**PART-1** (To be filled by the Company before the meeting)

1. **COMPANY INFORMATION**

|  |  |
| --- | --- |
| **Company Name:** |  |

1. **STRUCTURED DIALOGUE INFORMATION**

|  |
| --- |
| **Structured Dialogue Rules** |
| Before requesting a structured dialogue meeting; please first review MDR, other relevant guidelines, and documents published by SZUTEST to verify whether the questions have clear answers for the relevant topics.  If the proposed agenda/questions fall in a group where SZUTEST has got already a clear response from frequently asked questions, SZUTEST may suggest providing a response via e-mail instead of arranging a dedicated meeting.  The structured dialogue aims to provide the company with necessary information and guidance regarding the process, not consultancy. Both parties shall follow the defined process and requirements, ensuring that applications and further processes are completed more effective and smoothly. The structured dialogue process shall be conducted in accordance with the principles of independence, impartiality, and objectivity as per the requirements of MDR;  - Ensuring open and effective continuous communication between the company and SZUTEST.  - Enhancing the efficiency and continuity of the conformity assessment process.  - Making the timeline and requirements of the assessment process transparent.  The main purpose of structured dialogue is to clarify requirements, not to provide solutions. The manufacturer is ultimately responsible for fulfilling the requirements therefore the outputs of the structure dialogue cannot be a base of the assessment. The questions shall be specific rather than open-ended and shall not seek guidance on "how to comply," thereby preventing any consultancy services from being provided.  The structured dialogue cannot propose specific solutions and cannot provide conclusions that can only be provided as a result of routine conformity assessment tasks. The manufacturer shall acknowledge that new or altered requirements may come into force after performing structured dialogues.  The structured dialogue cannot include topics that are under the responsibility of the authorities and expert panels.  The structured dialog shall be free of charge. However certain limitations apply. There is no limitation on written responses; however, SZUTEST may require the company to comply with the questions and handle them in a meeting. The following limitations apply to the meeting;  - During the pre-application and application stage: Limited to 3 meetings.  - Changes and Scope Extensions: Limited to 2 meetings.  - Ongoing Conformity Assessments: Limited to 2 meetings per project per year. |

|  |
| --- |
| **Scope of Structured Dialogue** |
| **We can discuss below topics;**  **Prior to the application (pre-application):**  • Timelines for conformity assessment until certification, including estimated timelines for possible special procedures, e.g. drug-device combinations, companion diagnostics, or orphan devices  • Clarification on the data /documentation to be provided with the application  • If applicable, procedure related to the onboarding as a customer, including access to a possible portal, and relevant procedural guidance  • Options of conformity assessment procedures and - for legacy devices - timing for submission of individual technical documentation, i.e. discussion about the manufacturer's "conformity assessment program"  • Information on all necessary conformity assessment activities - e.g., initial audit, (annual) surveillance audits, technical documentation assessments, assessment of changes/change notification  - and any special (process) audits or additional (sub-) assessments/reports for TD assessment not explicitly mentioned in the Regulations; it should be specified if such activities are required or not and if they will be performed once or more often  • Pricing and fees  • Exchange of information about involved persons for different conformity assessment activities on both sites (Notified body and manufacturer) including contact persons  • Applicable standards and guidance documents  • How to apply and reference standards or guidelines  • Referring to the possibility of getting advice from EMA expert panels (Art. 106, Art. 61 (2) MDR)  • Possibility of "modular approach" (e.g., review of specific parts of the technical documentation / clinical evaluation at different points in time, to allow (earlier) feedback on testing/evaluation  strategies)  • General requirements regarding and acceptance of (third party) test reports/certificates  • Leveraging evidence from previous assessment  • Qualification and Classification of a product (Annex VII 4.2 (d) MDR)  • Requirements for sampling of devices for technical documentation assessments  • Best practice guidance for technical documentation (TD), including the preferred structure of TD  **During the conformity assessment activities (post-application):**  • Clarification of missing data  • If test reports were initially not accepted, the next steps regarding the submission of new test data  • Timelines for providing additional missing data  • Early information/discussion on a planned significant/substantial change of a product (design) and the consequences for the certification process  • Leveraging evidence from previous assessment  • Appropriateness of equivalence claim (see Art. 61(4), second indent, MDR  • Sufficiency of quality/quantity of clinical data  • Applicability of Article 61(10) MDR  • Appropriateness of PMCF plan  • Clarification of non-conformities raised |
| **We cannot discuss (non-exhaustive examples):**  − Complete gap analyses  − Check for MDR/IVDR readiness  − Review mock files for MDR/IVDR conformity  − Provide technical solutions  − Explain how the manufacturer should meet specific regulatory requirements  − Provide answers that could only be answered by performing a complete review during the routine conformity assessment process  − Verify the acceptability of existing clinical data. |

1. **REQUESTED AGENDA FOR THE MEETING**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Please write the topics as detailed that you want to discuss:** | |  |  | | --- | --- | | No.: | 1 | | Question/Agenda Item |  | | Background Information  *Refer to relevant requirements of MDR or guidelines* |  | | Current Understanding / Proposed Answer |  | | Attachments |  |  |  |  | | --- | --- | | No.: | 2 | | Question/Agenda Item |  | | Background Information  *Refer to relevant requirements of MDR or guidelines* |  | | Current Understanding / Proposed Answer |  | | Attachments |  | |

|  |  |
| --- | --- |
| **Please choose the meeting type** | Please choose. |

|  |
| --- |
| **Note 1:** All required IT arrangements shall be initiated by the company, prior to starting the meeting, and the formal meeting durations shall not be spent on these preparations and arrangements.  **Note 2:** SZUTEST Konformitätsbewertungsstelle GmbH may demand testing on IT, network, and software arrangements prior to the meeting.  **Note 3:** Please provide translation tools and methods, if necessary.  **Note 4:** The meeting duration can be planned between half an hour to 1 hour.  **Note 5:** No audio or video recordings are allowed during the meeting.  **Note 6:** The company is requested to have the relevant and qualified personnel attend the meeting.  **Note 7:** If any changes are to be made to the meeting agenda, please inform SZUTEST Konformitätsbewertungsstelle GmbH at least 2 days before the meeting.  **Note 8:** The company is responsible for submitting complete and accurate documents related to the meeting subject at least 5 business days in advance.  **Note 9**: After the meeting, the company shall send the meeting minutes related to the discussed topics via email to the [mdsales@szutest-germany.de](mailto:mdsales@szutest-germany.de) or the relevant head of audit team’s e-mail address within a maximum of 2 business days. |

|  |
| --- |
| **Please send the completed form to** [**mdsales@szutest-germany.de**](mailto:mdsales@szutest-germany.de) **or the relevant head of audit team’s e-mail address.** |

**PART-2** (To be filled by the Company after the meeting)

1. **MEETING SUMMARY**

|  |  |
| --- | --- |
| **Location** |  |
| **Date / Time** |  |
| **Name of Attendees** |  |
| **Meeting Summary** | |  |  | | --- | --- | | Question/Agenda Item No.: | 1 | | Summary Response |  |  |  |  | | --- | --- | | Question/Agenda Item No.: | 2 | | Summary Response |  | |

**PART-3** (To be filled by the SZUTEST as an approval of the meeting summary)

|  |  |  |  |
| --- | --- | --- | --- |
| **Version** | **Date** | **Description of Change** | **Approved by SZUTEST Konformitätsbewertungsstelle GmbH**  **(Name Surname, Signature)** |
|  |  |  |  |
|  |  |  |  |