In this text,

- The word “SZUTEST” shall refer to SZUTEST Uygunluk Değerlendirme Anonim Şirketi;
- The word “Agreement” shall refer to one of the following agreements; 93/42/EEC Product Conformity and ISO 13485 Assessment Agreement, 93/42/EEC Product Conformity Assessment or ISO 13485 Quality Management System Assessment Agreement issued by SZUTEST;
- The word “Company” shall refer to the company that has executed agreement with SZUTEST.

General Terms for Medical Devices constitutes an inseparable part of agreements and SZUTEST is entitled to update this document when it considers necessary. If the General Terms for Medical Devices is updated and there occurs any difference with the provisions of the agreement previously executed, the provisions of this document shall prevail and the company shall be obliged to comply with the provisions that are replaced. The customers shall be informed whenever this document is amended. General Terms for Medical Devices shall be available at www.szutest.com.tr.

The General Terms for Medical Devices defines the product conformity and ISO 13485 assessment activities and the rules to be observed by the company and SZUTEST hereunder and also contains a summary of the assessment processes.

1. Assessment Process

1.1. Application Review and Agreement Process

1.1.1. Applications for product conformity and ISO 13485 assessment concerning Medical Devices shall be filed in writing along with an application form. Verbal applications shall not be accepted. The company must fill in and sign the application forms completely. The documents required in the application form must be delivered to SZUTEST along with this form. The company declares that the information it has provided is correct and complete and agrees that any discrepancy may lead to variations in the terms and conditions of the agreement or termination of the agreement by signing the application form.

1.1.2. SZUTEST shall initiate the application assessment process upon receiving the application documents. It may demand the company to provide additional documents other than those specified in the application form during this process. SZUTEST may consult to the Competent Authority during the process of application assessment.

1.1.3. SZUTEST may contact the previous Notified Body or Certification Body of the company or demand the company to provide the reports and documents issued by that notified body or certification body for transfer applications.

1.1.4. The application assessment may result positively or negatively. In case it is negative, the company shall be duly informed.

1.1.5. In case the application assessment results positively, an agreement shall be signed with the company.

1.1.6. Upon the signature of the agreement, the company must perform the financial obligations provided in the agreement and deliver all the documentation including specifically the Technical File, Design dossier and quality management system documentation to SZUTEST within maximum 10 business days.

1.1.7. As for transfer applications, SZUTEST may demand the company and the previous notified body to execute a transfer agreement with no financial value.

1.1.8. SZUTEST may contact the previous notified body or certification body of the company for transfer applications and reject the application of the company according to the information given. If it is not possible to receive information from the previous notified body or certification body, SZUTEST may evaluate the application as a new application or else reject it.

1.1.9. After the agreement is executed, the documentation delivered by the company shall be reviewed and missing documents, if any, shall be determined and notified to the company. The company must deliver the missing documents within maximum 10 business days. In the event that the documentation demanded is not provided by the company following the execution of the agreement, SZUTEST may cancel the agreement.

1.1.10. The previously certified customers must notify the changes in the legal status of company, notification address, quality management system and in the products covered by the agreement, if any, by means of the change notification form and application form, if applicable. SZUTEST shall review the notifications of changes and determine the actions necessary to be taken and approve or reject the change subsequently. The change may require updating the agreements or collecting additional charges.

1.1.11. In case of conflict during the applications, the company shall be demanded to provide additional information and an application shall be filed to Turkish Ministry of Health, the Competent Authority, for resolution of the dispute. The costs arising from the application shall be paid by the company.

1.1.12. The application file for products with drug components shall be sent to Turkish Ministry of Health, the competent authority. The costs arising from the review of the competent authority shall be covered by the company. The company may not hold SZUTEST for delays arising from the review conducted by the competent authority.

1.1.13. Re-assessment applications shall be filed, agreements shall be signed and the requirements of the agreements shall be fulfilled at least 6 months earlier than the expiry date of the certificates, If the application date is less than 6 months before the expiry date SZUTEST may refuse the application after the evaluation of the application however if such application is accepted the Company shall accept the deadline limitations for the non-conformity corrections found during the re-assessment.

1.1.14. Supplementary documents to be provided during the applications and other technical documentation shall only be provided in digital form and files shall only be sent to e mail addresses using SZUTEST domain. Only controlled copies of documents shall be shared with SZUTEST.

2. Audits

2.1. Audits in the scope of 93/42/EEC are one of the conformity assessment processes used for assessment of conformity with 93/42/EEC directive by evaluating the quality management system. During the audits the EN ISO 13485 Annex-ZB, the rules defined in EN ISO/IEC 17011 and 93/42/EEC shall be taken into the consideration.

2.2. Audits in the scope of ISO 13485 used for the assessment of the quality management system implemented by the company against related standard and the company’s own rules for certain applied scope.

2.3. Audits shall be performed according to SZUTEST procedures. Sampling method shall be used for audits.

2.4. Any nonconformity revealed in the audits shall be recorded by means of FR.MED.52 Finding Report. As part of the audits, the technical files and design dossiers prepared in line with 93/42/EEC directive may be reviewed.

2.5. If any nonconformity revealed in audits requires follow-up audit, this might be performed only if the corrective and preventive actions submitted by the company to SZUTEST are found effective.

2.6. The audits may cover the critical sites and critical suppliers of the company. SZUTEST shall determine which sites shall be audited.

2.6.1. Under normal conditions, the period granted for correcting Stage 1 nonconformities shall be maximum 5 months and it shall be 4 months for other audits. If the company requests the relevant period to be extended with justifiable reasons, SZUTEST may determine to extend the relevant period. It should be noted that the maximum extension period to be granted might be until 2 months before the next surveillance audit.

2.7. Stage 1 Audits

2.7.1. Stage 1 audits shall be performed during the initial assessment application. The purpose of those audits is to check whether or not the company is ready for 93/42/EEC and ISO 13485 stage 2 audit.

2.7.2. Stage 1 audits may be performed on site or off-site. SZUTEST shall determine which audits shall be performed on site and which ones shall be performed off-site according to the rules defined in the procedures. SZUTEST audit team may demand the company to ensure conference call and provide video, images, etc. documents during the audits to be performed off-site.

2.7.3. If minor nonconformities are detected during stage 1 audits, those nonconformities shall be checked during stage 2 audits.

2.7.4. If major nonconformities are detected during stage 1 audits, the company must correct those nonconformities and provide the evidence documentation to SZUTEST. If the nonconformities that are detected are corrected to a great extent and the remaining nonconformities do not obstruct the performance of stage 2 audits, SZUTEST shall inform the company of the remaining nonconformities and they shall be checked during stage 2 audits.

2.8. Stage 2 Audits

2.8.1. These audits shall be performed after stage 1 audits during the initial assessment applications. During the audits, a detailed assessment shall be performed to determine if the quality management system that is established and implemented as well as the infrastructure conditions comply with the requirements provided in 93/42/EEC and ISO 13485.

2.8.2. The company must deliver to SZUTEST the corrective and preventive actions for all nonconformities determined during stage 2 audits.

2.8.3. For ISO 13485 assessments the time between stage 1 audit and stage 2 audit cannot be more than 6 months. In other case stage 1 audit shall be renewed.

2.8.4. If the company cannot provide evidences for closure of major findings of stage 2 audit in 6 months the stage 2 audit shall be renewed.

2.9. Surveillance Audits

2.9.1. The purpose of this audit is to perform a detailed review in order to determine whether the management systems and infrastructure conditions provided by the company for the product or service continue to conform to the requirements of 93/42/EEC directive and ISO 13485 standard as well as the effectiveness of post market surveillance, clinical follow-up and vigilance systems created by the company for the continuation of the product and service safety and performance and availability of parallel implementations as declared by the company.

2.9.2. Some of the sections may be left outside the scope during surveillance audits but SZUTEST must have assessed all the relevant points that are required to be assessed in a certification cycle which is 5 years for 93/42/EEC and 3 years for ISO 13485.

2.9.3. Surveillance audits must be performed minimum once a year however first surveillance audit must be completed within 12 months as from the certification starting date. Surveillance audits may be performed at a time earlier than 12-month periods if necessary. Surveillance may be postponed in case of acts of God, epidemics, organisational problems and similar conditions not attributable to the company. In those cases, the approval for postponement shall be given by the Certification section.

2.9.4. Where a company certified by SZUTEST wants to use extension period according to the (EU) 2017/745 Regulation amending Regulation (EU) 2023/607, applications for surveillance assessment transfer shall be received only if the following issues are fulfilled according to MDR Article 120(3c). Within this scope;

(a) Those devices continue to comply with Directive 93/42/EEC as applicable.

(b) There are no significant changes in the design and the intended purpose.

(c) The devices do not present an unacceptable risk to the health or safety of patients, users, or other persons, or to other aspects of the protection of public health.

(d) No later than 26 May 2024, the company has put in place a quality management system in accordance with Article 10(9);

(e) No later than 26 May 2024, the company or the authorized representative has lodged a formal application with a notified body assigned under MDR for conformity assessment of the certified device or a device intended to replace this device and no later than 26 September 2024, the notified body and the manufacturer shall sign a written agreement under the second subparagraph of Section 4.3 of MDR Annex VII.

2.9.4.1 SZUTEST shall apply the requirements of the MDR on post-market surveillance, market surveillance and audit, vigilance, registration of economic operators and devices in place of the requirements corresponding to the Medical Device Directive 93/42/EEC for devices referred to in points (a) and (b) of Article 10 of this document.

2.9.4.2. The transfer application of the manufacturer shall be received by the Sales Unit with the FR.MED.201 Application Form for Transferring Surveillance Assessments and approved proof documents requested in the annex of the official letter that the manufacturer has made an official application to a Notified Body assigned under MDR until 26 May 2024 and that this Notified Body and the manufacturer have signed a written agreement specified in Article 2.9.4(e), no later than 26 September 2024. At the same time, the Confirmation Letter that is published by MDR Notified Body and "Manufacturer Declaration" shall be requested from the manufacturer.

