GENERAL TERMS FOR MEDICAL DEVICES

In this text,

- The word “Agreement” shall refer to one of the following agreements; the Regulation (EU) 2017/745 Product Conformity Assessment Agreement issued by SZUTEST Konformitätsbewertungsstelle GmbH;
- The word “Company” shall refer to the manufacturer that has executed agreement with SZUTEST Konformitätsbewertungsstelle GmbH.

General Terms for Medical Devices constitutes an inseparable part of agreements and SZUTEST Konformitätsbewertungsstelle GmbH 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 https://www.szutest-germany.de/ .

The General Terms for Medical Devices defines the conformity assessment activities based on a quality management system and on assessment of technical documentation regarding to Annex IX of the Regulation (EU) 2017/745 and conformity assessment activities based on product conformity verification - production quality assurance regarding to Annex XI - Part A of the Regulation (EU) 2017/745 and the rules to be observed by the company and SZUTEST Konformitätsbewertungsstelle GmbH 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 assessment regarding to the Regulation (EU) 2017/745 concerning Medical Devices 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, the QMS documentation and the Technical Documentation shall be submitted to SZUTEST Konformitätsbewertungsstelle GmbH 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.

Application shall be made by authorised person of the applicant company. Application forms should be filled out by authorized person of the company.

EU Authorised Representative of the company can make application on behalf of the company.

1.1.2. SZUTEST Konformitätsbewertungsstelle GmbH shall initiate the application review 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 Konformitätsbewertungsstelle GmbH may consult to the Federal Institute for Drugs and Medical Devices listed in the https://www.bfarm.de web site based on their scope of coverage in Germany or competent authorities of other Member States during the process of application assessment. During the application the company shall inform SZUTEST Konformitätsbewertungsstelle GmbH for the missing parts of the Technical Documentation together with a plan and declaration for completeness. SZUTEST Konformitätsbewertungsstelle GmbH shall take into consideration this information. If the application review identifies missing parts for the Technical Documentation, the company shall submit these documents not later than the imposed deadline by SZUTEST Konformitätsbewertungsstelle GmbH. If the required documentation will not be received within maximum 15 days after the imposed date, SZUTEST Konformitätsbewertungsstelle GmbH may cancel the application.

1.1.3. SZUTEST Konformitätsbewertungsstelle GmbH 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 shall perform the financial obligations provided in the agreement and submit all the documentation including specifically the Technical Documentation and Quality Management System Documentation to SZUTEST Konformitätsbewertungsstelle GmbH within maximum 15 days after the imposed date.

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

1.1.8. SZUTEST Konformitätsbewertungsstelle GmbH may contact the previous notified 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, SZUTEST Konformitätsbewertungsstelle GmbH may evaluate the application as a new application or else reject it.

1.1.9. After the agreement is executed, the documentation submitted by the company shall be reviewed and missing documents, if any, shall be determined and notified to the company. The company shall submit the missing documents within maximum 15 days after the imposed date. In the event that the documentation demanded is not provided by the company following the execution of the agreement, SZUTEST Konformitätsbewertungsstelle GmbH may cancel the agreement.

1.1.10. In case of conflict during the applications, the company shall be demanded to provide additional information and an application shall be filed to the Competent Authority in which the company or its authorized representative is placed and request information regarding the resolution of the conflict. In cases where the company has no registered place of business in the European Union and has not yet designated an authorized representative, the matter shall be referred to the competent authority in which the person or organization to be appointed as the authorized representative has its registered place of business. The costs arising from the application shall be paid by the company.

1.1.11. For several devices consultation to the authorities may be necessary. In this case the related expenses shall be covered by the company. The company may not hold SZUTEST Konformitätsbewertungsstelle GmbH for delays arising from the review conducted by the authorities.

1.1.12. Re-certification applications shall be filed, agreements shall be signed and the requirements of the agreements shall be fulfilled at least 12 months earlier than the expiry date of the certificates, If the application date is less than 12 months before the expiry date SZUTEST Konformitätsbewertungsstelle GmbH 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-certification as well as possible waiting periods for authority consultations.

1.2. Document Submission and Format of the Documents During Application

1.2.1. 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-germany.de domain. Only controlled copies of documents shall be shared with SZUTEST Konformitätsbewertungsstelle GmbH. Hard copies of Technical Documentation shall not be accepted. All submitted Technical Documentation and any related correspondence for application (including test results) shall be in English language.
As a general principle, if any of the information requested in some part of technical documentation is not available in English, the manufacturer

shall provide translations of documents (procedures, instructions, protocols, reports, etc.) in Technical Documentation.

1.2.2. Documents shall be provided as paginated, fully searchable bookmarked PDF files. Other software formats may be acceptable, but it may be result of delay while files converting to fully searchable bookmarked PDF format. PDF files and attachments shall not be file protected or locked. For scanning directly from printed pages shall utilise Optical Character Recognition (OCR).

1.2.3. File names of Technical Documentation shall be reflected the information covered within that part and documents.

2. TECHNICAL DOCUMENTATION PRE-REVIEWS

Initial assessments of the Regulation (EU) 2017/745 starts with technical documentation pre-reviews. At this stage the technical documentation is assessed in a limited duration to check, if proper documentation is available. The findings that are reported in this stage shall be closed within maximum 6 months.

3. AUDITS

3.1. Audits in the scope of the Regulation (EU) 2017/745 are one of the conformity assessment processes used for assessment of conformity with Regulation (EU) 2017/745 by evaluating the quality management system. During the audits the rules defined in Regulation (EU) 2017/745, EN ISO 13485 Annex-ZB and EN ISO/IEC 17011 shall be taken into consideration.

3.2. Audits shall also cover the company's own rules for certain applied scope.

3.3. Audits shall be performed according to SZUTEST Konformitätsbewertungsstelle GmbH procedures. Sampling method shall be used for audits.

3.4. Any nonconformity revealed in the audits shall be recorded by means of FR.MED.52 Finding Report. As part of the audits, the technical documentation prepared in line with the Regulation (EU) 2017/745 may be reviewed.

3.5. 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 Konformitätsbewertungsstelle GmbH are found effective.

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

3.6.1. Under normal conditions, the period granted for correcting nonconformities shall be maximum 4 month. If the company requests the relevant period to be extended with justifiable reasons, SZUTEST Konformitätsbewertungsstelle GmbH may determine to extend the relevant period. It shall be noted that the maximum extension period to be granted might be for 1 more month. In order to be able to request extra time in case of a reported major non-conformity the company shall have downgraded all major non-conformities to minor level within 4 months.

3.6.2. Conformity assessment activities documentation shall be in English Language. In case of different languages are spoken or some part of QMS documentation is not available in English in audits following actions shall be applied;

- An independent and impartial translator shall be assigned in the audits. In this situation, before assignment, FR.275 Confidentiality and Impartiality Commitment for Translators shall be signed by the translator and/or
- If the audit team includes a team member with the same native language as the company, that member can perform the audit without a translator.

3.7. Stage 1 Audits

3.7.1. 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 the Regulation (EU) 2017/745 Stage 2 audit.

3.7.2. Stage 1 audits shall be performed off-site according to the rules defined in the procedures. Head of audit team may demand the company to ensure conference call and provide video, images, etc. documents during the audits to be performed off-site.

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

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

3.8. Stage 2 Audits

3.8.1. These site 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 the Regulation (EU) 2017/745.

3.8.2. The company shall submit to SZUTEST Konformitätsbewertungsstelle GmbH the corrective and preventive actions for all nonconformities determined during Stage 2 audits.

3.9. Surveillance Audits

3.9.1. 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 Regulation (EU) 2017/745 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.

3.9.2. Some of the sections may be left outside the scope during surveillance audits but SZUTEST Konformitätsbewertungsstelle GmbH shall have assessed all the relevant points that are required to be assessed in a certification cycle which is 5 years.

3.9.3. The first surveillance audit shall be performed in maximum 12 months after the certification date. Other following routine surveillance audits shall be performed in maximum 12 months after the previous surveillance audit however, SZUTEST Konformitätsbewertungsstelle GmbH may choose to perform early surveillance audits.

3.9.4. Surveillance audits may cover testing where necessary. Samples may be taken from the company or market and tests may be performed either by using company's existing capabilities or by using 3rd party test laboratories.

3.10. Re-Certification Audits

3.10.1. 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 the Regulation (EU)2017/745 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.

3.10.2. All the necessary sections shall be audited under those audits.

3.10.3. If the last assessment task takes place less than 4 months before the expiration date of the certificates, the maximum time for closing non-conformities shall be limited to 15 working days before the expiration date of the certificates.

3.11. Transfer Audits

3.11.1. The transfer audits are those performed due to transfer applications. 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.

3.11.2. The company shall provide to SZUTEST Konformitätsbewertungsstelle GmbH the evidence of the corrective actions for all nonconformities independently from the nonconformity categories in transfer audits.

3.12. Scope Extension Audits

3.12.1. When the company intends to extend the scope of the existing certificates, if SZUTEST Konformitätsbewertungsstelle GmbH decides that the expansion requires on-site audit, such audits shall be performed.

3.12.2. New agreements may be executed for scope extensions.

3.13. Change Audits

3.13.1. 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 Regulation (EU) 2017/745. The company shall inform SZUTEST Konformitätsbewertungsstelle GmbH for all of the changes that may affect the quality management system.

3.14. Unannounced Site Audits

3.14.1. The purpose of unannounced site audits is to evaluate the conditions related to product safety by means of a risk-based audit approach.

3.14.2. Unannounced site audit is only a part of Regulation (EU) 2017/745 Product Conformity Assessments.

3.14.3. The company shall not be informed of unannounced site audits.

3.14.4. The frequency of unannounced site audits shall be determined by SZUTEST Konformitätsbewertungsstelle GmbH to be increased in case of necessity.

3.14.5. 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 shall execute agreements with critical suppliers about unannounced site audits.

3.14.6. Under unannounced site audits, samples may be taken from the company or market and tests may be performed either by using company's existing capabilities or by using 3rd party test laboratories.

3.14.7. The flow of unannounced site audits is different from that of the routine audits and this flow shall be declared by SZUTEST Konformitätsbewertungsstelle GmbH during the unannounced site audits. No audit plan shall be provided in advance.

3.14.8. The company shall inform SZUTEST Konformitätsbewertungsstelle GmbH for annual shut downs and non-manufacture periods for all applicable sites including the ones for critical suppliers. If the unannounced site audit team cannot reach to the site out of these periods the unannounced site audit fee and ,audit team expenses shall still be invoiced to the company.

3.15. Critical Supplier Audits

3.15.1. 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.

3.15.2. Any nonconformity determined in relation to critical suppliers shall be reported to the company and not to the critical supplier.

3.15.3. The company shall be responsible for obtaining necessary permits for the audits to be conducted in critical suppliers and therefore, the company shall execute agreements about routine audits with the critical suppliers.

3.16. Follow-up Audits

3.16.1. Follow-up audits refer to the 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.

3.16.2. The decision for a follow-up audit may be made for not only routine audits but also as certainly the correction of nonconformities determined as a result of the internal controls performed by SZUTEST Konformitätsbewertungsstelle GmbH, checking the activities performed after suspension of the certificates, checking the nonconformities determined by the Competent Authorities, Authorities Responsible for Notified Bodies and EU Commission and checking vigilance system and post market surveillance data.

3.16.3. Even if the audit team does not recommend any follow-up audit, SZUTEST Konformitätsbewertungsstelle GmbH certification committee may decide to perform a follow-up audit for checking the nonconformity conditions.

3.16.4. The charges for the follow-up audit shall be calculated according to SZUTEST Konformitätsbewertungsstelle GmbH pricing procedures and invoiced separately.

3.17. Hybrid Audits and Entirely Remote Audits

3.17.1 Hybrid audit is the method that includes both remote and on-site activities to assess compliance with MDR.

3.17.2 Entirely remote audit is an audit performed remotely using electronic means and no on-site activity plans with any auditor.

3.17.3 All decisions on performing, stopping, canceling, invalidating, and repeating Hybrid Audits / Entirely Remote Audits shall be going to be taken solely by SZUTEST Konformitätsbewertungsstelle GmbH.

