In this text,

- The word “SZUTEST” shall refer to SZUTEST Uygunluk Değerlendirme Anonim Şirketi;
- The word “Agreement” shall refer to the ISO 13485 Quality Management System Assessment Agreement issued by SZUTEST;
- The word “Company” shall refer to the company that has executed an agreement with SZUTEST.

Medical Devices General Terms constitutes an inseparable part of the agreement, and SZUTEST is entitled to update this document when it considers necessary. If the Medical Devices General Terms 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 by publication of the updated version on the website. Medical Devices General Terms shall be available at www.szutest.com.tr.
Medical Devices General Terms defines ISO 13485 certification activities and the rules to be observed by the company and SZUTEST hereunder, and also contains a summary of the certification processes.

1. Certification Process

1.1. Application Review and Agreement Process

1.1.1. Applications for ISO 13485 certification shall be filed in writing along with an application form. Verbal applications shall not be accepted. The company shall fill in and sign the application forms completely. The documents required in the application form shall be submitted 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.
1.1.3. SZUTEST may contact the previous certification body of the company or demand that the company provide the reports and documents issued by that certification body for transfer applications. Based on the information received, SZUTEST may reject the company's application. In case no information can be obtained from the previous certification body, SZUTEST may either treat the application as a new one or reject it.
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 shall perform the financial obligations provided in the agreement and submit all the documentation, including specifically quality management system documentation, to SZUTEST within 10 business days at the latest.
1.1.7. 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 shall deliver the missing documents within 10 business days at the latest. In the event that the documentation demanded is not provided by the company following the execution of the agreement, SZUTEST may cancel the agreement.
1.1.8. The previously certified customers shall notify the changes in the legal status of company, notification address, quality management system, certified scope and in the products covered by the agreement, if any, by means of the change notification form and application form with relevant annexes, 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 agreement and collecting additional charges.
1.1.9. Recertification requests are received at least 6 months before the expiration of the company's certificate, an agreement is signed with the company, and the contractual obligations are fulfilled. If the recertification application is submitted less than 6 months before the certificate expiration date, SZUTEST reserves the right to reject the application based on the evaluation. In such cases, the company is deemed to have accepted the limitation of the nonconformity closure periods determined as a result of the recertification audit.
1.1.10. Supplementary documents to be submitted during the application shall only be provided in digital form. Document submissions shall be made only in controlled copy format and sent to email addresses with the SZUTEST domain.

2. Audits

2.1. ISO 13485 certification audits are conducted to evaluate the quality management system within the scope of the company’s application and to verify its compliance with both the relevant standard and the company's own rules.
2.2. Audits shall be performed according to SZUTEST procedures. The sampling method shall be used for audits.
2.3. Any nonconformity determined in the audits shall be recorded by means of FR.MED.52 Finding Report.
2.4. If any nonconformity determined in audits requires follow-up audit, this shall be performed only if the corrective and preventive actions submitted by the company to SZUTEST are found effective.
2.5. The audits may cover the critical sites and critical suppliers of the company. SZUTEST shall determine which sites shall be audited.
2.6. Under normal conditions, the maximum period granted to address nonconformities identified during Stage 1 audits is 5 months, while it is 4 months for other audits. If the company requests an extension with justified reasons, SZUTEST may evaluate the request and decide an extension accordingly. It should be noted that, for surveillance audits, the maximum extension period shall not exceed 2 months before the next surveillance audit. In Stage 2 audits, the total time granted for resolving major nonconformities shall not exceed 6 months.
2.7. The reporting language following ISO 13485 audits may be either English or Turkish. In audits conducted in coordination with SZUTEST Konformitätsbewertungsstelle GmbH, the reporting language shall be English.