2.9.4.3. The surveillance transfer applications under the scope of the Article 120 (EU) 2017/745 Regulation shall be accepted and assessed in accordance to the PR.MED.16 Procedure for Receiving and Evaluating Applications for Medical Devices, Contract and Control of Incoming and PR.MED.27 Medical Devices Procedure For Product Conformity Assessments.

Applicant company shall submit necessary documentation for the assessment of SZUTEST.

2.9.4.4. After the approval of company's transferring of surverveillance assessment application, FR.MED.202 Transfer Agreement For Surveillance Of Legacy Devices shall be signed between the MDR notified body, SZUTEST and the manufacturer. FR.MED.02 93/42/EEC Product Conformity Assesment Agreement shall be issued and approved by parties. Transfer conditions and responsibilities shall explain in this agreement.

SZUTEST shall issue FR.MED.203 Confirmation Letter and the company shall issue "Manufacturer Declaration" until 26 September 2024, after the agreement has been signed. The traceability of this confirmation letter shall be followed up with it's letter number and revision history on the form.

2.9.4.5. Planning Unit shall make the necessary changes regarding the transferring of surveillance assessments on the assessment program.

2.9.4.6. SZUTEST is not responsible for conformity assessment activities carried out by MDR Notified Body.

2.9.4.7. No later than 26 September 2024, SZUTEST that has signed FR.MED.02 93/42/EEC Product Conformity Assesment Agreement, shall be responsible for the surveillance in respect of the devices covered by the agreement. In cases where the agreement covers a device intended to replace a device with a certificate issued under Directive 93/42/EEC, the surveillance shall be carried out according to the device (within the scope of the current certificate) to be replaced.

2.9.4.8. For the assessment fee of MDR Article 120 transition period surveillance requirements, the man/day fee shall be determined according to the resources to be spent in surveillance transfers.

2.10.Re-Certification Audits

2.10.1. The purpose of this audit is to perform a detailed review in order to determine whether the management systems and infrastructure conditions provided by the company for the product or service continue to conform to the requirements of 93/42/EEC directive and ISO 13485 standard as well as the effectiveness of post market surveillance, clinical follow-up and vigilance systems created by the company for the continuation of the product or service safety and performance and availability of parallel implementations as declared by the company.

2.10.2. All the necessary sections must be audited under those audits.

2.10.3. The period granted for correction of the nonconformities under this audit may be up to 15 business days before expiration date of the certification at a maximum if it is less than 4 months before the expiration of the certification.

2.11.Transfer Audits

2.11.1. The transfer audits are those performed due to a transfer application. If this audit is decided, the process shall be regarded as a new application. In this case all sections shall be audited without excluding any of them.

2.11.2. The company must provide to SZUTEST the evidence of the corrective actions for all nonconformities independently from the nonconformity categories in transfer audits.

2.12. Scope Extension Audits

2.12.1. When the company intends to extend the scope of the existing certificates, if SZUTEST decides that the expansion requires site audit, such audits shall be performed.
2.12.2. New agreements must be executed for scope extensions.
2.13. Change Audits
2.13.1. These audits shall be performed for checking if the changes made for the quality management system by the company are performed effectively and if the system that is changed continues to conform to the requirements of 93/42/EEC and ISO 13485. The company shall inform SZUTEST for all of the changes that may effect the quality management system.
2.13.2. As of 26 May 2021, in accordance with Article 120(3) of the (EU) 2017/745 Regulation, in case manufacturer with CE certificate issued by SZUTEST within the scope of the 93/42/EEC Medical Device Directive (MDD) wants to make significant changes in the design and intended use of the certified device; SZUTEST shall not accept these change assessment requests.
Manufacturer with CE Certificate within the scope of the 93/42/EEC Medical Device Directive are required to adapt MDCG 2020-3 guidance document into their quality management system and take it into account when they plan to make changes to the certified device.
Change notifications of the manufacturer are received by SZUTEST in writing with the FR.MED.51 Change Notification Form. Where applicable, the FR.MED.01 Application Form should be filled in by the manufacturer for the change request.
SZUTEST issuing the MDD certificate, after examining the manufacturer's description of the (proposed) change, may confirm in writing with the FR.MED.171 Certificate Information Amendment Form that the implementation of the change does not represent a significant change in design or intended use pursuant to MDR Article 120 (3). In this case, the MDD certificate remains valid. However, this written approval period cannot be longer than the expiration date of the certificate or 26 May 2024. This written consent corrects or supplements the information in an existing certificate, but issuing an 'additional document' as this is prohibited under Section 3. When the FR.MED.171 Certificate Information Amendment Form is issued, the Competent Authority shall be informed by the Competent Authority Communication and Committee Coordinator according to the PR.MED.06 Procedure for legal notification to competent authority and communication with other notified bodies.
In requests from the competent authorities, the manufacturer shall present these documents obtained from SZUTEST, numbered and together with the main certificate.

