CERTIFICATION RULES & GENERAL CONDITIONS

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.23.01 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 "Product Conformity Certificate" according to EU 2017/745 Medical Device Regulation Annex IX, EU Quality Management System Certificate, EU Technical Documentation Assessment Certificate and according to EU 2017/745 Medical Device Regulation Annex XI, Part A, article 10, EU Quality Assurance Certificate.

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 manufacturing, 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. Quality management system documents and technical documentation documents created within the scope of the EU 2017/745 Medical Device Regulation must be delivered on the date declared in the M.FR.07.01 Application Form. If a justified reason is presented after the declared date, the delivery of the documentation can be postponed for a maximum of 365 days. Otherwise, the pre-application evaluation process returns to the beginning.
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 In the framework of relevant common specification, standard, regulations and other documents published or accepted by MDCG, the customer is obliged to comply with any kind of written or verbal information and instruction taken from NOTICE for operation of the management system, product conformity assessment, inspection and testing services.
3.6 The customer whose management system or the product related to the management system is certified shall assign one of the personnel for ensuring the implementation and continuity of the established system, provide auditors' access to all the required areas in working hours, guarantee the provision of all national legislations or special requirements apart from the management system standard.
3.7 Auditors in the training process, observers or guides can accompany NOTICE in the inspections, 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. Any member of the audit team can be assigned as guide. 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 customer and auditors are informed of participation of auditors in the training process, guide and observers prior the audit and customer's approval are taken. Guides and observers cannot interfere the audit.
Auditors in the training process, on the other hand, can ask questions to the Customer 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 or inspection activities while necessary.
3.9 The customer shall inform NOTICE within duration specified in the Certification Agreement of changes in management system or the certified product related to the 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 as well as the product in the certificate scope for its shelf life. 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 inspection and audit.
3.12 NOTICE can carry out inspections or audits in order to evaluate the effect of the applied changes on the system or product.
The customer shall apply the changes occurred to NOTICE inspection and certification system (standard procedure or regulations) in the defined period.
3.13 In the scope of the certificate the customer shall record the complaints received from its customers or third parties and shall inform NOTICE of the complaints during the audit. The customer shall inform NOTICE and the Competent Authority of any adverse event and the performed actions in that regard.
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. Companies willing to receive product conformity certificate, are required to comply with all requirements defined in the directive and CE marking requirements.
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 and national legislations for product(s) design and production and the conformity assessment requirements according to 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 In case of providing others with copies of certification documents (certificate, report, etc.) the customer shall replicate the documents as whole.

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 personnel will keep confidential any kind of verbal and written information received from the companies in relation with certification and inspection activities, this information is shared only upon request of TURKAK, Ministry of Health of Turkey or the competent authorities of medical devices in EU member states and EU Commission. For other third parties, the information will be shared only on court decision. In this case, the customer will be certainly informed.

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 For the risks in the scope of certification and inspection which may cause loss or harm, NOTICE owns "Professional Liability Insurance" in which limits and scope are defined. NOTICE has taken the necessary precautions for all the situations not covered by insurance and provides assurance to all customers regarding such conditions. In case the certificates are not identified by third parties, no responsibility lies with NOTICE.

4.4 NOTICE will inform its certified customers of significant changes in certification and inspection 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 shall announce document changes to certified and applicant companies through website, fax, or email. In case the occurred changes will cause a situation in favor of the previous customers, it will be applied in a way to cover them as well.

4.6 NOTICE is responsible for issuing and updating certified, suspended, and withdrawn customers on the website.

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 Other than the above-mentioned situations, NOTICE undertakes to comply with standards, directives, TURKAK guidelines, IAF guidelines and EU commission documents for certification and inspections.

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 ISO 13485 Medical Devices Quality Management System includes the following processes for initial certification;

- Stage 1 on-site audit
- Stage 2 on-site audit
- Verification of audit nonconformities, if any
- Certification Decision

5.2.2 The following processes are carried out for the initial certification of EU 2017/745 MDR, EU Quality Management System, EU Quality Assurance and EU Technical Documentation Assessment;

- Application review
- Stage 1 on-site audit if necessary
- Clinical evaluation asssessment (for class IIa, class IIb and class III devices)
- Technical documentation evaluation on post-sales surveillance
  - Evaluation of device technical documentation
  - Onsite Quality Management System Audit
  - SSCP (Summary of Safety and Clinical Performance) validation (for class III and implantable devices only)
  - PSUR (Periodic Safety Update Report) (for Class IIa, Class IIb and Class III devices)
  - Confirmation of assessment nonconformities, if any
  - Final review and certification decision

5.3 5.3 Surveillance;

For customers whose ISO 13485 Medical Devices 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 is carried out within 12 months from the date of certification decision. 2. (second) Postponement requests from organizations for surveillance audit are evaluated by NOTICE, provided that the justified reason is stated, for temporary situations (such as Fair, Conference, Business Trip, Intensive Workload, Temporary Health Problems, Temporary Stopping of Production and Service) can be postponed for a maximum of three months. Postponement request is received in written (e-mail or fax). 2. Audit is carried out for one calendar year. If not, the certificate is suspended. 5.3.1 For customers whose certification of EU 2017/745 MDR, EU Quality Management System, EU Quality Assurance and EU Technical Documentation Assessment has been completed, surveillance audit every 12 months after the certification decision is made If it cannot be performed, the document is suspended.

5.4 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, maximum 5 years for product conformity certificates). This certification includes the principles in the initial certification.

5.5 Short Notice Audits;

In the case of complaints containing objective evidence against the customer, NOTICE may decide to conduct an extraordinary audit by contacting the customer, even though it is not in the audit program. Short notice audits are notified before a period of time (this period is not longer than 1 day) that will not allow the customer to change the current situation, and the audit is carried out.

