarding the subject.

The KAREV logo can be used alone, the accreditation agency logo can be used together with the KAREV logo. An example is given below.

The logos must be of a size so that all features are visible in detail.
The accreditation body's logo cannot be in a big or separate place from the KAREV logos.
Guidelines and documents regarding the use of accreditation agency logos are valid (TÜRKAK Guide R.10.06). In this context, the accreditation agency logo is the same size as the KAREV logo. KAREV Logo cannot be used on customer test reports, calibration and inspection reports.

KAREV audit team performs the necessary checks in terms of compliance with the IAF, TURKAK guidelines and this procedure regarding the use of certificates, brands and logos during the audits, and records the results in the relevant section of the audit report. For this purpose, the audit team takes samples, takes pictures, when necessary, checks on brochures, catalogues, business cards, advertising materials and products.

It determines and initiates the necessary sanctions if the customers use the logos and certificates in violation of this procedure. Information about corrective actions is communicated to the customer in writing. After the certification agreement is canceled, the customer stops the use of KAREV certificates and logos and returns the certificate to KAREV.

The KAREV logo is subject to the trademark registration carried out by the Turkish Patent Institute. In case of unauthorized use of the KAREV logo by third parties, the General Manager is responsible for initiating legal sanctions in accordance with the Turkish Commercial Code.

5.1.1. Use of Combined Mark (IAF MLA-Türkak)

A sub-license agreement has been signed for the use of the IAF MLA mark by certification bodies accredited by Türkak. Guidelines and documents regarding the use of Accreditation agency logos regarding the use of combined mark (Türkak and IAF MLA) is valid (TÜRKAK Guide R.10.06). IAF ML 2 must be used in accordance with the requirements set out in "General Principles for the Use of the IAF MLA Mark".

The IAF MLA Mark should only be used together with the TÜRKAK Accreditation Mark, it cannot be used alone.

It can be used in combined mark accredited certificates only if the scope of the certificate includes IAF MLA sub-scopes. KAREV can also use it in the combined mark letterheads, job offers, advertisements and on the website if it is related to the scopes they are accredited.

The combined mark cannot be used on products or in a way that can be associated with the product or evoke the suitability of the product.

KAREV's customers cannot use the combined mark. Customers should be prevented from using the combined mark.

The IAF MLA Mark cannot be used when the TÜRKAK Accreditation Mark and KAREV's name or logo are not present on the displayed page at the same time.

The combined mark obtained by using the IAF MLA Mark and the TÜRKAK Accreditation Mark is used only as it was created by TÜRKAK.

An example of a combined mark use is given below.

5.1.2. TÜRKAK Document Verification System (TBDS) and Use of QR Code

In the certificates issued, the TBDS QR Code produced by the TÜRKAK Document Verification System is placed next to the TÜRKAK brand (on the left or right or above or below), provided that it is not less than 20x20 mm in size, in the following figures.

(a)

(b)

(c)

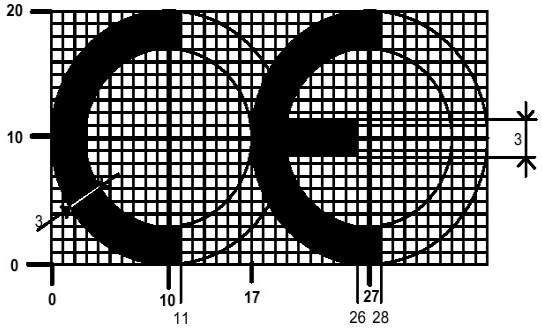
(d)

The TÜRKAK code to be used under the QR code is given by the system after the information is entered on the TBDS platform.

In the issued certificates, it is stated that the query of the certificate can be done by reading the QR code produced by TBDS with mobile devices or by using the TBDS Certificate number at https://tbds.turkak.org.tr.

5.2. CE Marking and Notified Body Identification Number

"CE" Marking;



- It consists of the letters "CE" in accordance with the above-mentioned figure, and the design of the sign cannot be changed, except by reducing and enlarging it in accordance with the proportions in the drawing,

- Unless otherwise specified in the relevant technical regulation, it shall be at least 5 mm in size,

- In cases where this is not possible or guaranteed permanence due to the nature of the product or on the product plate, the product stipulated by the relevant technical regulation is placed in the accompanying certificates in a visible, readable and indelible manner,

- The "CE" mark is placed before the product is placed on the market.