2.14. Unannounced Site Audits
2.14.1. The purpose of unannounced site audits is to evaluate the conditions related to product safety by means of a risk-based audit approach.
2.14.2. Unannounced site audit is only a part of 93/42/EEC Product Conformity Assessments.
2.14.3. The company shall not be informed of unannounced site audits in advance.
2.14.4. The frequency of unannounced site audits shall be determined by SZUTEST to be increased in case of necessity.
2.14.5. The critical sites and critical suppliers may also be audited under unannounced site audits. The company shall be responsible for receiving the necessary permit for audits to be conducted at critical suppliers. In that regard, the company must execute agreements with critical suppliers about unannounced site audits.
2.14.6. Under unannounced site audits, samples may be taken from the company or market and 2nd Party or 3rd Party tests may be performed.
2.14.7. The flow of unannounced site audits is different from that of the routine audits and this flow shall be declared by SZUTEST during the unannounced site audits. No audit plan shall be provided in advance.
2.15. Critical Supplier Audits
2.15.1. The critical suppliers that may have an impact on product or service safety and performance of the company may be included in the scope of the audit as part of the routine audits.
2.15.2. Any nonconformity determined in relation to critical suppliers shall be reported to the company and not to the critical supplier.
2.15.3. The company shall be responsible for obtaining necessary permits for the audits to be conducted in critical suppliers and therefore, the company must execute agreements about routine audits with the critical suppliers.
2.16. Follow-up Audits
2.16.1. Follow-up audits refer to assessment of correction of any nonconformity determined in an audit by means of the site audits. This audit is part of the audit in which the nonconformity has been determined.
2.16.2. The decision for a follow-up audit may be made for not only routine audits but also ascertaining the correction of nonconformities determined as a result of the internal controls performed by SZUTEST, checking the activities performed after suspension of the certificates, checking the nonconformities determined by the competent authorities and accreditation agencies, and checking vigilance system and post market surveillance data.
2.16.3. Even if the audit team does not recommend for any follow-up audit, SZUTEST certification committee may decide to perform follow-up audit for checking the nonconformity conditions.
2.16.4. The charges for the follow-up audit shall be calculated according to SZUTEST pricing procedures and invoiced separately.

3. File Reviews
3.1.1. One of the product conformity assessment processes under 93/42/EEC is the review of technical file and design dossier.
3.1.2. Clinical assessment and technical expert consultation is included in the scope of file review activities.
3.1.3. File review activities may be part of the entire conformity assessment stages and they may also be more than surveillance frequency especially if the company has multiple technical files.
3.1.4. File review activities may be performed at the office or partly on site.
3.1.5. File review activities may be performed before or after the site audits. SZUTEST may demand the file review nonconformities to be united with the nonconformities determined at site audits in case of necessity.

4. Processes after Nonconformity Report
4.1.1. The nonconformities determined by SZUTEST must be documented by means of FR.MED.52 Finding Report which shall be signed mutually. This form shall be binding even if it is not signed by the company but the company may file a written objection to the nonconformities that are determined.
4.1.2. Based on the finding reports, the company must fill in FR.MED.53 Nonconformity Follow-up report and deliver it to SZUTEST withi maximum 15 business days. The Company shall indicate the root cause of the nonconformities in addition to the corrections and the plan for corrective actions in this form. While making the planning, it is necessary to take into account the duration, nature and emergency of nonconformity, and conformity to SZUTEST procedures.
4.1.3. FR.MED.53 Nonconformity Follow-up Report provided by the company shall be assessed by SZUTEST audit team as a result of which either it shall be approved or correction shall be demanded.
4.1.4. The company shall perform the corrective actions and corrections with due regard for the activities and durations available in the duly approved FR.MED.53 Nonconformity Follow-up Report.
4.1.5. In case the closing of corrective actions are required to be approved by SZUTEST, the company shall deliver the evidence of corrective actions to SZUTEST. The corrective actions shall be assessed by as a result of which they shall be either approved or rejected.

5. Certification Committee
5.1. The certification committee established by SZUTEST shall make a decision on product conformity and ISO 13485 assessment activities.
5.2. The certification committee shall be authorized to make such decisions as issuing, suspending, withdrawing, releasing

suspension of certificates as a result of audits conducted in a normal manner.

5.3. The certification committee may make decisions for suspending and reinstating and withdrawal of certificates in case of critical nonconformities requiring technical assessment and following the control of the nonconformities.

6. Issuing Certificates

6.1. After the assessment activities result positively, SZUTEST shall issue ISO 13485, EC Certificates and, if necessary, EC Design Review certificates according to the application in the name of the company.

6.2. SZUTEST shall decide how many certificates to issue.

6.3. The certificates that are issued and information about their validity shall be published on www.szutest.com.tr.

6.4. All the details about the 93/42/EEC certificates shall be disclosed to Turkish Ministry of Health.

6.5. SZUTEST reserves the right to change the terms and the validity period of the certificates in case of a revision of a regulation, directive, standard or a legislation.