2.8. Stage 1 Audits

2.8.1. Stage 1 audit is conducted as a part of initial certification applications. The purpose of this audit is to assess whether the company is ready for Stage 2 Audit.
2.8.2. Stage 1 audits may be performed on-site or off-site. SZUTEST shall determine which audits can 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.
2.8.3. If minor nonconformities are detected during Stage 1 audits, those nonconformities shall be checked during Stage 2 audits.
2.8.4. If major nonconformities are identified during the Stage 1 audit, the company shall address these nonconformities and submit the relevant evidence documents to SZUTEST. If the nonconformities have been largely resolved and the remaining issues do not prevent the conduct of the Stage 2 audit, SZUTEST shall inform the company of the remaining nonconformities, which will then be reviewed during the Stage 2 audit.

2.9. Stage 2 Audits

2.9.1. Stage 2 audits shall be performed after Stage 1 audits during the initial certification applications. During these 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 of ISO 13485 standard.
2.9.2. The company shall submit to SZUTEST the corrective and preventive actions for all nonconformities determined during Stage 2 audits.

2.9.3. For ISO 13485 certification the time between Stage 1 audit and Stage 2 audit shall not be more than 6 months. In other case, Stage 1 audit shall be renewed.
2.9.4. If the company cannot provide evidence for closure of major findings of Stage 2 audit in 6 months, the Stage 2 audit shall be renewed.

2.10. Surveillance Audits
2.10.1. The purpose of this audit is to perform a detailed assessment of whether the company's management system and infrastructure related to the product or service continue to comply with the ISO 13485 standard requirements, to evaluate the effectiveness of post market surveillance, recall and vigilance systems, and to verify whether the company is implementing practices in line with its declarations.
2.10.2. Some of the sections may be excluded from the scope during surveillance audits; however, SZUTEST shall ensure that all the relevant points required to be assessed under ISO 13485 standard are evaluated within the 3-year certification cycle.
2.10.3. Surveillance audits shall be performed at least once a year; however, first surveillance audit shall 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 audits may be postponed in cases of force majeure such as natural disasters, pandemics, or organizational problems beyond the company's control. In those cases, the approval for postponement shall be given by the SZUTEST.
2.10.4. The Planning Unit shall make the necessary adjustments to reflect the surveillance audits in the assessment program.

2.11. Re-Certification Audits
2.11.1. 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 ISO 13485 standard as well as the effectiveness of post market surveillance, recall 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.
2.11.2. All the necessary sections shall be audited under those audits.
2.11.3. If there are less than 4 months remaining until the certificate expiration date, the maximum time allowed for the closure of nonconformities shall be up to 15 working days before the certificate expiration date.

2.12. Transfer Audits
2.12.1. These are the audits conducted by SZUTEST for transfer applications. They may be carried out to assess any unresolved issues identified during the pre-transfer review process.

2.13. Scope Extension Audits
2.13.1. If the company intends to extend the scope of its existing certificates, and SZUTEST determines that this extension requires an on-site audit, the relevant audit shall be conducted.
2.13.2. New agreements shall be executed for scope extensions.
2.13.3. If a nonconformity is identified during the scope extension audit and it is not resolved within the specified timeframe, the scope extension shall not be approved.

2.14. Change Assessment Audits
2.14.1. These audits are conducted to verify whether the changes notification submitted by the company has been effectively reflected in the quality management system and whether the modified quality management system still complies with the requirements of ISO 13485 standard.
2.14.2. If a nonconformity is identified during the change evaluation and it is not resolved within the specified timeframe, the change notification shall not be approved.
2.14.3. The company shall notify SZUTEST of any changes that may affect its quality management system.

2.15. Short Notice Audits
2.15.1. SZUTEST may subject a certified customer to short-notice or unannounced site audits to investigate complaints, evaluate notified changes, follow up on suspended customers, or verify the implementation of corrective actions.

2.16. Critical Supplier Audits
2.16.1. As a part of routine audits, critical suppliers that may affect the safety and performance of the product and service may be included in the audit scope.
2.16.2. The company shall be responsible for obtaining the necessary permissions for audits to be conducted at critical suppliers. Therefore, the company shall have agreements with its critical suppliers that cover routine audits.
2.16.3. Any nonconformities identified at critical suppliers shall be reported to the company, not to the critical supplier.