- "CE" mark is placed only by the manufacturer or its authorized representative.

- When required by the relevant technical regulation, the identification registration number of the notified body involved in the production control phase is also included next to the "CE" mark. The identification registration number is placed by the notified body itself or by the manufacturer or the manufacturer's authorized representative in accordance with the instructions of the body.

- Along with the "CE" mark, pictograms or other markings describing a particular risk or use may be placed on the product.

- No other signs or descriptions may be placed on the product to mislead third parties about the meaning and form of the "CE" mark. Any other mark may be placed on the product only in a way that does not impair the visibility, readability and meaning of the "CE" mark.

- The CE mark can only be used on products for which technical regulations are required and cannot be used on other products.

- KAREV has been appointed as the notified body numbered XXXX. Its use with the CE mark is as follows.

- If the responsibility for the application of the CE mark is given to the manufacturer with the authorization of KAREV; The CE mark, for which KAREV has evaluated conformity, is affixed to the medical device in an easily visible, legible and indelible manner, on its sterile packaging, instruction for use and sales packaging.

- The notified body identification number should be placed under or next to the CE mark “XXXX”. If the brand is reduced or enlarged, the ratio should adhere to the figure shown above. The mark must be indelible, not affected by chemical factors and temperature.

- Marks can be placed in more than one place on very large products.
- Regarding affixing and using the CE marking, it is obligatory to comply with the provisions of the Law on Attaching and Using the "CE" Conformity Mark to the Product, published in the Official Gazette dated 17/1/2002 and numbered 24643.

- The certificate owner cannot use the certificate and the relevant product certification logo outside the scope of certification and accreditation rules. In case of going beyond the specified scope, the certificate owner is first notified and corrective action is requested from the certificate owner to correct this irregularity. This process can be as extensive as taking legal action.

These:

- Modification of different models’ labels with the product certification logo printed on them,

- If it is placed on the market, recalling and informing its customers and sellers,

- If it cannot be corrected, its annihilation.

Upon successful completion of the KAREV certification process, a certificate is issued containing the details of the scope of application, place, and standard name for the audit. The product certificate is valid for 5 (five) years, provided that surveillance audits are passed successful.

If the certificate holder tends to cancel the right to use the certificate and the logo, if he does not want to continue the expired certificate, or if the certificate is canceled due to financial and other obligations; written approval of the customer is taken. In addition, the customer is requested to send back the original certificate.

In customer audits;
- Whether the CExxxx mark is used only on the products and on the technical documentation and packaging related to the product, whether the CExxxx marking is applied to any product out of the scope,
- Whether the CExxxx mark was struck after certification and before the product entered the market,
- It should be checked whether the certificates are used only when they are valid.

Any situation that does not comply with this procedure in the use of the certificate and CExxxx mark in audits must be reported and the customer should be warned. In addition, the competent authority should be immediately informed about the misuse.

In addition, if a complaint is made regarding the use of certificates and brands, it is submitted to the Objection, Complaint and Dispute Committee and the committee performs its evaluation according to PR.03 Objection, Complaint and Dispute Evaluation Procedure.

In case of deceptive or deceptive use or statements of the logos and documents issued by KAREV, the matter will be referred to the Republic of Turkey of Ankara Courts.

6. RELATED DOCUMENTS

- R10-06 “Conditions Regarding the Use of TURKAK Accreditation Mark by TÜRKAK Accredited Organizations” guide
- PR.03 Objection, Complaint and Dispute Evaluation Procedure
- CE Marking Regulation (Official Gazette dated 23 February 2012 and numbered 28213)
- 93/68/EEC European Union CE Marking Regulation
- (EU) 2017/745 Medical Device Regulation
- *IAF ML 2: 2016 General Principles on the Use of the IAF MLA Mark*

7. REVISION HISTORY

Rev. No	Rev. Date	Rev. Description	Reason for revision
00	-	First publication	-
01	13.03.2023	Turkak accreditation logo added. Items 5.1.1 and 5.1.2 have been added.	Obtaining the Turkak accreditation certificate.