7. Suspension and Withdrawal of Certificates

The certificates shall be suspended or withdrawn in the event that the company fails to perform the conditions specified in the agreement, general terms for medical devices and SZUTEST procedures, undertake the actions determined by SZUTEST, notify any critical change and any nonconformity determined in relation to the products and under similar conditions. The detailed conditions for suspension and withdrawal are defined below but SZUTEST is entitled to withdraw the certificates for each condition that creates basis for suspension according to project risks.

7.1. Suspension of Certificates

7.1.1. SZUTEST may suspend the issued certificates when the following conditions are applicable:

- Failure to deliver an action plan for the nonconformities determined as a result of the Audits and File Reviews, failure to correct the nonconformities in a timely manner, inadequacy of activities with respect to correction of nonconformities
- Determination of serious nonconformities that would cast suspicion on functionality of quality management system
- Failure of the company to make adequate cooperation for planning and performance of audits
- Determination of the fact that the company has not fulfilled the legal requirements completely
- Voluntary request of the company for suspension of certificates
- Misuse of CE marking, Notified Body number, SZUTEST brands and logos.
- Conditions that may discredit product safety and pose potential threat on human health and safety
- Failure of the customer to perform its financial obligations completely
- Failure to inform SZUTEST of critical changes
- Failure of the company to inform SZUTEST of the vigilance system records, recall decisions, warning cases, findings of competent authorities, critical post market surveillance findings
- Discrepancy between the information declared in the Technical Documentation and practice
- In case it is determined that non-standard requirements or legal sanctions (such as Occupational Health and Safety Rules, Personal Data Protection Rules or special requests required by the relevant product or service) regarding the product/service within the scope of the audit are not fulfilled.
- Failure of the company to authorize SZUTEST staff to visit all the sites in all audits including unannounced site audits in addition to restricting access to documentation, preventing the staff from conducting detailed queries, abandoning the staff, failing to take sufficient safety measures for the staff, keeping the staff waiting for a long time, applying pressure on the staff, threatening the staff,
- Determination of the fact that the company has marketed the products having the reference number of another notified body after SZUTEST has issued a certificate with the same scope without receiving consent from SZUTEST.

7.1.2. The certificates may not be used as from the date of suspension. New manufacture may not be realized and all references to SZUTEST brand and services shall be suspended as long as the certificates are suspended. Otherwise, SZUTEST may initiate legal action.

7.1.3. The company shall be informed of the suspension of certificates in writing which shall include information as to how long the certificates may remain suspended and when they shall be withdrawn unless necessary actions are taken.

7.1.4. Suspension of 93/42/EEC certificates shall be notified to the competent authorities.

7.1.5. Decisions for suspension and removal of suspension shall be made by SZUTEST Certification Committee with respect to matters requiring technical assessment.

7.2. Withdrawing or Restricting the Scope of Certificates

7.2.1. The scope of the certificates may be restricted if the company fails to perform the requirements specified in 93/42/EEC, ISO 13485 and SZUTEST documentation with respect to matters related to only a specific part of the certified scope.

7.2.2. SZUTEST may withdraw the certificates when the following conditions are applicable:

- Failure of the company to perform its financial obligations
- Determination of the fact that the company repeatedly commits the mistakes leading to suspension,
- Failure of the company to perform sufficient and effective correction for the suspended certificates during the period of suspension
- Violation of the contractual terms by the company
- If the company declares that it shall not observe any requirement
- If the company demands withdrawal of the certificate of its own accord
- If the company gives incorrect and misleading information
- Use of CE2195 marking in products not certified by SZUTEST

7.2.3. Whenever the certificates are withdrawn and restricted in terms of scope, the company shall be informed of this fact in writing. Withdrawal of 93/42/EEC certificates shall be notified to the competent authorities.

7.2.4. If the company persists in using the certificates, CE2195 marking, SZUTEST brand and logos after withdrawal, SZUTEST may take legal action.

8. Rights and Obligations of SZUTEST

8.1. SZUTEST and all the employees shall keep confidential all kinds of written and verbal information given by the companies and related parties concerning conformity assessment activities and they shall not disclose the relevant information to third parties under any circumstance. Nevertheless, the information may be disclosed to the legal authority (Ministry of Health), European Commission, Accreditation agencies or courts upon demand. If SZUTEST becomes obliged to give information to third parties due to legal reasons, it shall inform the relevant company unless it is legally impermissible.

8.2. SZUTEST shall perform all of the activities without racial, language and religious segregation.

8.3. SZUTEST has executed Impartiality and Non-Disclosure Agreements with its employees as part of its duty of impartiality and non-disclosure.

8.4. SZUTEST shall be obliged to inform the certified companies of material changes in the conformity assessment system (standard procedures or rules) as soon as possible in order to enable them to make the necessary arrangements within the transition period. Web page, e-mail etc. may be used for that purpose.

8.5. SZUTEST shall be entitled to make changes in conformity assessment procedures and pricing instructions. It may make changes in the duration of the audit based on the approval of the head of the Audit team and the relevant department supervisor according to the conditions that may arise during the audit.

