# CERTIFICATION RULES & GENERAL CONDITIONS
# (EU 2017/745 Article 16)

## 1. DEFINITIONS

**1.1** Notice Certification, Inspection and Audit Services Incorporated Company referred to as "NOTICE" hereinafter.
**1.2** Personnel performing conformity assessment on behalf of NOTICE on a permanent or contractual basis referred to as "Auditor" hereinafter.
**1.3** M.FR.36.01.a Certification Agreement document mutually signed by NOTICE & customer referred to as "Agreement" hereinafter.
**1.4** Signs and symbols defined in NOTICE Certificate and Use of Logo Procedure (M.PR.21) and described later in this document referred to as "Logos" hereafter.
**1.5** NOTICE and Customer will be referred to as "Parties" hereinafter.
**1.6** Services include application evaluation, document examination, site audit, reporting (certification, surveillance, recertification and follow-up audits in case necessary), and certification provided by NOTICE for Certification purpose will be referred to as "Services" hereinafter.
**1.7** "MDCG" European Commission Medical Device Coordination Group
**1.8** "Quality Management System Certificate" according to EU 2017/745 Medical Device Regulation Quality Management System Certificate according to EU 2017/745 Medical Device Regulation Article 16.

## 2. SERVICES AND AUDITORS

**2.1** Customer assigns NOTICE to provide services by signing the agreement. This agreement is considered complete together with attachments and correspondence if any; Certification Rules & General Terms constitute an integral part.
**2.2** NOTICE will apply necessary technical skills and sufficient attention while providing certification services.
**2.3** NOTICE does not take or accept any additional responsibility or duties regarding any not defined in this document.
**2.4** NOTICE may employ third parties for Services. This situation does not make the third party responsible. To maintain impartiality, it is guaranteed that there is not any conflict of interest or any other conflict between these third parties and the customer, and the third parties have not provided the customer with consultancy services.
**2.5** In case part of conformity assessment activities are subcontracted NOTICE will inform the Customer before starting the certification process.
**2.6** To maintain impartiality while providing services, auditors shall not have any conflict of interest or any other conflict with the customer. Auditors cannot give consultancy services to the customer.
**2.7** Auditors will stay away from any type of pressure (including commercial issues) which will affect the services to be provided.
**2.8** Selection procedures related to Auditors' expertise and duties are guaranteed by their training and experience. NOTICE owns required facilities and infrastructure for providing services in reasonable time.
**2.9** In case a certain part of the services is subcontracted, necessary information is communicated to the customer. NOTICE remains responsible for the subcontracted service.
**2.10** The customer is responsible for providing auditors' protection and necessary personal protective equipment.

## 3. CUSTOMER'S LIABILITIES

**3.1** The customer shall give NOTICE documents related to service places, facilities and activities covered by NOTICE's service scope. All changes occurring in this regard shall be communicated to NOTICE in written.
**3.2** The customer sends NOTICE the related documentation and give them access for document examination.
**3.3** The customer allows auditors to enter facilities, access system and records as agreed in different stages of services.
**3.4** The customer will not conceal from NOTICE any information related to the services.
**3.5** Within the framework of the relevant Common Specification, Standard, Regulations and other documents published or accepted by MDCG, the customer; Responsible for the operation of the management system.
**3.6** As part of the management system certification, the customer is responsible for appointing a personnel to ensure the implementation and continuity of the established system, allowing access to all necessary areas for auditors during working hours, and ensuring compliance with any existing legal requirements or specific requests, in addition to the management system standard related to the scope of the document.
**3.7** Auditors in the training process, observers or guides can accompany NOTICE in the audits or unplanned visits carried out in the customer's site. Observer may be there to observe a member of audit/ inspection team, may be an authorized person of customer, accreditation body or the related ministry. Guides are individuals accompanying the audit team for assistance. A guide may be assigned to each member of the audit team. Guide's responsibilities may include making communications, arranging meetings, organizing site audit, having site safety regulations applied, witnessing the audit on behalf of the customer, or providing the information requested by the auditor.
The client and the auditors are informed about the participation of the auditors, guides and observers in the audit during the training process and the client's approval is obtained. The guides or observers do not intervene in the audit. The auditors in the training process may ask questions to the Client under the supervision of the auditor in the audit team.
**3.8** The customer is obliged to declare any kind of verbal or written information to NOTICE personnel, TURKAK representatives or authorities of Ministry of Health of Turkey regarding audit activities while necessary.
**3.9** The customer shall inform NOTICE within duration specified in the Certification Agreement of changes in management system the company's system, or products in the certificate scope after certification and changes affecting system's structure (address(es), scope, number of workers, number of branches, address of branch(es), etc.)
**3.10** The customer shall maintain all the records related to the activities carried out by NOTICE (agreement, report, QMS records, etc.) for the certificate validity period. If the periods given for the storage of the relevant standard or regulation/regulation documents and records are longer, this period is valid.
**3.11** The customer shall make all the necessary documents for the application available to NOTICE before the audit.
**3.12** NOTICE may carry out additional audits for a fee to assess the impact of the changes made on the system. The client must carry out any significant changes that may occur in the NOTICE documentation system (standard procedures or rules) within the transition period notified to the client.
**3.13** The customer is obliged to record any objections or complaints received from their own customers or third parties within the scope of the document provided and to report them to NOTICE inspectors during the audit. They must inform NOTICE together with the Competent Authority regarding any adverse event notifications and work carried out.
**3.14** The customer shall comply with and follow the update status of documents such as Certificate and Use of Logo Procedure, Certification procedure, Certification regulations and General Condition, etc. Issued at www.notice.com.tr , related directives, standards and all the other legislations.
**3.15** The customer is required to pay the fees defined in the service agreement or the fees of specific audits of related standards or directives/ regulations or follow-up audits.
**3.16** Upon suspension, withdrawal and cancellation of the certificate, the customer is required to stop the use of certificate and any advertisement material referring to the certificate and shall sends the certificate back to NOTICE in case of withdrawal or cancellation.
**3.17** The customer shall comply with national legislation, regulations, standards/common specifications, MDCG documents and MDCG-adopted guidance documents.
**3.18** After the certification audits, the customer shall inform NOTICE of any changes occurring to internal and external processes.
**3.19** Customers file the complaints as described in M.PR.24 Objections and Compliant Evaluation Procedure issued at www.notice.com.tr and in case does not accept the Objection Committee's decision, can apply to the related legal authority (TURKAK or Ministry of Health of Turkey). In case NOTICE exceeds the time for resolving the complaint, the customer can apply to the related legal authority in the same way. The customer can object to the decision made by NOTICE within one month.
**3.20** The customer shall fulfill the general health & safety requirements or other statuary requirements stipulated in 2017/745 Medical Device Regulation.
**3.21** The customer can use the certificate for the address and scope written on the certificate. In case of violation, the customer accepts the consequences.

**3.22** If the customer provides copies of certification documents (documents, reports, etc.) to others, he/she is obliged to ensure that the documents are reproduced without compromising their integrity.
**3.23** The Customer acknowledges that NOTICE will in no way provide consultancy services to the company in the context of or in relation to conformity assessment and does not make any requests in this respect.