2.17. Follow-up Audits
2.17.1. A follow-up audit is conducted to evaluate, through on-site verification, whether a nonconformity identified during any audit has been resolved and whether the corrective action taken is effective. This audit is considered a part of the audit during which the nonconformity was identified.
2.17.2. A follow-up audit may be decided not only for routine audits but also to verify the closure of nonconformities identified through SZUTEST internal controls, to check the actions taken after a certificate has been suspended, to verify nonconformities identified by Competent Authorities and Accreditation Bodies, and to assess recall, vigilance systems, and post-market surveillance data.
2.17.3. Even if the audit team does not recommend a follow-up audit during an audit, the SZUTEST Certification Committee may decide to conduct a follow-up audit to verify the closure of nonconformities.
2.17.4. The result of the follow-up audit may indicate whether the nonconformities have been closed or not. If the nonconformities are not closed within the specified timeframe, the certificate shall be suspended or withdrawn.
2.17.5. Follow-up audit fees shall be calculated according to SZUTEST's pricing procedures and invoiced separately.

2.18. Hybrid Audits and Entirely Remote Audits
2.18.1. Hybrid audit is the method that includes both remote and onsite activities to assess compliance with MDR.
2.18.2. Entirely remote audit is an audit performed remotely using electronic tools and no on-site activity plans with any auditor.
2.18.3. All decisions on performing, stopping, canceling, invalidating, and repeating hybrid audits and entirely remote audits shall be going to be taken solely by SZUTEST.
2.18.4. All required IT, network, and software arrangements shall be initiated by the company and SZUTEST, prior to starting hybrid audit and entirely remote audit. The formal audit durations shall not be spent on these preparations and arrangements.
2.18.5. SZUTEST may demand testing on IT, network, and software arrangements prior to the hybrid audit and entirely remote audit.
2.18.6. Expenses due to stopping, cancelling, invalidating the hybrid audit and entirely remote audit shall be paid by the company.

3. Processes after Nonconformity Report

3.1. The nonconformities determined by SZUTEST shall 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; however, the company may submit a written appeal to the identified nonconformities.
3.2. Based on the findings reports, the company shall fill in FR.MED.53 Nonconformity Follow-up Report and submit it to SZUTEST within 15 business days at the latest. The Company shall indicate the root cause of the nonconformities in addition to the plan for the corrections and corrective actions in this form. When planning is carried out, attention shall be paid to the nature and urgency of the nonconformity, as well as compliance with SZUTEST procedures.

3.3. FR.MED.53 Nonconformity Follow-up Report provided by the company shall be evaluated by SZUTEST audit team; if found acceptable, it is approved; otherwise, a correction request shall be made.
3.4. The company shall implement its the corrective actions and corrections in accordance with the activities and timelines specified in the approved FR.MED.53 Nonconformity Follow-up Report.
3.5. In cases where the approval of corrective actions by SZUTEST is required, the company shall submit the relevant evidence to SZUTEST. This evidence shall be evaluated by SZUTEST, and the corrective actions shall be either approved or rejected accordingly.

4. Certification Committee

4.1. The decisions regarding certification activities under the ISO 13485 standard shall be made by the certification committee established by SZUTEST.
4.2. Based on the outcome of routine audits, decisions such as certificate issuance, suspension, withdrawal, or the release of suspension of the certificate shall be made by the certification committee.
4.3. In cases where there are critical nonconformities requiring technical evaluation, decisions regarding the suspension, withdrawal from suspension, or cancellation of certificates shall be made by the Certification Committee following the review of these nonconformities.

5. Issuing Certificates

5.1. As a result of a possitive evaluation, SZUTEST issues ISO 13485 Certificates, on behalf of the company.
5.2. The number of certificates to be issued shall be determined by SZUTEST.
5.3. The issued certificates and their validity information are published on www.szutest.com.tr.
5.4. In the event of a revision to the relevant standard and legal legislations, SZUTEST reserves the right to make changes to the provisions and validity periods stated on the issued certificates in accordance with the revision.

