1. **APPLICATION OWNER ORGANIZATION INFORMATION**

|  |  |
| --- | --- |
| **Company Title** |  |
| **Account Address** |  |
| **Signature Authority** |  |
| **Phone** |  |
| **Fax** |  |
| **Email** |  |
| **Web** |  |
| **Tax Office / Number** |  |
| **Management Representative** |  |
| **Contact Person** |  |
| **Contact Information** |  |
| **If your organization is part of a larger organization; please specify the organization you are part of.** |  |
| **Has your organization previously donated or sponsored the KAREV Foundation?** | [ ]  Yes:..................................[ ]  No |
| **Has your organization had a training from KAREV before?** | [ ]  Yes:..................................[ ]  No |
| ***Number of Total Employees*** |  |
| **Number of Active Employees** |  |
| **Critical Supplier**  | [ ]  Yes [ ]  No |
| **If there are Critical Suppliers; name, address, service received, and the documentation and scopes owned by the supplier.** |
|  |
| **Are there multiple locations?** | [ ]  **Yes** [ ]  **No** |
| **If there are multiple locations; select which processes are in place and type the name and address.** |
| [ ]  Design |  |
| [ ]  Production |  |
| [ ]  Storage |  |
| [ ]  Distribution  |  |
| [ ]  Setup |  |
| [ ]  Service |  |
| [ ]  Sterilization |  |
| **Shift** | [ ] Single Shift. [ ]  Double Shift [ ] Multi Shift |
| **Is there a quality management system that has been taken before?** | [ ]  Yes:..................................[ ]  No |

1. **APPLICATION INFORMATION**

|  |
| --- |
| **Reference Type** |
| [ ]  **New Reference** [ ]  **Re-Certification Changing\*** [ ]  |

**\***For change applications, FR.21 must be filled in with the Change Notification Form.

|  |  |
| --- | --- |
| **Application Scope** |  |
| **Out-of-Scope Items** |  |
| **Control Language** | [ ] Other [ ] English Turkish [ ] : ............. |
| **Sterility Status** | [ ]  Yes [ ]  No  |
| **If sterile, specify the sterilization method.** |  |
| **Is the product placed inside the body?** | [ ]  Yes [ ]  No. |
| **Does the product have a measuring function?** | [ ]  Yes [ ]  No |
| **Product class** | [ ]  Is/Im/Ir [ ]  IIa [ ]  IIb [ ]  III |
| **Is the product reprocessed?** | [ ]  Yes  |
| **Does it contain products?** |
| [ ]  Medical substance (Medicine) | [ ]  Animal tissue |
| [ ]  Human blood/derivatives | [ ]  Micromechanical |
| [ ]  Nanomaterial | [ ]  Other:................... |
| **Is the product absorbed?** | [ ]  Yes [ ]  No |
| **Is there a coating in the product?** | [ ]  Yes [ ]  No |
| **Does it feed on an energy source?** | [ ]  Yes [ ]  No |
| **Is the software available?** | [ ]  Yes [ ]  No |
| **Product Name** |  |
| **Product Use Purpose** |  |

1. **DOCUMENTS/DOCUMENTS REQUESTED IN THE APPLICATION**

|  |
| --- |
| **Docs** |
| Quality Handbook |
| Official documents indicating that the company is registered (Tax Plate, Commercial Register Newspaper, Chamber Activity Certificate, etc.) |
| Authorized Signature Circus to Sign the Contract |
| Official documents showing Number of Employees |
| Document Master List |
| Quality Management System Documentation (Procedures, Instructions, Forms, etc.) |
| Quality Certificates and Contracts of Critical Suppliers |
| Internal Audit Records |
| Management Review Meeting Recordings |
| Validation documents/operating protocols related to processes |
| CE certificates of manufactured medical devices (if applicable) |

1. **GENERAL INFORMATION**
* This application form will be filled out by the person authorized to represent the organization and each page will be paraded.
* Just because this application form has been filled out and KAREV has been submitted does not mean that your organization will be the certified.
* Regulations regarding System Certification are published in the "System Certification" section under the "Our Services" menu on the website [www.karevcert](http://www.karevcert).com.
* Even if the completed application form and attachments are sent by fax or e-mail, the original wet signed form must be delivered to KAREV.
1. **REPRESENTATIONS**
* With the signing of this form, the applicant declares the accuracy of the information specified in the application form and its annexes.
* With the signing of this form, the applicant company undertakes to fulfill the requirements of the approved quality system and to continue it completely and effectively.
* With the signing of this form, the applicant accepts that the terms of the contract and the pricing may change if the change of the information specified in the application form and attachments is determined.
* With the signing of this form, the applicant accepts that the application can be rejected according to the result of the application evaluation activities.
* With the signing of this form, the applicant accepts that the results of the application evaluation activities can be shared with the accreditation body.
* With the signing of this form, the applicant accepts that KAREV can contact the accreditation body using the company's information according to the results of the application evaluation activities.
* With the signing of this form, the applicant company declares that the critical suppliers who are declared to have carried out the production and design processes in its entirety do not carry out these processes to another company completely.
* The organization requesting certification; it acknowledges and undertakes to inform KAREV and the Legal Authority in any situation requiring non-compliance with laws and regulations and reporting, and, if necessary, unannounced inspections can be carried out by KAREV in its facilities and outsourced processes, in which case it will provide all kinds of conveniences.

This application applies to the organization information detailed above. I confirm the accuracy and up-to-dateness of the information.

Company Title:

Organization Official's First and Last Name:

Title:

Date, Signature and Stamp: