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| Please send the completed questionnaire to:  **TÜV Rheinland LGA Products GmbH**  Tillystraße 2  90431 Nürnberg  Phone: +49 911 655 5225 E-mail: medical-sales@de.tuv.com | | | |
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| **1. Company details** | | | |
| **Legal company name:** |  | | |
| Contact person: |  | Job title: |  |
| E-mail (contact person): |  | | |
| Street: |  | City, State, ZIP: |  |
| Phone no.*:* |  | Fax no.: |  |
| Website: |  | E-mail (general): |  |
| Questionnaire filled out by: (name and job title) |  | VAT ID no.: |  |

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| **2. Details about your Quality Management System** | |
| Please specify the scope of your QMS, as stated in your quality manual: | < Example for scope: Design and development, manufacture and distribution of dental implants > |
| Please mark activities **excluded** from the scope of the QMS (if applicable): | Production  Design & Development |
| Did you receive consultancy regarding the implementation of your QMS? | yes, by:  no |
| Do any QMS certificates for your company already exist? | yes  no |

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| **3. Total number of employees in full-time equivalent (FTE)** | | | | | | | | | | | |
| Please specify (approximate) number of employees in the particular departments  Name + address of headquarters, add. subsidiaries/branches | | Quality Management | Design and Development | Purchasing | Production | Warehouse | Sales | Service | Other | **Sum FTE** | No. of shifts |
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| Comments: | | | | | | | | | | | |
| **4. Details about your outsourced processes** | | | | | | | | | | | |
| **Processes** | **Name and location of subcontractors which perform outsourced processes** | | | | | | | | | | |
| Design & Development |  | | | | | | | | | | |
| Production |  | | | | | | | | | | |
| Packaging |  | | | | | | | | | | |
| Sterilisation |  | | | | | | | | | | |
| Warehouse |  | | | | | | | | | | |
| Service |  | | | | | | | | | | |
| Comments: | | | | | | | | | | | |

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| **5. Details about the Production Technologies applicable for your QMS/device(s)** | | | |
| Devices manufactured using metal processing (MDT + IVT 2001) |  | Devices which require knowledge regarding the production of pharmaceuticals (MDT + IVT 2007) |  |
| Devices manufactured using plastic processing (MDT + IVT 2002) |  | Devices manuf. in clean rooms and associated controlled environments (MDT + IVT 2008) |  |
| Devices manufactured using non-metal mineral processing (e.g. glass, ceramics) (MDT + IVT 2003) |  | Devices manufactured using processing of materials of human, animal, or microbial origin (MDT + IVT 2009) |  |
| Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper) (MDT + IVT 2004) |  | Devices manufactured using electronic components including communication devices (MDT + IVT 2010) |  |
| Devices manufactured using biotechnology  (MDT + IVT 2005) |  | Devices which require packaging, including labelling (MDT + IVT 2011) |  |
| Devices manufactured using chemical processing (MDT + IVT 2006) |  | Devices which require installation, refurbishment (MDT 2012) |  |
|  |  | Devices which have undergone reprocessing  (MDR 2013) |  |

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| **6. Controlled environmental/cleanroom conditions** |
| Please complete in case products are manufactured under defined environmental/cleanroom conditions:  Which parameters or certain areas are controlled and monitored?  temperature  humidity  ESD controlled areas  total particle counts  microbial counts  radiation protected areas  others:       If cleanroom conditions, please specify classification acc. to EN ISO 14644: |

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| **7. Sterilization processes** | | | |
| Sterilization processes | Applicable? Yes  No | | |
| If yes, please name sterilization method: | | In-house sterilization? | |
| Choose an item. | | yes | no |
| Choose an item. | | yes | no |
| Choose an item. | | yes | no |
| Choose an item. | | yes | no |

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| **8. Scope of the audit** |
| **EN ISO 13485  ISO 9001  ISO 15378  No QMS certificate** |
| **Further international programs:**  **TCP Taiwan**   **Market Access Ukraine** |
| **Further certification programs:  MDSAP  MDR/IVDR**  **(separate Questionnaire required)** |

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| **9. Language** | | | |
| In which language can audits be carried out? | German | English | \_\_\_ |
| In which language is your QM system described? | German | English | \_\_\_ |

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| **10. Please specify your desired dates** |
| **Stage 1 audit:       Stage 2 (Certification) audit:**  Please consider that the interval between stage 1 and stage 2 should be > 10 days and < 3 months. |

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| **Place** | **Date** | **Name** | **Legally binding signature** |

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| Checklist for new clients “Are you ready?” | |
| Please attach the following information: | |
| * Company brochure |  |
| * Relevant product information/brochures/instructions for use |  |
| * Copies of any valid **EC Directive/EU Regulation or QMS certificate** of your company |  |
| * Organization chart of the headquarter as well as of subsidiaries/branches (if applicable) |  |
| * Copies of any valid QMS or regulatory certificates of the subcontractors |  |