## PARTIES

This Agreement (the “Agreement”) and its applicable annexes are entered into by and between  located at the address of “”with its e-mail address being “”, telephone number “” and facsimile number “” (to be hereinafter referred to as the “**Company**”) and “**SZUTEST** **Konformitätsbewertungsstelle GmbH** located in “**Friedrich-Ebert-Anlage 36, 60325 Frankfurt am Main, Germany**” with its telephone number being “**-----**” and facsimile number “**-----**”.

## DEFINITIONS

**Notified Body**: The entity assigned by the designation authorities to undertake product conformity assessment activities under (EU) Regulation 2017/745.

**Auditing Organization (AO):** An organization that audits a medical device manufacturer for conformity with quality management system requirements and other medical device regulatory requirements.

**Product Conformity Assessment**: The process demonstrating whether the requirements of Regulation (EU) 2017/745 relating to a device have been fulfilled. Control of product conformity with the conditions provided in the Regulation (EU) 2017/745 by means of application review, documentation reviews, Technical Documentation reviews, audits, evaluation, decision and similar activities.

**Medical Device Single Audit Programme (MDSAP):** A single regulatory audit of a medical device manufacturer conducted by recognized Auditing Organization (AO) to meet the requirements of the following regulatory authorities (RAs): Australia’s Therapeutic Goods Administration (TGA), Brazilian Health Regulatory Agency (ANVISA), Health Canada (HC), Japan’s Ministry of Health, Labour and Welfare, and the Japanese Pharmaceuticals and Medical Devices Agency (MHLW/PMDA), U.S. Food and Drug Administration (USFDA)

**Regulatory Authority (RA):** A government body or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and that may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements

**Authorities Responsible for Notified Bodies:** The authorities in charge of assigning/designating Notified Bodies (ZLG in Germany.)

**Competent Authority:** Regulatory authority of the country responsible for medical devices. Competent Higher Federal Authority (The Federal Institute for Drugs and Medical Devices (BfArM)) listed in the <https://www.bfarm.de> web site based on their scope of coverage in Germany for MDR).

**Medicinal Products Authority:** Competent Authority assigned for Directive 2001/83/EC; The Federal Institute for Drugs and Medical Devices and other competent authorities listed in the <https://www.bfarm.de> web site based on their scope of coverage or the European Medicines Agency (EMA) for MDR.

**Certificates**: EU Certificates issued under the Regulation (EU) 2017/745 and/or certificates for Medical Device Singal Audit Programme (MDSAP).

**Sampling Method:** Assessment of the efficiency of any quality assurance system and documentation by means of reviewing implementation samples. This method is not based on reviewing all the documentation and files. The frequency of sampling may change.

**MDR:** Regulation (EU) 2017/745 - Medical Device Regulation

**PSUR:** Periodic safety update report

**SSCP:** Summary of safety and clinical performance

**EUDAMED:** Electronic System implemented by EU Commission.

**Company**: A natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured, or fully refurbished, and markets that device under its name or trademark. Synonymously used for the term manufacturer in Regulation (EU) 2017/745.

**VAT**: Value-Added Tax

## SCOPE

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Service Type** | **Product Conformity Assessment Method/ Scope** | **Product/Product Group Name** | **Product Class** | **Certificate Number\*** |
|  |  |       |  |       |
|  |  |       |  |       |
|  |  |       |  |       |
|  |  |       |  |       |

## PAYMENTS

## 4.1 INITIAL ASSESSMENT [ ]  / RE-ASSESSMENT [ ]  / SCOPE EXTENSION [ ]  / TRANSFER ASSESSMENT [ ]  / CHANGE ASSESSMENT [ ]  / FOLLOW-UP AUDIT [ ]  / CRITICAL SUPPLIER AUDIT [ ]

|  |  |  |
| --- | --- | --- |
| **Type** | **Duration** (man/day) | **Fees** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

|  |  |  |
| --- | --- | --- |
| **Total** |  |  |
|  |  |  |

##  SURVEILLANCE ASSESSMENTS

If this part left empty, the fees for surveillance assessment in the previous agreement remains valid, if not these fees replace the previous surveillance fees.)

## 4.2.1 SURVEILLANCE 1

|  |  |  |
| --- | --- | --- |
| **Type** | **Duration** (man/day) | **Fees** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

|  |  |  |
| --- | --- | --- |
| **Total** |  |  |

## 4.2.2 SURVEILLANCE 2

|  |  |  |
| --- | --- | --- |
| **Type** | **Duration** (man/day) | **Fees** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

|  |  |  |
| --- | --- | --- |
| **Total** |  |  |

## 4.2.3 SURVEILLANCE 3

|  |  |  |
| --- | --- | --- |
| **Type** | **Duration** (man/day) | **Fees** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

|  |  |  |
| --- | --- | --- |
| **Total** |  |  |

## 4.2.4 SURVEILLANCE 4

|  |  |  |
| --- | --- | --- |
| **Type** | **Duration** (man/day) | **Fees** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

|  |  |  |
| --- | --- | --- |
| **Total** |  |  |

## UNANNOUNCED SITE AUDITS

(If this part left empty, the fees for unannounced site audit in the previous agreement remains valid, if not these fees replace with the previous surveillance fees.)

|  |  |  |
| --- | --- | --- |
| **Type** | **Duration**(man/day) |  **Total Fee** |
|  |  |  |  |