## 4. NOTICE'S RESPONSIBILITIES

**4.1** NOTICE and all its employees; keep confidential all written and verbal information received from companies and related parties regarding certification and inspection activities, and only share it with TÜRKAK, which accredits and authorizes NOTICE according to the contracts it has signed, the Ministry of Health of the Republic of Turkey or the competent authorities of medical devices in EU member states and the EU Commission upon request, and if not prohibited by law. Sharing with other third parties is only possible with a court order. When NOTICE has to provide information to third parties due to a court order, it must inform the relevant customer.
**4.2** NOTICE retains its personnel under the control of Impartiality and Confidentiality as a requirement of impartiality and confidentiality and the accredited standards.
**4.3** NOTICE Certification has "Professional Liability Insurance" against risks that may cause or result in damage within the scope of inspection activities, and the scope and limits regarding its liability are specified in this insurance. NOTICE has taken the necessary precautions for all situations not covered by the insurance and provides assurance to all its customers for situations not covered by the insurance. NOTICE has no liability in the event that the issued documents are not recognized by third parties.
**4.4** NOTICE will inform its certified customers of significant changes in certification system (standard procedures, regulations) in the shortest time and announces the need to make the necessary modifications. Website, email, etc. can be used for this purpose.
**4.5** NOTICE has the right to make changes in procedures prepared related to services and the pricings. However, conditions before the change remain valid and the date of the document change is considered as base. NOTICE is obliged to announce the changes in the documents referenced for its services to all companies that have been documented and applied via web page, fax or e-mail. If the changes are in favor of the previous customers, the change is applied to cover the previous customers.
**4.6** NOTICE is responsible for publishing and updating the documented, document suspended and document cancelled customers on the website and/or EUDAMED.
**4.7** In case NOTICE decides to terminate its accreditation activities or related authorities decide so, the companies certified by NOTICE will be left to the supervision of a certification body accredited by an IAF member.
**4.8** In case NOTICE decides to terminate its notified body activities or related authorities decide so, NOTICE will transfer the company's file to a Notified Body defined by the company. In this situation, the requirements of the other notified body are liable, and NOTICE does not have any right to interfere the requirements.
**4.9** NOTICE undertakes to comply with the standards/common specifications, MDCG documents, MDCG-accepted guides, regulations, Türkak Guide Documents, Türkak Accreditation Agreement Conditions, IAF Guides and European Union Commission documents regarding the scope of certification, except for the conditions stated above.

## 5. CERTIFICATION ACTIVITIES

**5.1** Certification activities are initiated after the agreement regarding the service provided by the Customer is signed by the parties.
**5.2 Initial Certification;**
**5.2.1** The following processes are carried out for the initial certification of EU 2017/745 MDR Article 16, EU Quality Management System Assessment;

- Application review
- Onsite Quality Management System Audit
- Documentation evaluation
- Confirmation of assessment nonconformities, if any
- Final review and certification decision

**5.3.2** **5.4**

**5.3 Surveillance;**
**5.3.1** For customers whose EU 2017/745 MDR Article 16, EU Quality Management System certification has been completed, a surveillance audit is performed once in 12 months after the certification decision is taken, during the validity of the certificate. 1. (First) Surveillance audit shall be carried out within 12 months from the date of certification decision; if this is not carried out, the certificate of the company shall be suspended as of the date when the 12-month period expires. 2. (Second) Postponement requests from organizations for surveillance audits may be evaluated by NOTICE, provided that a justified reason is stated, and postponements may be granted for temporary situations (such as Fairs, Conferences, Business Trips, Heavy Workload, Temporary Health Problems, Temporary Stoppage of Production and Service) for a maximum of three months. Postponement requests are received in writing (e-mail or fax). 2. Surveillance is carried out for one calendar year. If it cannot be carried out, the document is suspended.

**5.4 Recertification;**

Certification renewal audits are audits conducted to re-certify the customer's quality management system and/or product conformity documents before the expiry of the certificate's validity period (3 years for system certification). This certification includes the principles in the initial certification.

**5.5 Unannounced Site Audits;**
These are inspections carried out within the scope of the Quality Management System to eliminate doubts about system security and within the scope of the EU 2017/745 Medical Device Regulation and without informing the customer.
If a complaint is detected that threatens product safety (limited to storage, shipment, label and user manual information), unannounced field inspections are carried out at the customer's facilities where the conformity assessment has been completed.
NOTICE may perform tests to verify the conformity of devices with the specifications in the approved technical documentation by taking a sufficient amount of samples from devices that have been released for sale or devices in the production line and/or devices that have been sold to the market during unannounced field inspections.