6. Suspension and Withdrawal of Certificates

If the company fails to comply with the requirements defined in the ISO 13485 standard, the agreement, the Medical Devices General Terms, or SZUTEST procedures; fails to implement the actions determined by SZUTEST, fail to notify critical changes; or fails to report any nonconformity identified regarding the product or service, the certificates may be suspended or withdrawn. The detailed conditions for suspension and withdrawal are defined below; however, SZUTEST reserves the right to withdraw the certificates for any condition that constitutes suspension based on project risks.

6.1. Suspension of Certificates

6.1.1. SZUTEST may suspend the issued certificates when the following conditions occur:

- Failure to submit an action plan for the nonconformities determined as a result of the audits, failure to correct the nonconformities on time, inadequacy of activities concerning the correction of nonconformities,
- Determination of serious nonconformities that would cast suspicion on the functionality of the quality management system,
- Failure of the company to make adequate cooperation for the 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 SZUTEST brands and logos,
- Failure of the customer to perform its financial obligations completely,
- Failure to notify SZUTEST of critical changes,
- Failure of the company to inform SZUTEST of the vigilance system records, recall decisions, warning cases,
- In all audits, including short-notice audits, if the company does not grant SZUTEST personnel the right to access all sites including critical suppliers, restricts access to documentation, prevents detailed questioning, leaves SZUTEST personnel unattended on site, fails to provide necessary safety measures, causes undue delays during the audit, exerts pressure, or threatens the personnel,
- 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.

6.1.2. The certificates shall not be used as from the date of suspension and new manufacture shall not be conducted. All references to the SZUTEST brand and services shall be discontinued. If the opposite situation is detected, SZUTEST may initiate legal action.
6.1.3. 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.
6.1.4. Suspension of ISO 13485 certificates shall be notified to the Accreditation Body.
6.1.5. In cases where technical evaluation is required, decisions for suspension and removal of suspension shall be made by the SZUTEST certification committee.

6.2. Withdrawing or Restricting the Scope of Certificates

6.2.1. The scope of the certificates may be restricted if the company fails to perform the requirements specified in ISO 13485 and SZUTEST documents concerning matters related to only a specific part of the certified scope.
6.2.2. SZUTEST may withdraw the certificates when the following conditions occur:

- Failure of the company to perform its financial obligations
- In case the company repeats the nonconformities that previously resulted in suspension,
- Failure of the company to perform sufficient and effective corrections for the suspended certificates during the period of suspension,
- Violation of the agreement terms by the company,
- If the company declares that it shall not observe any requirement,
- If the company voluntarily requests the withdrawal of its certificate,
- If the company gives incorrect and misleading information.

6.2.3. In case of withdrawal of certificates and restriction of their scope, the company shall be informed of this fact in writing. Withdrawal of ISO 13485 certificates shall be notified to the Accreditation Body.
6.2.4. If the company persists in using the certificates, SZUTEST brand, and logos after withdrawal, SZUTEST may take legal action.

7. Audits to be carried out in coordination with SZUTEST subsidiaries

7.1. In cases where SZUTEST subsidiaries conduct audits under a scope equivalent to or that go beyond the requirements of the ISO 13485 standard (e.g., (EU) 2017/745), the audits may be conducted in coordination with each other. All decisions on the coordination of these audits, including decisions on whether they will be conducted consecutively or independently, is entirely at the discretion of SZUTEST. The company shall agree that all information and objective evidence obtained during audits conducted under a scope equivalent to or that goes beyond the requirements of the ISO 13485 standard may also be used within the scope of ISO 13485 certification. The company shall accept that SZUTEST may contact its subsidiaries for planning the audits and obtain information in the context of this coordination.

