## SCOPE

This agreement defines the terms and conditions binding on the Company and SZUTEST Konformitätsbewertungsstelle GmbH with respect to the Regulation (EU) 2017/745 product conformity assessment services specified in article 3 of **“Main Agreement dated xx.xx.xxxx”**. “**General Terms for MDR (EU) 2017/745 Conformity Assessment**” issued by SZUTEST Konformitätsbewertungsstelle GmbH is an inseparable part of this annex and the Company shall be liable for conforming to these agreements including any amendments thereof unless these agreements are terminated. The Company shall be responsible for keeping up with the updated “General Terms for MDR (EU) 2017/745 Conformity Assessment”. The Company shall be obliged to keep up with the amendments introduced to the text.

## RIGHTS AND OBLIGATIONS

## RIGHTS AND OBLIGATIONS OF SZUTEST

1. SZUTEST Konformitätsbewertungsstelle GmbH shall perform the services under the scope of Regulation (EU) 2017/745 for the products specified in Main Agreement-Article 3in line with the methods and rules indicated in SZUTEST Konformitätsbewertungsstelle GmbH procedures and General Terms for MDR (EU) 2017/745 Conformity Assessment and it shall report the results accordingly. Conformity assessment activities shall be conducted with due regard for the principles of impartiality and confidentiality specified by SZUTEST Konformitätsbewertungsstelle GmbH and the company information shall not be disclosed to third parties apart from Competent Authorities, Authorities Responsible for Notified Bodies, European Commission, courts or required by law.
2. SZUTEST Konformitätsbewertungsstelle GmbH shall ensure that its personnel, committees, subsidiaries, subcontractors, any associated body or personnel of external bodies respect the confidentiality of the information and paying attention to the principles of impartiality while conducting conformity assessment activities, except to the Competent Authorities, Authorities Responsible for Notified Bodies, European Commission, courts and required by law. Reporting activities shall be conducted based on objective findings and sampling methods and EU Certificates shall be issued according to the type of application incase of a positive product conformity assessment result. In case of issuance of certificates, their validity and scope shall be published on [www.szutest-germany.de](http://www.szutest-germany.de). Upon the termination of the notification of SZUTEST Konformitätsbewertungsstelle GmbH, the company shall be served a written notification to provide the necessary information about the transfer to another Notified Body. The appeals and complaints referred by the company shall be evaluated and the company shall be informed of their outcome.
3. SZUTEST Konformitätsbewertungsstelle GmbH shall make it sure that the subcontractor does not further subcontract it’s duties to another company or person and shall fulfil the requirements of the Regulation (EU) 2017/745.
4. The number of surveillance assessments will be performed within 5 years of certificate validity is four (4) for Regulation (EU) 2017/745. However, SZUTEST may conduct extra surveillance audits, follow up audits, unannounced site audits and off-site audits based on the findings obtained from internal controls of SZUTEST Konformitätsbewertungsstelle GmbH and audits of the authorities responsible for notified bodies, competent authorities, and European Commission.
5. Normally, unannounced site audits are performed at least once in 5 years however SZUTEST Konformitätsbewertungsstelle GmbH may increase the frequency of unannounced site audits in case of necessity including its risk classification. The frequency of unannounced site audits shall be evaluated in terms of the risks having the potential to have an impact on the activities of the company. For example, withdrawal of critical personnel from their position, extremely frequent product conformity issues, extremely frequent complaints and highrisk devices may lead to increase of the frequency of unannounced site audits. Samples may be obtained from the market, company warehouse or production line in order to conduct tests under unannounced site audits. Critical suppliers of the company may be subject to unannounced site audits as well. All the costs arising from unannounced site audits shall be paid by the company. In order to give approval for unannounced site audits in advance, the visa invitation form to be provided in the attachment of this agreement shall be completed by the company which shall also issue a visa invitation letter in addition to this form upon request of SZUTEST Konformitätsbewertungsstelle GmbH.
6. SZUTEST Konformitätsbewertungsstelle GmbH reserves the right to include observers, auditors and reviewers under observation or training to the audits and other relevant conformity assessment tasks to be performed for the company.
7. Where the company request transfer of certificates issued by SZUTEST Konformitätsbewertungsstelle GmbH to another Notified Body, SZUTEST Konformitätsbewertungsstelle GmbH shall ensure that necessary information is submitted to the new Notified Body where there is a contractual obligation inplace.
8. SZUTEST Konformitätsbewertungsstelle GmbH shall ensure that company submit for prior approval plans for substantial changes to the quality management system, or the device-range covered and relevant information relating to such changes, assess the changes proposed and verify whether, after these changes, the quality management system, or the design of a device or type of a device, still meets the requirements of Regulation (EU) 2017/745, and notify the company of its decision. SZUTEST Konformitätsbewertungsstelle GmbH shall determine the actions necessary to be taken and approve or reject the change subsequently. The change may require updating the agreements or collecting additional changes.
9. SZUTEST Konformitätsbewertungsstelle GmbH shall be entitled to revoke this agreement and the previously issued certificates if the company fails to perform any of its contractual obligations. If it is discovered that the information provided in the application file has been subject to any change at the end of the application review or during the documentation review, it may alter the conditions of this agreement and reserves the right to revoke this agreement. If the audits reveal any information different from the one indicated in the application for such as the number of employees, product scope, sites, and critical suppliers, SZUTEST Konformitätsbewertungsstelle GmbH shall be entitled to alter the audit periods and fees and suspend the audit according to its procedures.
10. SZUTEST Konformitätsbewertungsstelle GmbH reserves the right to alter the surveillance audit fees and other prices after the signature of the agreement.
11. SZUTEST Konformitätsbewertungsstelle GmbH may demand the company to recall any product in case of any risk for public health and product safety.
12. SZUTEST Konformitätsbewertungsstelle GmbH reserves the right to suspend the certificates and revoke the agreements and certificates unless the relevant nonconformity is resolved until the specified deadline. SZUTEST Konformitätsbewertungsstelle GmbH does not have any obligation to remind the company of the expiration of the deadline specified for the resolution of the nonconformity or any other response.

## RIGHTS AND OBLIGATIONS OF THE COMPANY

1. The Company shall provide correct information during the entire product conformity assessment process including specifically the application and agree to be bound by all the sanctions to arise from failure in performing this obligation. The Company shall provide all the documentation including the technical documentation and quality management system documentation to SZUTEST Konformitätsbewertungsstelle GmbH within maximum 15 days after the imposed deadline.
2. The Company shall sign the Transfer Agreement without any financial value based on the recommendation of SZUTEST Konformitätsbewertungsstelle GmbH or shall provide an agreement which covers the required information in Transfer Agreement in case of any request to transfer a certificate issued by SZUTEST Konformitätsbewertungsstelle GmbH to another notified body. In that case, all the declarations and documents demanded by SZUTEST Konformitätsbewertungsstelle GmbH shall be submitted to SZUTEST Konformitätsbewertungsstelle GmbH within maximum 15 days after the imposed deadline.
3. The Company shall deliver all the documents demanded by SZUTEST Konformitätsbewertungsstelle GmbH within maximum 15 days after the imposed deadline if it intends to transfer the certificates issued by another notified body to SZUTEST Konformitätsbewertungsstelle GmbH. In case of any such certificate transfer request, it is agreed that SZUTEST Konformitätsbewertungsstelle GmbH may contact the existing notified body of the company. SZUTEST Konformitätsbewertungsstelle GmbH reserves the right to revoke the agreement during application review phase according to the information to be given by that notified body or in case of lack of any such information.
4. The company shall enable SZUTEST Konformitätsbewertungsstelle GmbH to conduct planned or unannounced witness audits along with the staff of European Commission, Authorities responsible for Notified Bodies, competent authorities. In order to visit critical suppliers as part of the audits, the company shall sign agreements with its suppliers providing that employees of SZUTEST Konformitätsbewertungsstelle GmbH, European Commission, Authorities responsible for Notified Bodies, competent authorities may conduct planned or unannounced site audits at the sites of suppliers.
5. The Company shall fulfill obligations for providing PSUR and SSCP in defined timelines to both SZUTEST Konformitätsbewertungsstelle GmbH and EUDAMED if it is required by the Regulation (EU) 2017/745.
6. The Company shall be obliged to use CE mark, and SZUTEST Konformitätsbewertungsstelle GmbH trademark correctly. CE mark shall not be attached to the products and such products may not be marketed so long as the certificates are suspended and invalid. CE mark may only be attached to products succeeding in conformity assessments conducted by SZUTEST Konformitätsbewertungsstelle GmbH. The Company may not place the products certified by SZUTEST Konformitätsbewertungsstelle GmbH into the market with the number of another notified body after the certification date.
7. The Company shall not file a parallel application to more than one Notified Body for the same products.
8. The company shall fulfil its financial obligations within the deadlines specified herein. The company shall agree that execution of the agreement should not be construed as an entitlement to the certificate and pay the prices for all the services that are conducted even if the process results negatively. 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 the termination fee.
9. The company shall not demand consultancy services from SZUTEST Konformitätsbewertungsstelle GmbH in any manner. SZUTEST Konformitätsbewertungsstelle GmbH employees shall be entitled to visit all the sites including design, manufacture, storage, testing and examination sites, ask questions to employees working on those sites, examine the products and documents at all sites, receive samples from manufacture and storage sites and bear witness in testing processes. SZUTEST Konformitätsbewertungsstelle GmbH may conduct deep and detailed inquiries during audits in case of necessity. The company shall make cooperation in order to enable SZUTEST Konformitätsbewertungsstelle GmbH employees to conduct the audits. In that respect, SZUTEST Konformitätsbewertungsstelle GmbH may suspend the audit and reserves the right to revoke the agreement in case of any condition damaging the order of the audit such as failure in answering questions in a timely manner, providing the necessary documents and accompanying the conformity assessment personnel. The company shall furnish information required for protecting the safety and health of audit staff and accompanying employees, take necessary measures and provide necessary equipment.
10. In the event that the accreditation or notification of SZUTEST Konformitätsbewertungsstelle GmbH is terminated for any reason after the signature of this agreement, the company may not make claims from SZUTEST Konformitätsbewertungsstelle GmbH in any manner including for pecuniary and non-pecuniary losses such as loss of revenue, investment costs etc. The parties irrevocably agree and acknowledge this condition mutually with their freewill.
11. The Company shall inform SZUTEST Konformitätsbewertungsstelle GmbH of any change in its address and contact details.
12. The Company shall assume all the liabilities arising from cancellation or suspension of its certificates including the liabilities towards customers and shall not hold SZUTEST Konformitätsbewertungsstelle GmbH responsible in that regard.
13. The Company shall comply with the request of SZUTEST Konformitätsbewertungsstelle GmbH to perform video conferences, telephone conversation and to supply video and photo as a part of audit.
14. The Company shall completely comply with the nonconformity resolution dates declared after the assessments, monitor compliance with those dates and shall not hold SZUTEST Konformitätsbewertungsstelle GmbH responsible for any failure in that regard.
15. The Company may appeal to the employees assigned by SZUTEST Konformitätsbewertungsstelle GmbH as well as the decisions on certifications within 10 business days by providing justifications for the appeal. Besides, it may file complaints in relation to the SZUTEST Konformitätsbewertungsstelle GmbH services and employees along with detailed explanations and evidence in line with the complaint and objection procedure published on [www.szutest-germany.de](http://www.szutest-germany.de). The company shall assume the expenses incurred for the experts, committee to be established for complaints and appeals and similar costs.
16. When complying with imposed deadlines the company shall consider availability of SZUTEST Konformitätsbewertungsstelle GmbH resources and time needed for planning. The company shall not make SZUTEST Konformitätsbewertungsstelle GmbH responsible for 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 time needed for resource allocation and planning when considering the response time.