## PAYMENT OBLIGATIONS

1. Prices do not include VAT. For each portion of the payment the VAT shall be included in the transfer.
2. Transportation and accommodation costs of SZUTEST Konformitätsbewertungsstelle GmbH employees, including the ones under observation or training, are not included in the prices indicated above and they shall be invoiced separately and shall be paid by the company within maximum 10 business days. Economy class (including seat selection, baggage, extra legroom) shall be preferred for flight tickets provided that SZUTEST Konformitätsbewertungsstelle GmbH reserves the right to demand “business” class tickets for flights over 7 hours. 4-star and higher-level hotels shall be preferred for the accommodation arrrangements. SZUTEST Konformitätsbewertungsstelle GmbH may request special transportation and accommodation alternatives in case any of its employees has a specific medical condition.
3. Where travelling is necessary for the conformance of the tasks, the Company shall pay fifty Euro (50 EUR) travel fee per hour. The time spent on travel is calculated for each individual traveling for conformity assessment tasks.
4. The Company shall pay 50% of the total initial assessment fee and/or transfer fee in advance within maximum 10 business days upon the signature of the agreement. SZUTEST Konformitätsbewertungsstelle GmbH shall not begin to perform its contractual obligations unless this payment is duly made.
5. The remaining portion of the initial assessment fee and costs shall be paid by the company in advance within maximum 10 business days after the completion of the activities for the assessment.
6. Total surveillance fee shall be paid by the company in advance 30 days before the scheduled surveillance audit date at the latest. The costs incurred for the surveillance audits shall be invoiced separately.
7. The prices and costs of unannounced site audits shall be paid by the company within maximum 10 business days after the unannounced site audit is conducted.
8. Scope extension assessment and change assessment fees shall be arranged through a separately and paid by the company in advance within maximum 10 business days following the notification. The assessments shall not be scheduled and certificates shall not be extended before the payment is made.
9. Follow-up audit fees shall be invoiced separately. The relevant fee shall be paid by the company in advance within maximum 10 business days after the invoice is issued. The audits shall not be scheduled before the payment is made.
10. Annual Certificate Usage Fee shall be paid annually once the certification is performed and shall not be refunded once it is paid even if the certificates are withdrawn.
11. The company shall be responsible for the payments of the planning costs and expenses incase of a request by the company for changing the agreed audit dates.
12. Any dispute between the company and SZUTEST Konformitätsbewertungsstelle GmbH is concerned, arising from the application of Annex VIII (such as implementation of classification rules or qualification of the product etc.) of the Regulation (EU) 2017/745, shall be referred for a decision to the competent authority in which the company has its registered place of business. In cases where the company has no registered place of business in the European Union and has not yet designated an authorised 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. All of the costs arising from such referral shall be paid by the company.
13. If consultation to the authorities is necessary for several devices for MDR assessment, the consultation fees required from the applied authority is not included in the prices and shall be invoiced separately. For the tasks to be performed for preparation to the consultation and if the feedback from the consultation requires changes in the assessments and additional documents, explanations, revisions for project files are required and in case of an additional time spent on repeating consultations or follow-up, a fee of one hundred euro (100 EUR) shall be charged per working hour and this shall separately be invoiced to the company.
14. SZUTEST Konformitätsbewertungsstelle GmbH shall invoice a flat fee depending on the highest risk classification of the devices contained in the company certificate portfolio for administrative work on controlling the completeness of change assessment applications.
15. The cost of tests to be performed/contracted under MDR assessments as well as the cost of the sample received from the market shall be invoiced separately to be paid by the Company within maximum 10 business days after the notification.
16. The above prices include one (1) time review for non-conformity corrections. SZUTEST Konformitätsbewertungsstelle GmbH shall invoice three hundred and fifty Euro (350 EUR) for the time spent on each additional reviews for each remaining non-conformity within allowed timeline for non-conformity corrections.
17. SZUTEST Konformitätsbewertungsstelle GmbH shall invoice five hundred Euro (500 EUR) for administative work incase of a transfer from SZUTEST Konformitätsbewertungsstelle GmbH to another notified body or authorization organisation.
18. 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 total unannounced site audit fee and conformity assessment personnel expenses shall be invoiced to the company.
19. SZUTEST Konformitätsbewertungsstelle GmbH shall invoice one hundred Euro (100 EUR) for per working hour incase of the company submits an appeal to the decisions taken on certification.

## 6. GENERAL PROVISIONS

**6.1** The disputes arising from this agreement shall be subject to German Law.

**6.2** The parties shall serve requests and notices for cancellation of agreements in writing.

**6.3** In case the company fails to perform any of the provisions herein, SZUTEST Konformitätsbewertungsstelle GmbH shall reserve the right to revoke the agreement. In such a case, the certificates issued under the revoked agreements shall be revoked automatically.

**6.4** The person signing this agreement shall be authorized to represent the Company.

**6.5** The addresses specified herein are the notification address of the parties and address change shall be notified to the other party in writing. Otherwise, the notices submitted to those addresses shall be deemed to have been validly served.

## 7. ANNEXES

☐ ANNEX-1 Regulation (EU) 2017/745 Conformity Assessment Activities Agreement

☐ ANNEX-2 MDSAP Certification Agreement

## ☐ ANNEX-3 Medical Devices General Terms for Regulation (EU) 2017/745

## ☐ ANNEX-4 Medical Devices General Terms for MDSAP Certification

## ☐ ANNEX-5 Visa Invitation Form

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)>**