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 certification activities, and they shall not disclose the relevant information to third parties under any circumstances. Nevertheless, the information may be disclosed to the relevant competent authorities, Accreditation Bodies, 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 is obliged to retain the records related to its certification activities in accordance with the relevant legislations and accreditation rules.
8.3. SZUTEST shall perform all of the activities without racial, language, and religious segregation.
8.4. SZUTEST shall execute the Confidentiality and Impartiality Commitment with its employees as part of its duty of confidentiality and impartiality.
8.5. SZUTEST shall be obliged to notify certified companies of any significant changes in the certification system, including standards, procedures, or rules, as soon as possible. Companies shall be expected to implement the necessary adjustments within the transition period to be determined. Communication channels such as the website and e-mail may be used for this purpose.
8.6. SZUTEST reserves the right to make changes to the certification procedures and pricing instructions. Depending on the conditions that may arise during the audit, the audit duration may be changed upon the recommendation of the head of audit team and the approval of the relevant department responsible.
8.7. SZUTEST shall be responsible for announcing the companies receiving certificates, becoming subject to suspension and withdrawal of certificates on its website.
8.8. In case SZUTEST voluntarily discontinues its certification activities or such activities are suspended by the competent authorities, the transfer of relevant documents to another certification body to be designated by the company shall be ensured. In that case, the conditions of the new certification body shall be valid for certification, and SZUTEST shall not have any right of disposition on those conditions.
8.9. SZUTEST shall undertake to comply with the documentation of the relevant competent authority, and Accreditation Body concerning certification bodies in addition to the abovementioned requirements.
8.10. SZUTEST may amend the terms of the agreement or cancel the agreement according to the outcome of the application review process.
8.11. SZUTEST may cancel the agreement in case the company fails to fulfil any contractual obligation.
8.12. If, during the audits, any information regarding the number of company employees, certification scope, site scope, critical supplier scope etc. is found to be different from the one indicated in the application form, SZUTEST may alter the audit duration and fees according to its procedures and issue invoices to the company for the difference.
8.13. SZUTEST may subcontract the certification 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 reserves the right to change surveillance audit fees or other related fees after the agreement has been signed. In such cases, the revised fees shall be communicated to the company. If the company does not accept the new fees, SZUTEST may unilaterally terminate the agreement.
8.15. If the company wishes to terminate the agreement during the execution of any service, including office reviews, SZUTEST may invoice the company for the activities carried out up to the date of termination, even if the service has not been completed.
8.16. SZUTEST may demand that the company recall products in case of any effect on human health and product safety.
8.17. SZUTEST may conduct extra office review, follow-up audit, short-term notice, or unannounced site audit according to the findings determined through the internal audits of SZUTEST, the competent authority, and Accreditation Body audits.
8.18. If the company fails to provide the requested documents within 10 business days following the signing of the agreement, SZUTEST may terminate the agreement.
8.19. SZUTEST may request the company to provide an interpreter and translations of necessary documents if the audit team, including committee members, does not speak the local language of the company.
8.20. If it is determined that legal requirements or sanctions outside the scope of the relevant standard related to the audited product or service (e.g., Occupational Health and Safety Law, Personal Data Protection Law, or specific regulations related to the product or service) have not been fulfilled, SZUTEST may unilaterally terminate the agreement.

9. Rights and Obligations of the Company

9.1. The company shall provide accurate information during the entire certification process, including the application stage, and shall accept all the sanctions arising from failure to fulfil this obligation.
9.2. The company shall be obliged to comply with all written and verbal information and instructions received from SZUTEST regarding the operation of its management system under the ISO 13485 standard.
9.3. The company certified under the management system shall be obliged to assign a responsible person to ensure the implementation and continuity of the established system, to grant the audit team access to all necessary areas during office hours, and to guarantee compliance with the applicable product/service standards and local or international regulations required of the company, if any.
9.4. Observers, guides and candidate auditors/experts may accompany the audits to be carried out by SZUTEST at the company's premises or offices, including short-notice and unannounced site audits.
The observer may be a person observing a member of the audit team, a customer's authorized person, or a representative of the Accreditation Body.
A guide is a person who accompanies the audit team to provide support throughout the audit. If necessary, a separate guide may be assigned to each member of the audit team. Responsibilities of the guide may include facilitating communication, coordinating interviews, organizing site visits, ensuring compliance with site safety rules, witnessing the audit on behalf of the customer, and providing any information requested by SZUTEST personnel. For audits other than unannounced site audits, the customer and audit team members shall be informed in advance about the participation of guides and observers, and the customer's approval shall be obtained.
9.5. The company shall be obliged to provide all individuals involved in the audit activity, including SZUTEST personnel and representatives of the Accreditation Body, with all necessary written and verbal information upon request.
9.6. The company shall notify SZUTEST within 5 business days in the event of any of the following situations:

- 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,
- Significant changes in management system processes,
- Changes in critical supplier and outsourced processes.

9.7. The company shall be obliged to record any complaints or appeals received from customers or third parties regarding the products or services within the scope of the certificate and to notify SZUTEST accordingly.
9.8. The company shall fulfill the requirements of vigilance under ISO 13485 Quality Management System. The company whose quality management systems have been certified by SZUTEST is responsible for reporting any serious adverse events related to the products they place on the market to the competent authority and SZUTEST, within the timeframes specified in the relevant legislation, based on the severity of the

event. To ensure timely reporting, the company may provide an initial report before a full report when necessary.

9.9. The company shall be obliged to submit the documentation to SZUTEST in a signed, approved, or controlled copy format. This requirement shall also be valid for documents submitted in digital format. All submitted documents shall be in English or Turkish.

9.10. The company shall be obliged to retain all records related to the activities performed by SZUTEST (such as agreements, reports, CAPA records, etc.) throughout the validity period of the certificate, unless otherwise specified in the relevant legal legislations.

9.11. The company shall be obliged to submit all requested documents and records related to the application process to SZUTEST within the specified timeframe.

9.12. SZUTEST may, if deemed necessary, conduct an additional audit for a fee to assess the impact of changes on the certified quality management system.

9.13. The company shall be obliged to implement the requirements of any significant changes in SZUTEST's certification system, including standards, procedures, or rules, within the transition period notified to them.

9.14. The company shall be obliged to comply with and monitor updates to SZUTEST instructions and procedures, including the "Certificate and Mark Usage Procedure" and this text (Medical Devices General Terms), which are published in their current version at www.szutest.com.tr.

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 legislation.

9.16. Following the suspension or withdrawal of its certificate, the company shall be obliged to cease the use of the SZUTEST mark and certificate. It shall also be required to discontinue the use of any documents or promotional materials that refer to the certificate or mark, and to return the certificate to SZUTEST if necessary.

9.17. The company shall be obliged to comply with all applicable local/international legal legislations, laws, and standards relevant to its activities.

9.18. The company can submit its complaints regarding SZUTEST certification activities and appeals to its decisions in accordance with the PR.04 Complaints and Appeals Assessment Procedure. SZUTEST shall evaluate the appeal within the scope of the relevant procedure and inform the company of the outcome. The company has the right to appeal to SZUTEST for the second time regarding the decision taken by the appeal committee and the activity carried out. If the company does not accept the decision of the appeal committee for the second time, it may apply to the relevant legal authorities. If SZUTEST fails to resolve the appeal within the timeframe specified in the PR.04 Complaint and Appeal Assessment Procedure, the company similarly has the right to apply to the relevant legal authorities. The company may appeal to a decision taken by SZUTEST regarding itself within 10 working days. The company shall be responsible for covering the costs of the committee to be established for the appeal or complaint, any experts to be assigned, and other similar expenses that may arise.

9.19. It is obliged to notify SZUTEST of the type of valid or invalid certificate(s) and the name of the relevant certification body, if there are any such certificates issued by another certification body for the scope declared in its application. In cases where the certificates are invalid, the justification for invalidity shall also be reported.

9.20. 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 essential requirements of Regulation (EU) 2017/745.

