1. OUR TERMS OF SERVICE

As KAREV, we carry out the compliance of management systems with international standards with our independent auditors.

Applications will be made by downloading the FR.20 Management System Application Form from our website www.karevcert.com and sending it to info@karevcert.com.

2. APPLICATION ACCEPTANCE/ REJECTION TERMS

The customer is obliged to complete the application form in full and send the official documents specified in the contract to KAREV. Incomplete or incorrect information detected may cause the application to be rejected. Your application may be rejected due to the fact that the scope applied is not covered by KAREV accreditation and/or there are no auditors/technical experts in the scope or the appropriate audit team cannot be formed.

3. AUDIT PROCESS

Information about certification process processes will be made by KAREV. To apply for certification, you must ensure that your management system fully complies with the relevant standard or criteria requirements and that you operate your management system. For changes in the execution of the quality system such as production, infrastructure, personnel, etc., you must complete it by requesting an FR.21 Change Notification Form from KAREV and notify KAREV within 15 days at the latest.

To ensure the continuity of your systems, we will conduct inspections at appropriate intervals, not longer than a 12-month period. This time may vary depending on the audit results you spend or your organizational structure. For nonconformity to be detected in audits; You need to create your corrective action plans within 15 days and close your corrective activities within 3 months.

KAREV will notify you of the plans and teams for the planned audits before the audit. You reserve the right to object in writing to the audit date and audit team.

During the audit, during your company's normal working hours; you are obliged to allow KAREV authorized personnel to access your workplaces, operations, services, management system, all your records and personnel, and to show at least one of the production processes in practice.

The first certification of conformity assessments is carried out in two stages: Stage 1 and Stage 2.

3.1.Stage 1 Audit

The purpose of this audit is to check whether your company is ready for Stage 2 auditing. In this context, it is evaluated that the necessary systemic and physical infrastructures have been created,

critical processes have been determined and performance criteria and targets have been established for these processes, that the personnel are ready for detailed evaluation, that legal requirements have been met, that the scope of the company is correct, and that the effectiveness of internal audit and management review is evaluated. For the Stage 2 audit, the points to focus on are determined.

3.2.Stage 2 Audit

The purpose of this audit is to check in detail whether the management system and infrastructure requirements established by your company comply with en iso 13485 standard requirements and whether the system created is applied effectively.
All production sites are visited within the scope of audits.

3.3.Surveillance Audit

The purpose of this audit is a detailed check of whether the management system and infrastructure conditions established by the company continue to comply with EN ISO 13485 requirements and whether the company has made applications in parallel with its declaration.

3.4.Unannounced Surveillance Audit

The purpose of unannounced surveillance audit is to address doubts about product safety within the scope of product compliance. Unannounced surveillance audits are carried out in the company's field at least once in 3 years without prior notice to the company. When planning unannounced surveillance audits, it is noted that the time cannot be estimated by the company.

If it cannot find any employees in the organization where it will carry out an unannounced surveillance audit, it registers with the minutes. Then, an unannounced surveillance audit is planned for the same company by the Customer Relations and Audit Planning Responsible. In case of the same situation for the second time, the company's certificate is suspended by the decision of the System Certification Committee.

3.5.Scope Extension Audit

The purpose of these audits is to evaluate the compliance of the quality management system extended by the company for the applied product to EN ISO 13485 standard requirements. All affected parts will be inspected.

3.6.Change Audits

The purpose of this audit is to assess whether the change notification made by the company can be reflected effectively in the quality management system and whether the changed quality management system still complies with EN ISO 13485 standard requirements. All areas that affect the change will be checked.

KAREV will prepare a report after the audits and present its findings in 3 ways;

Major Nonconformity

The following conditions are the main cause of nonconformity;

- Failure to document any article of the Standard or to have examples of application for any substance,
- If there is significant doubt that effective process control has been carried out or that the products/services are complied with the specified characteristics
- If there are many minor improprietys that indicate a systematic deficiency and thus constitute a major nonconformity,
- A significant case of doubt about the customer's ability to realize the intended results of the management system. Major nonconformity may require follow-up audit.

Minor Nonconformity

Although any article of the standard is documented and application examples are available; if any application that affects the management system to reach its intended results is found to be incomplete, the nonconformity detected falls into this class.

