1. **IMPORTANT INFORMATION**

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| Filling this form completely and correctly is crucial for the preparation of an offer and the determination of services correctly. Please add the following supporting documents for each product.  - The documents for justifying that the product is a medical device, its correct classification based on the applied jurisdiction, and relevant (EU) 2017/2185 Codes. - The documents (e.g., brochures, catalogs, promotional documents, instruction for use, web page info) for confirmation of product description, intended purpose, indications, type, model, components of the product, etc. - Copies of Already Existing Certificates (such as CE, QMS, GMP, national legislation certificates, etc.)  Please be informed that detailed information may be requested for further evaluation. If no obstacle is identified based on the provided information SZUTEST Konformitätsbewertungsstelle GmbH will draft an offer. If the offer is accepted further information will be requested together with supporting documents and SZUTEST Konformitätsbewertungsstelle GmbH will perform a detailed application review to set out a draft contract. The values and calculations documented in the official contract will differ from the offer if the detailed application review identifies additional parameters.  This form shall only be provided by the applicant manufacturer directly or its authorized representatives through the following functional e-mail, [mdsales@szutest-germany.de](mailto:mdsales@szutest-germany.de) Corresponding language shall be English.  \*MDSAP applications will be accepted when SZUTEST is authorized as an auditing organization for MDSAP. |

1. **MANUFACTURER\* INFORMATION**\*Manufacturer: 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.

|  |  |
| --- | --- |
| **Company Title** |  |
| **Company Address (City/Country)** |  |
| **Company SRN** |  |
| **REPs Facility ID (only for MDSAP\*)** |  |
| **Web address** |  |
| **Declaration for Sanctions**  **Please check from** ([**www.sanctionsmap.eu**](http://www.sanctionsmap.eu))**. The requirement includes the companies belonging to the same group.** | The manufacturer (including the group of companies) and their owners and applied medical devices are not in the EU Sanctions List  The manufacturer (including the group of companies) and their owners and applied medical devices are in the EU Sanctions List |
| **Contact Person Name/Job Title** |  |
| **Contact Information (e-mail, telephone)** |  |
| **If your company is a part of a bigger entity; please state the name of this entity** |  |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Number of Employees** |  | **Number of Effective Employees** |  | **Total Number of Locations** | |  | **Total Number of Technical Documentation** | |  |
| **Outsourced Processes** | Sterilization | | | Manufacturing | | Packaging | | Semi-Finished Product | Design |
| If “**yes**”, please identify the address (city and country) of the outsourcing company. | | |  | | | | | |
| Other (Please explain) | | |  | | | | | |
| **Do you re-label the applied product which is already in the market and manufactured/designed by another company?** | | | |  | | | | | |
| **Is your Company a SME according 2003/361/? See the table for the requirements applied in order to be considered as SME.** | | | | **No**  **Yes**   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Company Category | Staff Headcount | Turnover | Or | | Balance sheet Total | | Medium | <250 | ≤ € 50 m | | ≤ € 43 m | | | Small | <50 | ≤ € 10 m | | ≤ € 10 m | | | Micro | <10 | ≤ € 2 m | | ≤ € 2 m | | | | | | | |
| **Language of**  **Technical Documentation** |  | | | **Language of QMS Documentation** |  | | | | |
| **Requested Certificates**  **(EU) 2017/745 Regulation**    **MDSAP\*** | **Annex IX QMS Chapter I, III**  **Annex IX Chapter II Technical Documentation**  **Annex XI Part-A Production Quality Assurance(1)(2)**   1. **EU Type Examination certificate is required for these products from another Notified Body when selected for Class III and Class IIb devices.** 2. **Annex II and III Technical Documentation assessed per device category for Class IIa.** | | | **Annex IX QMS Chapter I, III** (Limited to Class I devices (in sterile condition, with measuring function or reusable surgical instruments) and sterile systems or procedure packs)  **Annex XI Part-A Production Quality Assurance** (Limited to Class I devices (in sterile condition, with measuring function or reusable surgical instruments) and sterile systems or procedure packs)  **Application for QMS Certification According to Article 16 Section 3** | | | | | |
| **MDSAP\*** | | | | | | | | |
| **Do you implement a Medical Quality Management System?** | | | | Type of valid/expired certificates   |  |  |  |  | | --- | --- | --- | --- | | 93/42/EEC | Valid | Expired on | Given By | | (EU)2017/745 | Valid | Expired on | Given By | | ISO 13485 | Valid | Expired on | Given By | | FDA | Valid | Expired on | Given By | | MDSAP**\*** | Valid | Expired on | Given By | | UKCA | Valid | Expired on | Given By | | Other Local Regulation/Standard  Specify: | Valid | Expired on | Given By | | | | | | |
| **Did you log an application or sign a contract with another Notified Body for any of your devices included in this application?** | | | | **No**  **Yes**  If yes please also select below and provide details  **Application is withdrawn by the manufacturer**  **Application/certification is refused by the Notified Body**  **None (Considering Transfer)**  Please provide details and summary: | | | | | |

1. **PRODUCT INFORMATION**

**Please fill in FR.MED.01 Annex-3 Application Form - Product Information Table.**

1. **SPECIFIC INFORMATION**

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| --- | --- |
| **If there is any incomplete activity, part of a technical documentation for your devices please indicate here.**  **For example: Ongoing tests, ongoing clinical investigations** |  |
| **Do you intend to change / modify the intended use and design of legacy devices for MDR application? If yes please state which device have which kind of modification** |  |

1. **ADDRESS INFORMATION**

|  |  |  |
| --- | --- | --- |
| **Location (Head Office, Factories, Sales Offices, etc.)** | **City** | **Country** |
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1. **OTHER INFORMATION**

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| **How did you hear about SZUTEST Konformitätsbewertungsstelle GmbH?** |  |

1. **APPROVAL BY THE COMPANY**

|  |  |  |  |
| --- | --- | --- | --- |
| **Company Representative**  **Assuring that the provided information in this form and in FR.MED.01 Annex-3 is correct.** | **Name, Surname, Title** | **Signature** | **Date** |
|  |  |  |