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| Please send the completed questionnaire to:**TÜV Rheinland LGA Products GmbH**Tillystraße 290431 NürnbergPhone: +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 departmentsName + address of headquarters, add. subsidiaries/branches | Quality Management  | Design andDevelopment | 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
 | [ ]  |