8.6. SZUTEST shall be responsible for announcing the companies receiving certificates and becoming subject to suspension and withdrawal of certificates on its web page.
8.7. If SZUTEST, in its own discretion, waives from acting as a notified body and certification body or its activities are suspended by the relevant competent authorities, the files of the company shall be delivered to a notified body or a certification body to be determined by the company. In that case, the conditions of the new notified body or a certification body shall be valid for certification and SZUTEST shall not have any right of disposition on those conditions.
8.8. SZUTEST undertakes to comply with the documentation of the Ministry of Health, European Commission and Accreditation Agencies concerning notified bodies and certification bodies in addition to the abovementioned requirements.
8.9. SZUTEST may amend the terms of the agreement or cancel the agreement according to the outcome of the application assessment process.
8.10. SZUTEST may cancel the agreement in case the company fails to fulfil any contractual obligation.
8.11. SZUTEST may amend the terms of the agreement or cancel the agreement if it is ascertained that there is any change in the information given in the application process during the file review.
8.12. If, during the audits, any information regarding the number of company employees, product range, site scope, critical supplier scope etc. is found to be different from the one indicated in the application form, SZUTEST may alter the audit period and charges according to its procedures and issue invoices to the company for the difference.
8.13. SZUTEST may subcontract the product conformity assessment processes partially if it deems necessary. The details of the activities to be subcontracted and the subcontractor shall be shared with the company and unless any objection is made within 5 business days, the subcontractor shall be considered to have been accepted by the company. Even in case of subcontracted activities, SZUTEST shall remain responsible for the certification decision as well as all the relevant activities.
8.14. SZUTEST may make variations in the pricing of surveillance audit or other charges after the agreement is signed. In such cases, it shall duly inform the company of the change. If the company does not give consent to the change of prices, SZUTEST may cancel the agreement unilaterally.
8.15. If the company wishes to cancel the agreement during the performance of any service including office reviews, it shall be possible to issue an invoice to the company for the value of the activities performed for the service during the period until the cancellation date even if the relevant service has not been completed.
8.16. It may demand the company to recall products in case of any effect on human health and product safety.
8.17. It may conduct extra office review, follow-up audit or unannounced site audit according to the findings determined through the internal audits of SZUTEST, European Commission, competent authority, Accreditation Agency audits.
8.18. It may cancel the agreement unless the company provides the necessary documentation within 10 business days as from the signature of the agreement.
8.19. SZUTEST may demand interpreter or all kinds of document translation incase of the assessment team including the committee members does not know the local language of the company.
8.20. SZUTEST may unilaterally cancel the contract if it is determined that non-standard requirements or legal sanctions (for example; Occupational Health and Safety rules, Personal Data Protection rules or special requests required by the relevant product or service) regarding the product/service within the scope of the audit are not fulfilled.

9. Rights and Obligations of the Company

9.1. The company must provide correct information during the entire assessment process including application and accept all the sanctions that shall arise from failure to fulfil this obligation.
9.2. The company shall be obliged to comply with all kinds of written and verbal information and instructions received from SZUTEST with respect to the operation of the management system and product conformity assessment under the relevant Standard and Directive.
9.3. Following the certification of its management system or product under the management system, shall be obliged to assign an executive to be responsible for ensuring the implementation and continuation of the established system, make it possible for the audit team to have access to all the necessary sites during office hours, guarantee that the requirements of the directive, standards related to the product, if any, or the domestic and international documentation binding on the manufacturer are satisfied with respect to the certified product.
9.4. Observers, guides and candidate auditors/experts may accompany SZUTEST in the audits or unannounced site audits it shall perform on the site or office of the company. An observer may either be any person that observes a member of the audit team or else a representative of the customer, accreditation agency or the relevant ministry. A guide, on the other hand, is the person accompanying the audit team for assistance. A guide may be assigned for each member of the audit team. The guide shall be responsible for ensuring communication, arranging contacts, organizing site visits, ensuring implementation of safety rules on site, witness the audit in the name of the customer or providing the information demanded by the auditor. Information shall be given to the customer and members of the audit team and approval shall be received from the company regarding the participation of guides and observers in the audit excluding unannounced site audits.
9.5. The company shall be obliged to provide all kinds of written and verbal information required for the audit to the relevant people including SZUTEST staff, ministerial representatives and accreditation agency representatives.
9.6. The company must inform SZUTEST of following conditions within 5 business days.

- Change of the legal and commercial standing of the entity
- Change of company partnership structure
- Changes in key personnel of the enterprise
- Changes in notification address and operating areas
- Change of the scope of the certified management system and product composition
- Material changes in management system processes and changes in critical subcontractor and outsourced processes
- The company must immediately inform SZUTEST of any change that may occur in technical documentation after certification and the product must not be marketed without receiving consent from SZUTEST if the relevant change requires consent of SZUTEST.