**3. TRANSITION REQUIREMENTS UNDER REGULATION (EU) 2023/607**

**3.1** Regulation (EU) 2023/607 of the European Parliament and the Council of 15 March 2023 amending Regulations (EU) 2017/745, as regards the transitional provisions for certain medical devices, has entered into force on 20 March 2023.

**3.2** In line with the amendments made by Regulation (EU) 2023/607 and (EU) 2017/745 Medical Devices Regulation (MDR) Article 120 'Temporary Provisions', certificates issued under Directive 93/42/EC 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.

**3.3** For the devices specified in Article 6.2, the Company may place its devices on the market or put them into service until the dates referred to in points (a) and (b) of Article 6.2 only if the following conditions are fulfilled:

(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 manufacturer has put in place a quality management system in accordance with MDR Article 10(9);

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

**3.4** In surveillance assessments for devices referred to in paragraphs 6.2 (a) and (b); the requirements of the MDR on post-market surveillance, market surveillance and surveillance, vigilance, registration of economic operators and devices shall be applied instead of the corresponding requirements in Directive 93/42/EC.

**3.5** Until 26 September 2024, unless the company agrees with SZUTEST Konformitätsbewertungsstelle GmbH that it shall carry out the surveillance specified in Article 6.4, MDD Notified Body shall continue to be responsible for the necessary surveillance assessment 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. These surveillance assessments shall also include unannounced site audits.

**3.6** No later than 26 September 2024, SZUTEST Konformitätsbewertungsstelle GmbH that has signed the written agreement referred to in point (e) of Article 6.3, 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.

**3.7** Arrangements for the transfer of surveillance from MDD Notified Body to SZUTEST Konformitätsbewertungsstelle GmbH shall be clearly defined in an agreement between the Company, SZUTEST Konformitätsbewertungsstelle GmbH, and MDD Notified Body where applicable.

**3.8.** SZUTEST Konformitätsbewertungsstelle GmbH shall not be responsible for the conformity assessment activities carried out by MDD Notified Body.

**4.** **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.

## 5. GENERAL PROVISIONS

**5.1** SZUTEST Konformitätsbewertungsstelle GmbH shall not be responsible for the time spent for review of the files by competent authority for any reason.

**5.2** All Regulation (EU) 2017/745 Certificates shall have a maximum 5 years of validity period. In case of certificate transfers, the validity period of the certificate shall be limited to the certificate validity period applicable for the previous notified body. Certificate validity period may be limited accordingly incase of a revision on standards, regulations, due to specific concerns, etc.

Date:

Agreed on behalf of Agreed on behalf of the Company

SZUTEST Konformitätsbewertungsstelle GmbH the COMPANY

Germany <place >

……………………… ………………………

**<name> <name>**

**General Manager <position (Authorized Person)>**