3.17.4. All required IT, network, and software arrangements shall be initiated by the company, prior to starting Hybrid Audit / Entirely Remote Audit and the formal audit durations shall not be spent on these preparations and arrangements.

3.17.5 SZUTEST Konformitätsbewertungsstelle GmbH may demand testing on IT, network, and software arrangements prior to the Hybrid Audit / Entirely Remote Audit.

3.17.6 Expenses due to stopping, cancelling, invalidating the Hybrid Audit shall be paid by the Company.

4. TECHNICAL DOCUMENTATION REVIEWS

4.1. One of the product conformity assessment processes under The Regulation (EU) 2017/745 is the review of Technical Documentations.

4.2. Clinical assessment is included in the scope of Technical Documentation review activities.

4.3. Technical Documentation 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 Documentations.

4.4. Technical Documentation review activities shall be performed off-site.

4.5. Technical Documentation review activities may be performed before or after the site audits. SZUTEST Konformitätsbewertungsstelle GmbH may demand the Technical Documentation review nonconformities to be united with the nonconformities determined at site audits in case of necessity.

5. PROCESSES AFTER NONCONFORMITY REPORT

5.1. The nonconformities determined by SZUTEST Konformitätsbewertungsstelle GmbH 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 but the company may file a written appeal to the nonconformities that are determined.

5.2. Based on the finding reports, the company shall fill in FR.MED.53 Nonconformity Follow-up Report and submit it to SZUTEST Konformitätsbewertungsstelle GmbH within maximum 10 working 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 Konformitätsbewertungsstelle GmbH procedures.

5.3. FR.MED.53 Nonconformity Follow-up Report provided by the company shall be assessed by the assessment team as a result of which either it shall be approved or correction shall be demanded. The time spent on submitting, evaluation and approval of FR.MED.53 Nonconformity Follow-up Report shall be included in the maximum available timeframe allowed for effectively closing the non-conformities.

5.4. 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.

5.5. In case the closing of corrective actions is required to be approved by SZUTEST Konformitätsbewertungsstelle GmbH, the company shall submit the evidence of corrective actions to SZUTEST Konformitätsbewertungsstelle GmbH within defined deadline. The corrective actions shall be assessed by SZUTEST Konformitätsbewertungsstelle GmbH and as a result of which they shall be either approved or rejected.

6. CERTIFICATION COMMITTEE

6.1. The certification committee established by SZUTEST Konformitätsbewertungsstelle GmbH shall make a decision on product conformity assessment activities.

6.2. 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.

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

6.4. The certification committee may decrease the validity period of certificates based on technical concerns.

6.5. Committee members make a decision within the framework of the matters stated below;

- based on the assessment documentation and additional information available, whether the requirements of Regulation (EU) 2017/745 are fulfilled,
- based on the results of its assessment of the clinical evaluation and risk management, whether the post-market surveillance plan, including the PMCF plan, is adequate,
- decide on specific milestones for further review by SZUTEST Konformitätsbewertungsstelle GmbH of the up-to-date clinical evaluation,
- decide whether specific conditions or provisions need to be defined for the certification,
- decide, based on the novelty, risk classification, clinical evaluation and conclusions from the risk analysis of the device, on a period of certification not exceeding five years.
- decide the acceptability of reports based on the majority of details of the level of justifications provided by the assessment team.
- whether special procedures of Regulation (EU) 2017/745 such as consultation procedures are performed correctly,

7. ISSUING CERTIFICATES

7.1. After the assessment activities result positively, SZUTEST Konformitätsbewertungsstelle GmbH shall issue, EU Certificate according to the application in the name of the company.

7.2. SZUTEST Konformitätsbewertungsstelle GmbH shall decide how many certificates to issue. SZUTEST Konformitätsbewertungsstelle GmbH issue a certificate or certificates in accordance with the minimum requirements laid down in Annex XII Regulation (EU) 2017/745 for a period of validity not exceeding five years and shall indicate whether there are specific conditions or limitations associated with the certification. Specific conditions or limitations shall be issued on certificates.

SZUTEST Konformitätsbewertungsstelle GmbH shall issue the certificate(s) only for one company and shall not issue certificate(s) covering multiple entities. The name and address of the manufacturer included in the certificate shall be the same as that registered in the electronic system (EUDAMED) referred to in Article 30 of Regulation (EU) 2017/745.

7.3. The issued certificates and information about their validity shall be published on www.szutest-germany.de .

7.4. All the details about the Regulation (EU) 2017/745 certificates shall be disclosed to Competent Authority. Certificates shall be entered electronic system referred to in Article 57 of Regulation (EU) 2017/745.

7.5. SZUTEST Konformitätsbewertungsstelle GmbH 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.

7.6. Certificates shall be drawn up in English languages. SZUTEST Konformitätsbewertungsstelle GmbH shall issue validity of certificates as 5 years.

7.7. Each certificate shall refer to only one conformity assessment route.

7.8. The scope of the certificates shall unambiguously identify the device or devices covered:

a. EU technical documentation assessment certificates shall include a clear identification, including the name, model and type, of the device or devices, the intended purpose, as included by the manufacturer in the instructions for use and in relation to which the device has been assessed in the conformity assessment route, risk classification and the Basic UDI-DI as referred to in Article 27(6) 30 of Regulation (EU) 2017/745.
b. EU quality management system certificates and EU quality assurance certificates shall include the identification of the devices or groups of devices, the risk classification, and the intended purpose for class IIb devices.

7.9. SZUTEST Konformitätsbewertungsstelle GmbH shall be able to demonstrate on request, which (individual) devices are covered by the certificate. SZUTEST Konformitätsbewertungsstelle GmbH shall have a system that enables the determination of the devices, including their classification, covered by the certificate with the app software system.

7.10. Certificates shall contain, if applicable, a note that, for the placing on the market of the device or devices it covers, another certificate issued in accordance with this Regulation is required.

7.11. EU quality management system certificates and EU quality assurance certificates for class I devices for which the involvement of the Notified Body is required pursuant to Article 52(7) shall include a statement that the evaluation by the SZUTEST Konformitätsbewertungsstelle GmbH of the quality management

system was limited to the aspects required under that paragraph. For sterile systems and procedure packs the certificates shall contain a statement that the evaluation is restricted to aspects of the sterilization procedure for ensuring sterility until the sterile package is opened or damaged.

7.12. Where a certificate is supplemented, modified or reissued, the new certificate shall contain a reference to the preceding certificate and its date of issue with identification of the changes.

8. 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 Konformitätsbewertungsstelle GmbH procedures, undertake the actions determined by SZUTEST Konformitätsbewertungsstelle GmbH, notify any substantial 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 Konformitätsbewertungsstelle GmbH is entitled to withdraw the certificates for each condition that creates basis for suspension according to project risks.

8.1. Suspension of Certificates

8.1.1. SZUTEST Konformitätsbewertungsstelle GmbH may suspend the issued certificates when the following conditions are applicable:

- Failure to submit an action plan for the nonconformities determined as a result of the audits and technical documentation 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 the functionality of the 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 Konformitätsbewertungsstelle GmbH brands and logos,
- Conditions that may discredit product safety, product safety issues or lack of insufficient clinical evidence and pose potential threat on human health and safety,
- Failure of the customer to perform its financial obligations completely,
- Failure to inform SZUTEST Konformitätsbewertungsstelle GmbH of substantial changes,
- Failure of the company to inform SZUTEST Konformitätsbewertungsstelle GmbH of the vigilance system records, recall decisions, warning cases, findings of competent authorities, critical post market surveillance findings,
- The vigilance system records, recall decisions, warning cases, critical findings and notifications of BfArM and other competent authorities related products, critical post market surveillance findings related products,
- Discrepancy between the information declared in the Technical Documentation and practice,
- Failure of the company to authorize SZUTEST Konformitätsbewertungsstelle GmbH personnel to visit all the sites in all audits including unannounced site audits in addition to restricting access to documentation, preventing the personnel from conducting detailed queries, abandoning the personnel, failing to take sufficient safety measures for the personnel, keeping the personnel waiting for a long time, applying pressure on the personnel, threatening the personnel,
- Determination of the fact that the company has marketed the products having the reference number of another notified body after SZUTEST Konformitätsbewertungsstelle GmbH has issued a certificate with the same scope without receiving consent from SZUTEST Konformitätsbewertungsstelle GmbH.

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

8.1.3. 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.

8.1.4. Suspension of Regulation (EU) 2017/745 certificates shall be notified to the competent authorities through EUDAMED or through other applicable ways until the EUDAMED is fully functional.

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

8.2. Withdrawing or Restricting the Scope of Certificates

8.2.1. The scope of the certificates may be restricted if the company fails to perform the requirements specified in Regulation (EU) 2017/745 and SZUTEST Konformitätsbewertungsstelle GmbH documentation with respect to matters related to only a specific part of the certified scope.

8.2.2. SZUTEST Konformitätsbewertungsstelle GmbH may withdraw the certificates if the company fail to perform sufficient and effective correction for the suspended certificates during the period of suspension.

8.2.3. SZUTEST Konformitätsbewertungsstelle GmbH may directly withdraw without a suspension period the certificates when the following conditions are applicable:

- Failure of the company to perform its financial obligations,
- Repeating failures to the contractual obligations
- Direct (intentional) violation of the contract terms.
- Determination of the fact that the company repeatedly commits mistakes leading to suspension,
- Repeating the same major non-conformities which require suspension
- If the company declares that it shall not fulfill any requirement,
- If the company demands withdrawal of the certificate of its own will.
- If the company gives incorrect, falsified, and misleading information,
- Use of CE marking in products not certified by SZUTEST Konformitätsbewertungsstelle GmbH.
- The vigilance system records, recall decisions, warning cases, critical findings and notifications of BfArM and other competent authorities related to public health and safety, critical post market surveillance findings related products**.**
- Declaring or performing acts that disallow SZUTEST Konformitätsbewertungsstelle GmbH to execute conformity assessment tasks.
- Obvious intentional acts which may decrease the reputation of SZUTEST Konformitätsbewertungsstelle GmbH.

8.2.4. Whenever the certificates are withdrawn and restricted in terms of scope, the company shall be informed of this fact in writing. Withdrawal of Regulation (EU) 2017/745 certificates shall be notified to the competent authorities through EUDAMED or through other applicable ways until the EUDAMED is fully functional.

8.2.5. If the company persists in using the certificates, CE marking, SZUTEST Konformitätsbewertungsstelle GmbH brand and logos after withdrawal, SZUTEST Konformitätsbewertungsstelle GmbH may take legal action.

9. RIGHTS AND OBLIGATIONS OF SZUTEST KONFORMITÄTSBEWERTUNGSSTELLE GMBH

9.1 SZUTEST Konformitätsbewertungsstelle GmbH and all the employees shall keep confidential all kinds of 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 Competent Authority, Authorities Responsible for notified bodies European Commission or courts upon demand. If SZUTEST Konformitätsbewertungsstelle GmbH becomes obliged to give information to third parties due to legal reasons, it shall inform the relevant company unless it is legally impermissible.

9.2 SZUTEST Konformitätsbewertungsstelle GmbH shall perform all of the activities without racial, language and religious segregation.

9.3 As part of its duties, SZUTEST Konformitätsbewertungsstelle GmbH has signed a Confidentiality and Impartiality Commitment with its employees.

9.4 SZUTEST Konformitätsbewertungsstelle GmbH 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.

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

9.6 SZUTEST Konformitätsbewertungsstelle GmbH shall be responsible for announcing the companies receiving certificates and becoming subject to suspension and withdrawal of certificates on its web page.

9.7 If SZUTEST Konformitätsbewertungsstelle GmbH, in its own discretion, waives from acting as a notified body or its activities are suspended by the relevant Authorities Responsible for notified bodies, the documentation of the company shall be submitted to a notified body to be determined by the company. In that case, the conditions of the new notified body shall be valid for certification and SZUTEST Konformitätsbewertungsstelle GmbH shall not have any right of disposition on those conditions.

9.8 SZUTEST Konformitätsbewertungsstelle GmbH undertakes to comply with the documentation of the Competent Authority, Authorities Responsible for notified bodies, European Commission concerning notified bodies and certification bodies in addition to the abovementioned requirements.

9.9 SZUTEST Konformitätsbewertungsstelle GmbH may amend the terms of the agreement or cancel the agreement according to the outcome of the application assessment process.

9.10 SZUTEST Konformitätsbewertungsstelle GmbH may cancel the agreement in case the company fails to fulfill any contractual obligation.

9.11 SZUTEST Konformitätsbewertungsstelle GmbH 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 technical documentation review.

9.12 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 Konformitätsbewertungsstelle GmbH may alter the audit period and charges according to its procedures and issue invoices to the company for the difference.

9.13 SZUTEST Konformitätsbewertungsstelle GmbH may subcontract the product conformity assessment processes partially in case of necessity. The details of the activities to be subcontracted and the subcontractor shall be shared with the company and unless any appeal 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 Konformitätsbewertungsstelle GmbH shall remain responsible for the certification decision as well as all the relevant activities.

9.14 SZUTEST Konformitätsbewertungsstelle GmbH 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 Konformitätsbewertungsstelle GmbH may cancel the agreement unilaterally. SZUTEST Konformitätsbewertungsstelle GmbH will publish current available fees in www.szutest-germany.de.

9.15 If the company wishes to cancel the agreement during the performance of any service including off-site 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.

9.16 If the company make a request to transfer of valid certificates issued by SZUTEST Konformitätsbewertungsstelle GmbH to another Notified Body, the certificates are withdrawn by the Certification Committee and the contract is terminated on the transfer date or the expiry date of the validity period of certificates, which one is earlier. SZUTEST Konformitätsbewertungsstelle GmbH shall submit all relevant documentation to Incoming Notified Body. In this situation, it shall be possible to issue an invoice to the company as abovementioned.

9.17 It may demand the company to recall products in case of any effect on human health and product safety.

9.18 It may conduct extra off-site review, follow-up audit or unannounced site audit according to the findings determined through the internal audits of SZUTEST Konformitätsbewertungsstelle GmbH also the audits performed by European Commission, Competent Authority and Authorities Responsible for notified bodies.

9.19 It may cancel the agreement unless the company provides the necessary documentation within 15 days from the signature of the agreement.

9.20 SZUTEST Konformitätsbewertungsstelle GmbH may demand interpreter or all kinds of document translation in case of the assessment team including the committee members does not know the local language of the company.

9.21 SZUTEST Konformitätsbewertungsstelle GmbH shall keep all documentation that needs to be uploaded to EUDAMED, according to PR.02 Quality Records Procedure, until EUDAMED is fully functional. When EUDAMED becomes functional, all necessary documentation shall be uploaded to the EUDAMED database by Committee and Competent Authority Communication Coordinator according to PR.MED.06 Procedure for Legal Notification Consultation Coordination and Communication for Regulation (EU) 2017/745. If BfArM or other authorities have any notifications, related to documents that shall be uploaded to EUDAMED, SZUTEST Konformitätsbewertungsstelle GmbH shall apply its notifications in its Quality Management System until EUDAMED is functional.

9.22 Surveillance activities and post-certification monitoring
SZUTEST Konformitätsbewertungsstelle GmbH in question shall, upon receipt of information about vigilance cases from a manufacturer or competent authorities, decide which of the following options to apply:

- not to take action on the basis that the vigilance case is clearly not related to the certification granted,
- observe the manufacturer's and competent authority's activities and the results of the manufacturer's investigation so as to determine whether the certification granted is at risk or whether adequate corrective action has been taken,
- perform extraordinary surveillance measures, such as document reviews, short-notice or unannounced site audits, and product testing, where it is likely that the certification granted is at risk,
- increase the frequency of surveillance audits,
- review specific products or processes on the occasion of the next audit of the manufacturer, or
- take any other relevant measure related to situations
- where necessary, impose specific restrictions on the relevant certificate, or suspend or withdraw.

9.23 If SZUTEST Konformitätsbewertungsstelle GmbH decides to cease its conformity assessment activities, it shall inform the ZLG and

the certified manufacturers as soon as possible and in the case of a planned cessation not later than one year before ceasing its activities. SZUTEST Konformitätsbewertungsstelle GmbH shall first communicate with ZLG for the period for which the certificates will remain valid after ceasing the activities. Once the roadmap is finalized SZUTEST Konformitätsbewertungsstelle GmbH shall inform its manufacturers. The certificates may remain valid for a temporary period of 9 months after cessation of SZUTEST Konformitätsbewertungsstelle GmbH's activities on condition that another Notified Body has confirmed in writing that it will assume responsibilities for the devices covered by those certificates

9.24 Where SZUTEST Konformitätsbewertungsstelle GmbH's designation has been suspended, restricted, or fully or partially withdrawn, it shall inform the manufacturers concerned at the latest within 10 days.

9.25 If SZUTEST Konformitätsbewertungsstelle GmbH decides to take over the certificates of a Notified Body which ceases its activities, it shall confirm in writing to the relevant competent authorities, that it will assume responsibilities for the devices covered by those certificates.

9.26 If SZUTEST Konformitätsbewertungsstelle GmbH decides to take over the certificates of a withdrawn Notified Body, ZLG or SZUTEST Konformitätsbewertungsstelle GmbH shall immediately inform the Commission, the other Member States and the other notified bodies thereof. SZUTEST Konformitätsbewertungsstelle GmbH shall confirm in writing, to the relevant competent authorities, that it will assume immediate responsibilities for the devices and will have completed assessment of them within 12 months of the withdrawal of the designation.

10. RIGHTS AND OBLIGATIONS OF THE COMPANY

10.1. The company shall provide correct information during the entire assessment process including application and accept all the sanctions that shall arise from failure to fulfill this obligation.

10.2. The company shall be obliged to comply with all kinds of written information and instructions received from SZUTEST Konformitätsbewertungsstelle GmbH concerning the operation of the management system and product conformity assessment under the relevant Standard and Regulation.

10.3. 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, making 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.

10.4. Observers, guides and candidate auditors/experts may accompany SZUTEST Konformitätsbewertungsstelle GmbH 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 or the Authorities Responsible for notified bodies, EU Commission or Competent Authorities. 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.

10.5. The company shall be obliged to provide all kinds of written and verbal information required for the audit to the relevant people including SZUTEST Konformitätsbewertungsstelle GmbH personnel and to the representatives of Authorities Responsible for notified bodies, EU Commission or Competent Authorities.

10.6. The company shall submit plans for changes that can affect SZUTEST Konformitätsbewertungsstelle GmbH's audit and technical documentation review tasks, data presented on the certificates and agreements, data used for SZUTEST Konformitätsbewertungsstelle GmbH' planning activities, legal changes, critical personnel changes and substantial changes in the approved quality management system or systems or to the product-range covered, the approved design of a device, the intended use of or claims made for the device and any substance incorporated in or utilised for the manufacturing of a device and being subject to the specific procedures in accordance with Section 4.5.6 of Annex VII of MDR in 5 business days. The submission shall include a plan for changes. The changes shall not be implemented prior to the review of SZUTEST Konformitätsbewertungsstelle GmbH. For reporting substantial changes, the company shall use FR.MED.51 Change Notification Form available in www.szutest-germany.de. This form may include some examples for changes to be reported but it should be noted that the items listed in FR.MED.51 Change Notification Form is not exhaustive and changes which may not fall in defined types shall be reported as selecting "other" in this form. If the company is not sure whether a change need to be reported to SZUTEST Konformitätsbewertungsstelle GmbH or not, it shall report anyway.
Examples of main change topics to be reported (not exhaustive)

- 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, relocation, new locations,
- Changes in critical suppliers and subcontractors,
- Changes in critical personnel,
- Change of the scope of the approved quality management system or systems or to the product-range covered,
- Changes in the QMS structure and procedures for MDR compliance,
- Changes in the validated processes,
- Changes in the controlled environments,
- Changes in EU Authorized Representative,
- Changes to the EU-type examination test and certificates,
- Change of the intended use of or claims made for the device,
- Change of the approved performance of the device,
- Change in the critical components
- Change in the variants
- Change of any substance incorporated in or utilised for the manufacturing of a device and being subject to the specific procedures in accordance with specific procedures of the Regulation (EU) 2017/745.

The company shall immediately inform SZUTEST Konformitätsbewertungsstelle GmbH of any change that may occur in technical documentation after certification and the product shall not be marketed without receiving consent from SZUTEST Konformitätsbewertungsstelle GmbH.

10.7. The company shall be obliged to inform SZUTEST Konformitätsbewertungsstelle GmbH of vigilance system records, incidents, recall decisions, warning cases, findings of competent authorities, and critical post market surveillance findings immediately and not later than business 5 days. Timescale for incident reporting shall be applied regarding the requirements of Regulation (EU) 2017/745 by the company. SZUTEST Konformitätsbewertungsstelle GmbH shall evaluate the company about vigilance situations and decide which of the following options to apply; not to take action on the basis that the vigilance case is clearly not related to the certification granted, observe the company's and competent authority's activities and the results of the company's evaluation so as to determine whether the certification granted is at risk or whether adequate corrective action has been taken, perform extraordinary surveillance measures, such as document reviews, short-notice or unannounced site audits and product testing, where it is likely that the certification granted is at risk, increase the frequency of surveillance audits, review specific products or processes on the occasion of the next audit of the company or take any other relevant measure related situations.

10.8. The company shall be obliged to record the appeals or complaints posed by the customer or third parties under the certificate

and communicate them to SZUTEST Konformitätsbewertungsstelle GmbH.

10.9. The company shall be obliged to inform SZUTEST Konformitätsbewertungsstelle GmbH and competent authorities for vigilances cases of the products certified by SZUTEST Konformitätsbewertungsstelle GmbH according to the Regulation (EU) 2017/745 after these devices enter into the market.

The company shall fulfill the requirements of Regulation (EU)2017/745 Article 87, 88 and 89 for Vigilance.

The company shall be responsible for notifying SZUTEST Konformitätsbewertungsstelle GmbH and the relevant Competent Authorities for any Serious Incident, Field Safety Corrective Action, Field Safety Notice, Periodic Summary Reports, Trend Reports, Recalls and other competent authority requests within the defined periods in (EU)2017/745 Article 87, 88 and 89.

If, after becoming aware of a potentially reportable incident, the company is uncertain about whether the incident is reportable, it shall nevertheless submit a report within the required timeframe. This includes cases where the company does not retrieve objective evidence or information about the non-existence of a causal relationship between the incident and the device.

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

The company shall report its field safety corrective action without delay before executing the action, except for emergencies that require immediate field safety corrective action.

If the company considers that the incident is not a serious incident or is an “expected undesirable side effect” that will be covered by trend reporting in accordance with Regulation (EU)2017/745 Article 88, it shall submit an explanatory statement to SZUTEST Konformitätsbewertungsstelle GmbH and the relevant Competent Authorities.

10.10. The company shall be obliged to submit the Technical Documentation in executed, approved, and controlled copy to SZUTEST Konformitätsbewertungsstelle GmbH. This rule shall apply to the documentation to be submitted in digital media. All of the documentation to be submitted shall be in English.

10.11. The company shall be obliged to preserve all the records related to the activities performed by SZUTEST Konformitätsbewertungsstelle GmbH (agreement, report, CAPA records etc.) during the validity period of the certificate unless otherwise specified in the relevant directive or legal regulation.

10.12. The company shall be obliged to submit all the papers and documents required for application to SZUTEST Konformitätsbewertungsstelle GmbH in a timely manner.

10.13. SZUTEST Konformitätsbewertungsstelle GmbH may conduct additional audits for a certain charge when required for evaluating the impact of the changes on the system or product.

10.14. The company shall perform the requirements of important changes that may occur in the assessment system of SZUTEST Konformitätsbewertungsstelle GmbH (concerning standard procedures or rules) within the transition period that is notified to it.

10.15. The company shall be obliged to comply with the Certificate and CE Mark Usage Procedure, this text (Medical Devices General Terms) and similar SZUTEST Konformitätsbewertungsstelle GmbH procedures of which updated versions are available at www.szutest-germany.de and keep up with their updated versions.

10.16. 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 regulation.

10.17. The company shall be obliged to discontinue using SZUTEST Konformitätsbewertungsstelle GmbH brand and notified the 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 Konformitätsbewertungsstelle GmbH when necessary.