9.7. The company shall be obliged to record the objections or complaints posed by the customer or third parties under the certificate and communicate them to SZUTEST.
9.8. The company shall be obliged to inform SZUTEST and competent authorities for vigilances cases of the products certified by SZUTEST according to 93/42/EEC after these devices enter into the market.
9.9. The company shall be obliged to deliver the Technical Documentation in executed, approved and controlled copy to SZUTEST. This rule shall apply to the documentation to be submitted in digital media. All of the documentation to be delivered shall be either in English or in Turkish.
9.10. The company shall be obliged to preserve all the records related to the activities performed by SZUTEST (agreement, report, CAPA records etc.) during the validity period the certificate unless otherwise specified in the relevant directive or legal regulation.
9.11. The company shall be obliged to deliver all the papers and documents required for application to SZUTEST in a timely manner.
9.12. SZUTEST may conduct additional audits for a certain charge when required for evaluating the impact of the changes on the system or product.
9.13. The company must perform the requirements of important changes that may occur in the assessment system of SZUTEST (concerning standard procedures or rules) within the transition period that is notified to it.
9.14. The company shall be obliged to comply with the Certificate and Brand Usage Procedure, Certification Procedure, this text (General Terms for Medical Devices) and similar

SZUTEST instructions and procedures of which updated versions are available at www.szutest.com.tr and keep up with their updated versions.

9.15. The company shall be obliged to pay the fees indicated in the pricing instruction and service agreement and the fees for special or follow-up audits provided in the relevant standard or directives.

9.16. The company shall be obliged to discontinue using SZUTEST brand and notified body identification number and certificate after the certificate is suspended or withdrawn. It shall be obliged to discontinue using all kinds of documents and promotion materials making reference to the certificate, brand or notified body identification number and return the certificate to SZUTEST when necessary.

9.17. The company shall be obliged to comply with the local/international legal regulations and laws, directives and standards related to its activities.

9.18. If the company makes an objection as provided in PR.04 Assessment of Complaints and Objections procedure and it does not accept (get satisfied with) the decision rendered by the objection committee, the company may file an application to the relevant authority (Ministry of Health). If SZUTEST is in excess of the period granted for resolving the objection as indicated in PR.04, the company may file an application to the relevant legal authority in the same manner. The company may file an objection to any decision rendered by SZUTEST in relation to the company within 5 business days. The company shall be responsible for covering the cost of the relevant committee, experts and similar other costs to be incurred in relation to the objections and complaints.

9.19. The company shall be obliged to inform the name of the notified body and justifications for withdrawal if any agreement has been signed with another Notified Body about the products subject to the application under 93/42/EEC.

9.20. The company shall be obliged to indicate the name of the notified body and document type if there is/are any valid/invalid certificate/certificates issued by another Notified Body for the products subject to the application. If the certificates are invalid, it must indicate the justifications for the invalidity.

9.21. The company shall be obliged to inform SZUTEST of the reason for rejection if any of its applications has been rejected by another Notified Body for the products subject to the application (along with the name of the notified body, its decision and justifications).

9.22. The company shall be responsible for designing and manufacturing the product/products in line with the fundamental or other legal requirements specified in the relevant European harmonized standards and national regulations and keeping up with the updated version of this regulation and implementing the changes. The company may develop alternative methods instead of fully complying with any harmonized standard in which case it shall be responsible for proving and explaining in detail that the methods meet the fundamental requirement of 93/42/EEC directive.

9.23. The company shall be obliged to accept and make payment for the invoices issued by SZUTEST prior to the implementation of activities subject to conformity assessment process.

9.24. The company must agree that the agreement that is duly signed shall not be construed as entitlement for the certificate.

9.25. The company accept and make payment for the invoices issued by SZUTEST for the duly completed services even if the result is negative.

9.26. The company must pay for the services which have been previously performed in case the agreement is terminated for any reason.

9.27. The company must serve a written notice if it intends to terminate the agreement.

9.28. The company must make timely payments.

9.29. The company must accept and make payment for the invoice issued for the activities performed for a service even if that service has not been completed in the event that the agreement is terminated during the period SZUTEST performs any service.

9.30. The company must submit all the declarations and documents required by SZUTEST within maximum 10 business days if the company intends to transfer any certificate issued by SZUTEST to another notified body.

9.31. If the company intends to transfer any certificate issued by another notified body to SZUTEST, it must submit the documents required by SZUTEST within maximum 10 business days. In case of any such certificate transfer demand, it must accept that SZUTEST may contact the existing notified body. It must also agree that SZUTEST may cancel the agreement during application assessment stage according to the information given by the notified body. If the notified body does not give any response within maximum 15 business days, SZUTEST may suspend certificate transfer process.

9.32. The company must not implement any product design changes without receiving consent from SZUTEST.

9.33. The company must complete the visa invitation form to be provided in attachment to the agreement to give permission for unannounced site audits in advance and also provide a visa invitation letter to SZUTEST additionally in case of such demand.

9.34. The company must authorize SZUTEST staff to visit all of the sites including design, manufacture, warehouse, test and examination sites, to ask questions to employees assigned in those sites and examine the products and documents in all of the sites.

9.35. The company must allow SZUTEST staff to make intensive and detailed questioning in case of necessity.

9.36. The company must agree to and allow all the audits to be conducted by SZUTEST at the site of the company including unannounced site audits.