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

9.22. The company shall acknowledge that the agreement that is duly signed shall not be construed as an entitlement to the certificate.

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

9.24. The company shall pay for the services that have been previously performed in case the agreement is terminated for any reason.

9.25. The company shall be obliged to notify SZUTEST in writing if it intends to terminate the agreement.

9.26. The company shall fulfill its payment obligations within the specified timeframes and on time.

9.27. The company shall be obliged to accept and pay the invoice for the activities carried out under that the service, even if the service has not been completed, in the event that the agreement is terminated during the period SZUTEST performs any service.

9.28. The company shall be obliged to submit all the declarations and documents requested by SZUTEST within maximum 10 business days if the company intends to transfer any certificate issued by SZUTEST to another certification body.

9.29. The company shall be obliged to submit all declarations and documents requested by SZUTEST within 10 business days at the latest if it intends to transfer any certificate issued by another certification body to SZUTEST. In case of any such certificate transfer demand, the company shall accept that SZUTEST may contact the existing certification body. It shall also agree that SZUTEST may cancel the agreement during the application review according to the information given by the certification body. If the certification body does not give any response within 15 business days, the documents submitted by the company shall be considered valid.

9.30. The company shall not implement any product design changes without receiving consent from SZUTEST.

9.31. The company shall give SZUTEST personnel the authority to visit all sites, including but not limited to design, manufacture, warehouse, testing, and inspection sites; to question the personnel working in these sites; and to examine the products and documents on sites.

9.32. The company shall allow SZUTEST personnel to make intensive and detailed questioning in case of necessity.

9.33. The company shall accept all audits to be conducted by SZUTEST, including unannounced site audits, and shall allow these audits to be carried out on its premises.

9.34. The company shall accept all audits to be conducted by Accreditation Bodies and other relevant competent authorities together with SZUTEST on the company's premises, including unannounced site audits and witnessed audits, and shall allow the participation of such authorities in these audits.

9.35. The company shall have agreements in place with its critical suppliers and subcontractors that allow SZUTEST, together with Accreditation Bodies and other relevant competent authority representatives, to conduct all audits — including unannounced site audits and witnessed audits — and to witness these audits. The company shall accept all consequences and sanctions that may arise in the event that such critical suppliers and subcontractors do not permit the mentioned audits.

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

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

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

9.39. The company shall acknowledge that SZUTEST is not held liable for any damages that may arise in the event of termination of its accreditation and agrees not to make any claims in this regard.

9.40. The company shall not file an application to more than one Certification Body for the same scope simultaneously.

9.41. The company shall use the brand and logo only in accordance with the rules defined by SZUTEST and shall immediately cease its use in the event of suspension or withdrawal of the certificates.

9.42. The company shall accept all the responsibilities that shall arise from suspension or withdrawal of certificates, including those to the customers, and shall not hold SZUTEST responsible for any consequences arising from such situations.

9.43. The company shall strictly adhere to the deadlines defined for the closure of nonconformities identified during audits, ensure proper follow-up, and shall not hold SZUTEST responsible for failure to close nonconformities on time. The company shall accept that the certificate may be suspended if the nonconformities are not closed by the specified deadlines.

9.44. The company shall acknowledge that SZUTEST is not obliged to be responsible for reminding expiration of nonconformity closure dates or any other date specified for any pending response.

9.45. The company shall acknowledge the findings of any additional office review, surveillance audit, follow-up audit, or short-notice and unannounced site audit conducted as a result of findings identified by the Accreditation Bodies, other relevant competent authorities, or SZUTEST internal controls, and shall implement the necessary corrections within the timeframe provided.

9.46. The company shall be responsible for covering all expenses related to committees established for the handling of complaints and appeals, including the costs of assigned experts, and any similar other costs.

9.47. The company shall be obliged to notify SZUTEST of all the critical changes related to its subcontractors and/or critical suppliers, including any changes made to existing certificates, within 5 working days at the latest.