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

10.19. The company may submit its complaints regarding SZUTEST Konformitätsbewertungsstelle GmbH conformity assessment activities and appeals to its decisions as mentioned in the PR.04 Complaints and Appeals Assessment Procedure. SZUTEST Konformitätsbewertungsstelle GmbH makes the necessary assessment within the scope of the PR.04 Complaints and Appeals Assessment Procedure and informs the company. The company has the right to appeal to SZUTEST Konformitätsbewertungsstelle GmbH 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, the firm may apply to the relevant legal authority. If SZUTEST Konformitätsbewertungsstelle GmbH is in excess of the period granted for resolving the appeal as indicated in PR.04 Complaints and Appeals Assessment Procedure, the company may file an application to the relevant legal authority in the same manner. The company may appeal to a decision taken by SZUTEST Konformitätsbewertungsstelle GmbH regarding itself within 10 business days by providing justifications for the appeal. The company shall assume the expenses incurred for the experts, committee to be established for complaints and objections and similar costs.

10.20. 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 Regulation (EU) 2017/745.

10.21. 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 shall indicate the justifications for the invalidity.

10.22. The company shall be obliged to inform SZUTEST Konformitätsbewertungsstelle GmbH of the reason for rejection if any of its applications have 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).

10.23. The company shall be responsible for designing and manufacturing the product/products in line with the essential or other legal requirements specified in the relevant European harmonized standards, Common Specifications 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 requirement of the Regulation (EU) 2017/745.

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

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

10.26. The company accepts and make payment for the invoices issued by SZUTEST Konformitätsbewertungsstelle GmbH for the duly completed services even if the result is negative.

10.27. The cancellation of the agreement shall not eliminate the obligation of the company to pay for the services. If the agreement is cancelled by the company the amount paid up to the termination date shall not be refunded and shall be considered as termination fee.

10.28. The company shall serve a written notice if it intends to terminate the agreement.

10.29. The company shall make timely payments.

10.30. The company shall 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 Konformitätsbewertungsstelle GmbH performs any service.

10.31. The company shall submit all the declarations and documents required by SZUTEST Konformitätsbewertungsstelle GmbH within maximum of 15 days if the company intends to transfer any certificate issued by SZUTEST Konformitätsbewertungsstelle GmbH to another notified body.

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

10.33. If the company intends to transfer any certificate issued by SZUTEST Konformitätsbewertungsstelle GmbH to another notified body, the company shall inform SZUTEST Konformitätsbewertungsstelle GmbH at least 2 months before. The company shall submit all necessary information and documentation for transfer assessment. The company shall cover the cost of the relevant committee, experts and similar other costs to be incurred in relation to the transfer assessment.

10.34. In case of any such certificate transfer demand, it shall accept that SZUTEST Konformitätsbewertungsstelle GmbH may contact the existing notified body. It shall also agree that SZUTEST Konformitätsbewertungsstelle GmbH may cancel the agreement during the application assessment stage according to the information given by the notified body. If the notified body does not give any response within maximum 15 days, SZUTEST Konformitätsbewertungsstelle GmbH may suspend the certificate transfer process**.**

10.35. The company shall not implement any substantial changes without receiving consent from SZUTEST Konformitätsbewertungsstelle GmbH.

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

10.37. The company shall authorize SZUTEST Konformitätsbewertungsstelle GmbH personnel 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.

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

10.39. The company shall agree to and allow all the audits to be conducted by SZUTEST Konformitätsbewertungsstelle GmbH at the site of the company including unannounced site audits.

10.40. The company shall give consent to all the audits, including unannounced site audits and witness audits, to be conducted by Authorities Responsible for notified bodies, 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 Konformitätsbewertungsstelle GmbH.

10.41. The company shall 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 Konformitätsbewertungsstelle GmbH and witnessed by the representatives of Authorities Responsible for Notified Bodies, European Commission and other Competent Authorities concerning the critical suppliers and subcontractors. The company shall accept the sanctions to be applicable in case critical suppliers and subcontractors do not give consent to such audits.

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

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

10.44. 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 Konformitätsbewertungsstelle GmbH as well as the accompanying employees. The necessary equipment shall be provided by the company.

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

10.46. The company shall not file an application to more than one Notified Body for the same products simultaneously.

10.47. The company shall use the brand, logo and CE marking of SZUTEST Konformitätsbewertungsstelle GmbH with due regard for the rules determined by SZUTEST Konformitätsbewertungsstelle GmbH. It shall not use the brand, logo, and CE marking in case of suspension or withdrawal of certificates.

10.48. 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 Konformitätsbewertungsstelle GmbH responsible for that.

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

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

10.51. The company shall not market any products with the identification number of another notified body without receiving consent from SZUTEST Konformitätsbewertungsstelle GmbH after SZUTEST Konformitätsbewertungsstelle GmbH issues a certificate with the same scope.

10.52. The company shall not undertake the manufacture and sale of products with CE marking when the certificate is subject to suspension and withdrawal or its validity period has expired.

10.53. The company shall not use CE marking for products not certified by SZUTEST Konformitätsbewertungsstelle GmbH.

10.54. The company shall accept the findings of the extra off-site review, committee review, follow-up audit, or unannounced site audit according to the findings determined through the SZUTEST Konformitätsbewertungsstelle GmbH internal audits and audits conducted by the European Commission and Competent Authorities and Authorities Responsible for Notified Bodies and make corrections in defined due time.

10.55. The company shall cover the cost of the relevant committee, experts and similar other costs to be incurred in relation to the appeals.

10.56. Companies shall inform SZUTEST Konformitätsbewertungsstelle GmbH about all the substantial changes related with their critical suppliers, including the changes in the critical supplier's certificates in maximum of 5 business days**.**

10.57. SZUTEST Konformitätsbewertungsstelle GmbH shall not make any refund in case of delay of a responsibility of the company such as technical documentation sending, nonconformity closure, etc. and having caused a delay in any responsibility while carrying out the projects which may cause SZUTEST Konformitätsbewertungsstelle GmbH not to be able to allocate efficient resource planning and effective assessment.