**5.6 Change Audits;**

**5.6.1 Changes by Customer;**
These are the audits carried out to control changes such as Change of Customer Title, Change of Customer Activity Scope, Change of Customer Address and Branches. If the official status of the customer (address, title, etc.) has changed before the change audits, the service agreement is renewed.
Change requests are received from the companies in written with the M.FR.08.15 OK/BK Change Notification Form. NOTICE can evaluate these changes with an on-site audit. If a document revision or additional document is required as a result of the change, the current document validity period does not change. If an additional document is given, the validity period of this document will be the same as the current document.
**5.6.2 Changes due to NOTICE**; NOTICE informs its customers about changes in certification requirements and related processes (restriction of scope, change in standards/regulations, changes in practices in its own system, etc.) via e-mail and publishes it on www.notice.com.tr.
Depending on the status of the change, NOTICE can conduct an audit at the customer's site. In case the Client does not accept the audit, it initiates the transfer process to another Certification Body determined by the Client. The customer's certificate remains valid during the period given to the customer for the transfer.

**5.7 Follow-up Audits;**
It can verify the nonconformities determined as a result of an evaluation made by NOTICE by performing an on-site audit at the customer's facility and/or its subcontractor and/or supplier's facility. The follow-up audit is carried out within the periods mutually agreed after the audit for the first certification audits. If the follow-up audit cannot be performed within this period (if no additional time is requested) and/or the non-conformities are not closed, the application of the customer is cancelled.

For other audits, the process is proceeded in the same way. Follow-up audit date is defined according to the time given to other audits.

**5.8 Audit Findings;** Following the audits/assessments carried out by NOTICE personnel, the findings are communicated to the customer through assessment/audit report. In case of negative findings (not fulfillment of standard/common specifications, regulations, MDCG documents and other documents accepted by MDCG requirements for the customer's service/ service scope), the findings are recorded in M.FR.08.01 Nonconformity and Follow-up Report and the customer is informed.

Negative findings are defined as follows:
**Major (Major) nonconformity:** Compliance with the requirements of the EU 2017/745 Medical Device Regulation, product-related standard/common specifications, regulations, MDCG documents and other documents accepted by MDCG, which may affect the continued implementation of the overall Quality Management System, or it is the situation where any of the standard articles or sub-headings that adversely affect the service or device it provides to be met under the desired conditions are not adequately defined and/or systematically applied.
**Minor (Small) nonconformity:** Unsystematic deviations, which do not affect the overall system, from quality management system standard requirements, EU 2017/745 Medical Device Regulation, product-related standard/common specifications, regulations, MDCG documents and other documents accepted by MDCG and/or customer's documentation requirements. Nonconformities that do not affect the ability of the management system to achieve desired results.

**5.9 Final Review and Certification decision;**

Auditors who evaluate the customer's quality management system only make recommendations regarding whether or not to issue quality management system compliance documents within the scope of the contract(s) signed by the customer. The decision whether to issue the document(s) is made as a result of the final review and decision evaluation made by NOTICE.

If, as a result of the evaluation, a decision is taken not to grant certification, to limit the certification or to grant it for a period of less than 3 years, the reason is notified to the customer in writing.
As a result of the evaluation, the final review and decision team may request additional documents or additional audit activities if it deems necessary before taking the certification decision.

**5.10 Certificate Issue;** The customer's certificate will be issued according to the information in audit/assessment report, after NOTICE the final review and decision team evaluates the customers' quality management system requirements, implementation of relevant standards and/or fulfillment of directive's requirements. Certificates are granted in the form of 1 Turkish and 1 English original copy. Requested additional copies will be charged. The certificate will be issued on www.notice.com.tr and will be accessible after the related fields are filled in the site. The information published in this area is public and is not confidential, it contains the following information.
- Organization Name
- Information on city, country of the organization addresses within the scope of certification
- Certificate scope
- Certificate status (Active, Cancelled, Suspended)

The organization may wish to have the above information limited due to security reasons or to the fact that it is confidential information. However, this limitation must be communicated to NOTICE by the applicant organization in written, stating the reasons and signed by the authorized person prior to the publication of the certificate. NOTICE will not accept liability for material or non-material damages if notification is not made. This limitation request does not restrict the certificate notification to EUDAMED.