Observation

Although any article of the standard is documented and its applications are fully fulfilled, the findings determined for the efficiency and effectiveness of the application based on the sectoral experience of the auditor fall into this class. If it is not implemented until the next audit, it is reported as minor nonconformity.

You will be agreed to pay all agreed fees and expenses related to the audit to the account numbers specified in your contract. Failures with payments may result in the suspension or even withdrawal of certification.

While the KAREV audit team is in your workplaces, we inform you that you are responsible for their health and safety. During the opening meeting during the audit or during the current field trip, you must brief the audit team about the health, safety and emergency evacuation procedures and the potential health and safety hazards they may encounter during their visits and provide appropriate safety equipment and clothing.

3.7.Re-Certification Audit

The purpose of this audit is a detailed check of whether the management system and infrastructure conditions established by the company continue to comply with EN ISO 13485 requirements and whether the company has made applications in parallel with its declaration.

In these audits, none of EN ISO 13485:2016 article can be excluded from the scope.

Before the audit, the Customer Relations and Audit Planning Responsible receives a re-certification application (up to 6 months before the document end date) and a new contract stage is followed. The decision to re-certify must be made before the end of the 3-year certification process. Exceeding this period is only possible for force majeure reasons. Force majeure events are natural disasters, epidemics, revolutions, wars, general strikes and economic crises. When force majeure arises, the maximum period to be given to the customer is 3 months, and if the audit cannot be carried out at the end of the 3-month period, the document expires.

Re-certification auditing is planned and implemented as in the initial certification process. The purpose of the re-certification audit is to confirm that the suitability, effectiveness and relationship and applicability of the management system as a whole is maintained. For this purpose, the re-certification audit includes a field audit to address the following items:

- Internal and external changes, the effectiveness of the management system in its entirety and its sustainable relevance and applicability to the scope of certification,
- Commitment to maintaining the effectiveness and improvement of the management system to improve total performance,
- The state of the work of the documented management system contributes to the realization of the policy and objectives of the organization.

The Stage 1 audit is not mandatory in the re-certification audit and is needed in the following cases:

- In the management system,
- In the customer,
- Within the scope in which the management system works (such as regulatory changes, changes in regulatory documents, etc.)

there are significant changes.

To do this, the customer must notify our organization of such changes. In addition, the customer is asked for the following documents for a preliminary evaluation:

- New or revised system documents of the organization
- Signature circular of the official who signed the contracts
- Copy of the Trade Registry Newspaper
- Activity Certificate

The new document is issued by the report written after the audit and by the certification committee by the decision to re-certify. The new document also specifies the first document editing date. The validity period of this new document is 3 years from the day the decision to re-certify is made.

4. CERTIFICATES

Conformity assessment documents issued by KAREV, certificates are controlled documents of KAREV and changes made to the relevant certificate; in case of withdrawal or cancellation of the document, it must be sent back to KAREV. Unless the relevant documents are withdrawn or cancelled, and the traceability of compliance with the relevant standard is proven, the published documents are valid for a certain period of time. Documents cannot be transferred automatically if the owner, structure, or address of the organization changes. Requests for transfer must be written and will be reviewed on a case-by-case basis for our KAREV authority to decide what kind of activity to take. After the decision, the activities will be communicated to you.

4.1.Suspension of the Certificate

If your company does not fulfill its responsibilities in a technical/administrative sense, your certificate may be suspended. Suspending a document is an interim measure implemented before document cancellation. Your certificate will be suspended if the following conditions occur.

- In case the company undergoes significant changes or suspends its activities (for the demand of the company),
- In case serious nonconformity is detected that will cast doubt on the functioning of the quality management system,
- If the company does not cooperate sufficiently in planning and carrying out the audits,
- In all audits, including unannounced field audits, the company does not give conformity assessment personnel the right to visit all its sites, including critical suppliers, restricts access to documents, prevents them from conducting detailed inquiries, abandons conformity assessment personnel, does not take adequate security measures for conformity assessment personnel, long-term retention of conformity assessment personnel, pressure of conformity assessment personnel, compliance in cases where evaluation personnel are threatened,
- If the root cause and corrective action plan for nonconformities detected as a result of the reviews is not submitted within 10 working days,
- In case of not completing the corrective actions within the given time limit in order to eliminate the nonconformities given as a result of the examinations,
- In case the company resists adapting the changes made to the certification system or KAREV procedures to its system,
- In case of finding that the company has not fully fulfilled the legal requirements,
- In case the company acts contrary to the spirit of the management system in a way that damages the reputation of the certification process,
- In the event that critical changes are not notified to KAREV,
- In cases where the company does not report the vigilance system records, recall decisions, warning cases, findings of the competent authorities, critical after-sales surveillance findings to KAREV,