9.37. The company must give consent to all the audits, including unannounced site audits and witness audits, to be conducted by Turkish Ministry of Health as the competent authority, European Commission and other relevant authorities at the site of the company and entitle the representatives of those authorities to make audits on its site along with SZUTEST.

9.38. The company must make agreements with suppliers and subcontractors in order to ensure that all kinds of audits, including unannounced site audits and witness audits, might be performed by SZUTEST and witnessed by the representatives of Turkish Ministry of Health, Accreditation Agencies, European Commission and other competent authorities concerning the critical suppliers and subcontractors. The company must accept the sanctions to be applicable in case the critical suppliers and subcontractors do not give consent to such audits.

9.39. The company must allow SZUTEST to choose products from its warehouse for examination purposes and conduct quality assurance tests on them during routine audits.

9.40. The company must agree that SZUTEST shall not offer any consultancy services to the company in relation to the services provided above and must not make any such demand.

9.41. The company must ensure that necessary information is given and necessary measures are taken for protecting the safety and health of the staff assigned by SZUTEST as well as the accompanying employees. The necessary equipment must be provided by the company.

9.42. The company must agree that SZUTEST shall not be responsible for any loss to be incurred as a result of the termination of Accreditation or Notification of SZUTEST and must not make any demands for those reasons.

9.43. The company must not file application to more than one Notified Body for the same products simultaneously.

9.44. The company must use the brand, logo and CE2195 marking of SZUTEST with due regard for the rules determined by SZUTEST. It must not use the brand, logo and CE2195 marking in case of suspension or withdrawal of certificates.

9.45. The company must accept all the responsibilities that shall arise from suspension or withdrawal of certificates including those to the customers and must not hold SZUTEST responsible for that.

9.46. The company must fully comply with the nonconformity closure dates declared after the assessments, follow-up those dates and must not hold SZUTEST responsible in case of failure in due observance of those dates. It must accept that the certificate may be suspended if the nonconformities cannot be closed within those dates.

9.47. The company must agree that SZUTEST shall not be responsible for reminding expiration of nonconformity closure dates or any other date specified for any pending response.

9.48. The company must not market any products with the identification number of another notified body without receiving consent from SZUTEST after SZUTEST issues a certificate with the same scope.
9.49. The company must not undertake manufacture and sales of products with CE2195 marking when the certificate is subject to suspension and withdrawal or its validity period has expired.
9.50. The company must not use CE2195 marking for products not certified by SZUTEST.
9.51. The company must accept the findings of the extra office review, follow-up audit or unannounced site audit according to the findings determined through the SZUTEST internal audits and audits conducted by the European Commission, Accreditation Agencies and competent authority and make corrections in due time.
9.52. The company must cover the cost of the relevant committee, experts and similar other costs to be incurred in relation to the objections and complaints.
9.53. Companies shall inform SZUTEST about all the critical changes related with their critical suppliers, including the changes in the critical supplier's certificates in maximum 5 working days.
9.54. According to the Regulation (EU) 2020/561; MDR – (EU) 2017/745 (Medical Device Regulation) shall come into force on May 26, 2021.
10. According to MDR Article 120 (3a) certificates issued under Directive 93/42/EEC as of 25 May 2017 and still valid on 26 May 2021 shall remain valid until the following dates for the relevant risk class of the devices after the expiry of the period specified in the certificate:
a) 31 December 2027, for all class III devices, and for class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors;
b) 31 December 2028, for class IIb devices other than those covered by point (a) of this paragraph, for class IIa devices, and for class I devices placed on the market in sterile condition or having a measuring function.
10.1. Until 26 September 2024, unless the COMPANY agrees with a notified body assigned under the MDR that it will carry out the surveillance specified in Madr Article 120 (3d), SZUTEST shall continue to be responsible for the necessary surveillance audit for all applicable requirements of 93/42/EEC provided that there is no significant change in the design and the intended use of the devices it has certified.
10.2. No later than 26 September 2024, the MDR Notified Body that has signed the written agreement referred to in Article 2.9.4(e), shall be responsible for the surveillance in respect of the devices covered by the written agreement. In cases where the written agreement covers a device intended to replace a device with a certificate issued under Directive 93/42/EEC, the surveillance shall be carried out according to the device (within the scope of the current certificate) to be replaced.
10.3. Arrangements for the transfer of surveillance from SZUTEST to the notified body assigned under the MDR shall be clearly defined in an agreement between the COMPANY, the Notified Body assigned under MDR, and SZUTEST where applicable. The Notified Body assigned under the MDR shall not be responsible for the conformity assessment activities carried out by SZUTEST.
10.4. Applications (significant changes such as scope extension), which will cause significant changes of your certificate according to MDR - Regulation (EU) 2017/745 should be submitted to Notified bodies, designated by this regulation.
10.5. SZUTEST shall not make any refund in case of delay of a responsibility of the client more than 7 days such as technical file sending, nonconformity closure etc and having caused at least one delay more than 7 days in any responsibility while carrying out the projects which may cause SZUTEST not to be able to allocate efficient resource planning and effective assessment.
10.6. No certificate can be issued after 20 May 2021 according to 93/42/EEC directive.