10.58. The company shall create all applicable documents according to Regulation (EU) 2017/745, regardless of whether EUDAMED is functional in whole or in part, and submit them to SZUTEST Konformitätsbewertungsstelle GmbH. Once EUDAMED is actively working, all necessary documents shall be uploaded to the EUDAMED.

10.59. When complying with imposed deadlines, the company shall consider the availability of SZUTEST Konformitätsbewertungsstelle GmbH resources and the time needed for planning. The company shall not make SZUTEST Konformitätsbewertungsstelle GmbH responsible for the inability to allocate necessary resources when the response is provided closer to the ending deadlines and which may effect the validity of the certificates. The company shall be responsible to communicate and confirm with SZUTEST Konformitätsbewertungsstelle GmbH to check the time needed for resource allocation and planning when considering the response time.

10.59. Where a company certified by MDD Notified Body wants to transfer the surveillance requirements of its certified products to SZUTEST Konformitätsbewertungsstelle GmbH, applications for surveillance assessment transfer shall be received only if the following issues are fulfilled.
In accordance to the Article 120 (3c) Regulation (EU) 2017/745, in cases 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 SZUTEST Konformitätsbewertungsstelle GmbH for conformity assessment of the certified device or a device intended to replace this device and no later than 26 September 2024, SZUTEST Konformitätsbewertungsstelle GmbH and the manufacturer shall sign a written agreement under the second subparagraph of Section 4.3 of MDR Annex VII.

10.60. SZUTEST Konformitätsbewertungsstelle GmbH 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 Article 10.64.

10.61. The surveillance assessment transfer application of the manufacturer shall be received by the Sales Unit with the FR.MED.01 Annex 4-Information Related to Transfer of Surveillance Assessments Form and approved proof documents requested in this annex until 26 May 2024 and that SZUTEST Konformitätsbewertungsstelle GmbH and the manufacturer shall sign a written agreement specified in Article 10.59 (e), no later than 26 September 2024. At the same time, the Confirmation Letter shall be published by SZUTEST Konformitätsbewertungsstelle GmbH and "Manufacturer Declaration" shall be requested from the manufacturer.

10.62. After the necessary documents are completed, planning is made according to the PR.MED.25 Medical Devices Audit and File Review Planning Procedure, and the final decision on the appropriateness of the transfer shall be made according to the PR.MED.27 Medical Devices Product Conformity Assessment Procedure. .

10.63. When necessary, approvals are obtained**,** Sales Unit shall document - FR.MED.90 (EU) 2017/745 Regulation Product Conformity Assessment Agreement, FR.MED.63 Medical Devices General Terms, FR.MED.202 Transfer Agreement For Surveillance Of Legacy Devices and FR.MED.65 Duration and Fee Calculation Form.

10.64. In accordance to the Article 120 (3a) (EU) 2017/745 Regulation, 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 WET devices (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.

10.65. In surveillance assessments for devices referred to in paragraphs 10.59(a) and (b); the requirements of the MDR on post-market surveillance, market surveillance and surveillance, vigilance, registration of economic operators and devices apply instead of the corresponding requirements in Directive 93/42/EC.

10.66. Until 26 September 2024, unless the company agrees with SZUTEST Konformitätsbewertungsstelle GmbH that it will carry out the surveillance specified in Article 10.60, MDD Notified Body 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.

10.67. No later than 26 September 2024, SZUTEST Konformitätsbewertungsstelle GmbH that has signed FR.MED.90 (EU) 2017/745 Regulation Product Conformity Assessment Agreement 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.

10.68. Arrangements for the transfer of surveillance from MDD Notified Body to the SZUTEST Konformitätsbewertungsstelle GmbH shall be clearly defined in an agreement between the COMPANY, MDD Notified Body, and SZUTEST Konformitätsbewertungsstelle GmbH where applicable. SZUTEST Konformitätsbewertungsstelle GmbH shall not be responsible for the conformity assessment activities carried out by MDD Notified Body.

10.69. Regulation (EU) 2017/745 and amendments of the Regulation (EU) 2023/607, the man/day fee is determined according to the resources to be spent in surveillance transfers.

11. TRANSITIONAL PROVISIONS FOR CERTAIN PRODUCTS WITHOUT AN INTENDED MEDICAL PURPOSE LISTED IN ANNEX XVI DEVICES

Commission Implementing Regulation (EU) 2023/1194 of 20 June 2023 amending Implementing Regulation (EU) 2022/2346 as regards the transitional provisions for certain products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council is published. In accordance to this implementing regulation, 31 December 2029 is the end of the transition period for Annex XVI products which require a clinical investigation. With regards to notified body agreements, the deadline to have a written agreement in place with a notified body for these products is 1 January 2028. Annex XVI products that do not require a clinical investigation, the end of the transition period is 31 December 2028. With regards to notified body agreements, the deadline to have a written agreement in place with a notified body for these products is 1 January 2027. SZUTEST

Konformitätsbewertungsstelle GmbH shall take into consideration these requirements for Annex XVI products during conformity assessment activities.

12. SIGNATURE METHODS

Signatures are required for any signed documents and records in the documentation. Signatures can be handled as below:

- Documents may be digitally signed (e-signature).
- Signature pages can be scanned in and inserted into the electronic document.
- The relevant documents and records can be signed with a wet signature by authorized personnel.

All documents and records which require approval such as reports, protocols, etc. except for the Declaration of Conformity, shall have approvals.

12.1 The company shall accept to follow the requirements presented by SZUTEST Konformitätsbewertungsstelle GmbH through e-mails, together with both signed and unsigned documents if provided within an email. The company shall also be responsible for the content provided within e-mails, together with signed and unsigned documents provided within the company's e-mails. These include the documents provided by the company through file sharing platforms. If not explicitly stated, SZUTEST Konformitätsbewertungsstelle GmbH shall consider all submitted documents as controlled copies.

12.2 As an alternative way of signing documents, SZUTEST Konformitätsbewertungsstelle GmbH may use e-signature software modules to sign its documents as well as require the company to sign documents by using these platforms. The company shall accept the usage of these platforms and shall accept the same legal responsibility as the other conventional signature types. SZUTEST Konformitätsbewertungsstelle GmbH may require the company to enter data or submit documents to its digital software platforms. The company shall accept full responsibility for the data and documents provided within these platforms.