**5.11 Suspension, Reduction in Scope and Withdrawal of Documents;** Suspension of all or part of the scope of certificates is an interim measure applied prior to certificate withdrawal. The suspension period is 4 months in case additional time is requested with justified reasons, the period can be extended for maximum 2 months. The suspension period of certificates cannot exceed 6 months.
In case customer seriously fails to fulfill certification requirements, partially or entirely, NOTICE reduces the customer's certificate scope so that the unfulfilled requirement's part will be excluded.
NOTICE informs the customer of suspension of the certificate together with the justification in written on its letterhead paper within 5 business days.

Once the reasons for suspension are successfully eliminated or in the case of certificates suspended upon customer's request, after the related *activity for lifting the suspension, depending on the suspension reason is carried out, the customer is informed of the continuation of the certificate and takes back all its right on that. Throughout the suspension period, the customer can keep the certificate, however, cannot benefit the rights.
Information regarding the suspension, narrowing of the scope or removal of the certificate is entered into EUDAMED by NOTICE. This information is publicly available.

NOTICE has the right to withdraw the Customer's certificates in case of suspension conditions. Certificates are suspended before withdrawal,
NOTICE may directly withdraw the certificate depending on the extent of nonconformity detected during the evaluations (situations showing that the customer knowingly violated the standards and regulatory principles for which the certificate was obtained) and in cases specified in the contract.
Other than these situations, customers themselves can request the certificate withdrawal. Withdrawal request is taken in written. The request is evaluated by NOTICE and the customer is informed following its approval.

NOTICE informs customers in written of certificate cancellation together with the justifications. The customer sends the original certificate(s) to NOTICE upon withdrawal.
Following informing the customer of the certificate withdrawal, the customer immediately stops the use of NOTICE and accreditation body (TURKAK)'s logo, CE mark and other phrases representing its certification. This is applied to advertisement, logos and marking used in the plants as well.

The certificate status is changed to cancelled on www.notice.com.tr web site. Customer who decide to retrieve the withdrawn certificate shall start over the application process. NOTICE informs customers of certificate suspension, scope reduction and withdrawal in written. NOTICE has the right to publicly release the necessary information about certificate suspension, scope reduction and withdrawal. Customers' can make objection to certificate suspension, scope reduction and withdrawal. NOTICE notifies the accreditation body and Competent Authorities of suspended and withdrawn certificates and those with reduced scope. Besides, suspended, withdrawn and certificates with reduced scope are announced at www.notice.com.tr.

In case of suspension or cancellation of the certificate, the customer has the right to appeal according to Article 8.

**5.12 Certificate and Use of Logo;**

Customer is entitled to use NOTICE's logos according to M.PR.21Certificate and Use of Logo Procedure, relevant IAF and EA regulations upon successful termination of audit activities and certification result.
According to the agreement made with the customer, the customer entitled to use the logo of the accreditation body from which NOTICE has got its authority, can use NOTICE's logo together with the accreditation body logo provided that the customer complies with accreditation body rules. Once the agreement is terminated, the customer is obliged to stop the use of the logos.

## 6. PAYMENTS

Fees defined in the agreement are paid to one of the NOTICE's accounts according to the conditions defined in "Fees" clause of the agreement. The transfer costs incurred during payment and any reductions arising from the similar matters are not accepted. In all audits, the audit team's travel, accommodation, etc. expenses are covered by the company separately.

**7. CANCELLATION OF THE AGREEMENT**

This document and the agreement become invalid in case the parties are informed in written at least one month in advance. NOTICE has the right to cancel the agreements if the information provided by the customer during application is proved to be misleading and wrong or the logos are proved to be used improperly. If the customer requests cancellation of the agreement, they will be charged for the services provided up to that point. Contract cancellations that occur after the contract has been signed will be considered as cancellation or withdrawal of the application and will be reported to the competent authority and to the EU Commission via EUDAMED as a rejection/withdrawal of the application. This information will be available to the competent authorities of the member states and other approved bodies via EUDAMED.

**8. APPEALS**

The customer has the right to file appeal to NOTICE for any kind of unresolved problem related to the received services from NOTICE. Customer's appeals are evaluated according to M.PR.24 Appeals & Complaints Evaluation Procedure.

**9. DOCUMENTS**

The updated versions of all the procedures and instructions referred to in this document are accessible at www.notice.com.tr.