5.6 Unannounced Site Audits;

These are the audits performed mandatory within the scope of EU 2017/745 Medical Device Regulation and carried out without informing the customer.

Unannounced site audits are carried out at least once during the validity of the certificate (at least once every 5 years, at least once every 3 years for class III and implantable devices). NOTICE may increase the frequency of these inspections according to the number and nature of the nonconformities that arise in the conformity assessment activities it carries out, the frequency and nature of the complaints about the device, or the vigilance events related to the device. During unannounced site audits, NOTICE performs tests to verify the conformity of the device with the specifications in the approved technical documentation and the approved design, by taking sufficient samples from the devices released for sale or the devices on the production line and/or the devices that have been sold to the market.

5.7 Change Audits;

5.7.1 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.

5.7.2 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.

5.8 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.

5.9 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.

5.10 Final Review and Certification decision; The auditors who perform the assessment of the customer's quality management system and/or devices only advise on whether to issue the quality management system and/or product conformity certificates under 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.
In case the certificate is decided not to be granted, to limit the use of the certificate for product conformity certificates, or to grant it for a period of less than 5 years, the justifications are communicated to the customer in written.
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.

5.11 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 and/or product technical documentation and/or product technical documentation, 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 (1 copy 100€ + KDV). 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)
- Information on the assessment standard /regulation

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.

5.12 Certificate suspension and withdrawal; Suspending certificate's entire scope or a part thereof is an intermediate precaution before withdrawing the certificate. Certificate suspension period cannot exceed 6 months.
NOTICE retains the right to suspend certificates in the following conditions:

- The Company enters significant changes or pauses the activities (on customer's request)
- The existence of nonconformities which impairs The Company's management system
- Surveillance audits could not be planned
- Corrective actions for rectifying the nonconformities have not been finished within 60 working days
- The customer resists adapting its management system to changes in certification system or NOTICE procedures.
- Incorrect representation of certification process, misuse or abuse of logo, certificate and related documents
- The customer acts contrary to management system principles and undermines certification process integrity
- The customer acts contrary to NOTICE's service agreement and the regulations mentioned in this document
- The Customer does not fulfill its financial liabilities towards NOTICE
- Major and minor nonconformities are identified after the Certification audit and have not been closed
- The customer cannot maintain compliance to the legal requirements essential for the certificate
- The customer has been involved in accidents or events (e.g.: events threatening public health) as a result of violating the principles of the base standard for the certificate and not being able to maintain compliance to it.
- Upon customer's request
- In case of sanctions placed on the company's origin country on the related sector (Health, medical device) by United Nations, European Commission and the United States

In case customer seriously fails to fulfill certification requirements, partially or entirely, NOTICE reduces the customer's certificate scope so that the unfulfilled requirements part will be excluded.
In all the situations not needing technical evaluation like not accepting surveillance audit, not fulfilling financial liabilities not timely closing of nonconformities certificate will be suspended directly without need to certification decision committee meeting. In all the other cases suspension decision is taken by certification committee.
NOTICE informs the customer of suspension of the certificate together with the justification in written on its letterhead paper.
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.
* If the suspension process is initiated upon the customer's request, correct understanding of the suspension reasons is important to start correcting processes after customer's request to lift the suspension. The removal of the suspension reasons declared by the customer shall be verified before the suspension is revoked. For instance, in case the certificate is suspended upon customer's request due to the address change and later the customer requests the suspension to be revoked, address change audit shall be conducted and once the fulfillment of

conditions have been verified, the suspension shall be lifted. Another issue is the possibility of suspension requests due to financial reasons.

When a request for lifting, the suspension is received after the financial problems are resolved, the certification cycle status is controlled. If the surveillance audit has just been carried out in the company before suspension request is placed, and the suspension revocation is requested before the next surveillance/certification audit, a no change declaration regarding the company's address and certificate scope is taken and in case it is verified, necessary procedure (address change, scope extension, etc.) is followed and the certificate suspension is lifted until the next audit date.

In case the decision to suspend the certificate partially or as a whole, the status of the certificate is marked as suspended in www.notice.om.tr Once the suspension conditions are removed the certificate status is marked as active in the web site.

In case the customer cannot eliminate the suspension reasons in 4 months, the certificate will be withdrawn.

NOTICE has the right to withdraw the customer's certificate in case the above-mentioned situations occur. Before withdrawal, certificates are suspended. Certificates may be directly withdrawn according to the magnitude of nonconformities (situations in which the customer violates the principles of the certificate's base standard and directive) and in the following situations:

- The customer goes bankrupt or ceases the activities
- The customer does not use the certificate for the address and scope defined on the certificate
- The customer presents false and misleading information during the audit
- The audits prove that the customer's management system is totally ineligible
- The customer tampers with the certificate and the annexes

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.

5.13 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. All the travel, accommodation
costs, etc. of the audit team are also borne by the company. For devices incorporating medicinal substances, absorbable devices, the costs of the assessment of the authority consulted are borne by the customer. In case the EU Commission's Expert Committee and Expert Laboratories are consulted for scientific, technical and clinical opinions and recommendations regarding the devices within the scope of the agreement and the EU Commission requests a fee for this consultation, the fee will be paid by the customer.

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, he will be charged for the services provided up to that point. Agreement cancellation cases that occur after the signing of the agreement will be considered as cancellation or withdrawal of the application and will be notified to the competent authority and the EU Commission as a rejection/withdrawal of the application. Through EUDAMED, this information will be made available to the competent authorities of the member states and other notified bodies.

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.