- In case of differences between the information declared in the Technical Documentation and the application,
- In case the company is unable to maintain its compliance with the legal requirements that are the basis for obtaining certificates,
- In situations that may cast doubt on product safety and pose a potential danger to human health and safety,
- In the event that the company voluntarily requests the suspension of its certificates.

All suspension decisions are taken by the System Certification Committee. The suspension decision taken in the committee is notified to the company in writing. In this article, information is given about the date until which the certificates are suspended and when they will be cancelled if the necessary actions are not taken.

The suspension period for a certificate is 3 months. The company may request additional time by notifying the reasons with a petition. The suspension period can be extended for a maximum of 3 months. The suspension period cannot exceed 6 months. Your company will be informed about the evaluation result.

4.2.Certificate Cancellation

Your company's certificate is suspended before it is cancelled. According to the extent of its nonconformity (cases indicating that the company knowingly violated the standards and regulations under which it received the document) and in the following cases, the certificate may be cancelled directly.

- If the company does not fully meet its financial requirements,
- In case the company repeats the errors caused by the hanger,
- In case the company does not make adequate and effective corrections to the suspended certificate within the suspension process,
- In case of violation of the contractual terms signed by the company with KAREV,
- If the company declares that it will not comply with any requirements,
- If the company voluntarily asks for the cancellation of the certificate,
- In the event that the company goes bankrupt or ceases operations,
- If the company gives false and misleading information,
- If the company does not use the certificate for the scope and address specified on it,
- In case of inspections, it is determined that the suitability of the company management system has been completely lost.

Certificate cancellation is taken by the decision of the System Certification Committee. You will be notified of the committee's decision in writing.

The cancelled certificate holder is obliged to pay its existing debts and costs arising from the cancellation and to stop the use of certificates and logos.

5. LOGO, BRAND AND CERTIFICATE USAGE

Where our logo is granted the right to use, the use of the logo is subject to specified restrictions. No rights can be claimed except for the certificate scope. The use of logos, trademarks, certificates and other rights should not be misused to refer to the certification of the product. Changes in scope are possible, but a field audit may be required.

6. PRIVACY AND ACCESS TO INFORMATION

All information and certificates about you are safely archived by KAREV staff. All information about your certificate will be covered and your application information will remain confidential by KAREV. However, once the certificate is decided, it will be published in www.karevcert.com. We also have the right to publish status changes for the document. Confidential information will not be disclosed without your consent. If such information is requested to be disclosed by the legal authorities, we will notify you.

We ask our auditors and other employees to protect all information about you when starting to work in our company and before coming to your company for audit, to comply with the principle of confidentiality, to declare that there are no interests that may arise from their participation in the audit process.

As KAREV, we would like to inform our employees that we are not responsible for any loss, damages or losses caused directly or indirectly by the person who does not comply with the confidentiality agreement. We will not be responsible for any privacy information known to our employees prior to your certification application or publicly known or disclosed with your consent without our fault.

7. COMPLAINTS AND OBJECTIONS

You may file an objection and complaint against KAREV for work or negligence against any findings or decisions of audit. Such complaints should be made in writing to KAREV. The evaluations obtained as a result of your objection will be notified to you in detail in writing. You can request your complaint/objection by downloading the relevant forms on the website www.karevcert.com or by e-mail from us.

Complaints about you from third parties will also be received. KAREV may review your address for a complaint about your management system. KAREV will not make a decision on any financial loss complaints.

8. OTHER TERMS

The standard terms of the service provided may be revised over time. You will be notified of any significant changes in writing. The standard requirements of the work will be managed and interpreted in accordance with the laws of TURKEY.

9. REVISION HISTORY

Rev. No	Rev. Date	Rev. Description	Reason for revision
00	-	First Publication	-