**Details of the company**

|  |  |
| --- | --- |
|  | Main site (address for the certificate) |
| Company (name and legal entity) |  |
| Street |  |
| Postal code, place |  |
| Country |  |
| Homepage |  |
| E-mail address (company) |  |
| Phone (switchboard) |  |
| Fax (company) |  |
| Company VAT (TVA) ID number |  |

# Main contact person

|  |  |
| --- | --- |
| First and last name |  |
| Position |  |
| Direct/mobile phone |  |
| Personal e-mail address |  |

# External consulting companies

|  |  |  |
| --- | --- | --- |
| Were you or are you assisted in implementation or maintenance of the quality system by an external consulting company? | Yes | No |
| If yes, please provide all involved consulting companies (company name, location) | | |
|  | | |

# Short description of the company’s activities and branch

|  |
| --- |
|  |

# Desired scope of the certificate(s)

|  |
| --- |
|  |

# Area of aimed certification

|  |  |  |  |
| --- | --- | --- | --- |
|  | the whole company |  | the following particular parts: |

# Aimed scope of certification

|  |  |  |  |
| --- | --- | --- | --- |
|  | Standard | | |
|  | EN ISO 13485 |  | EN ISO 13485 with additional acceptance in Taiwan[[1]](#footnote-1) |
|  | EN ISO 9001 | | |

# Information on your existing quality management system

|  |  |  |
| --- | --- | --- |
| Is your quality system certified?  *(If yes, please add copies of your certificates!)* | Yes | No |
| If yes, by which certification body? |  | |
| If yes, when does the validity of your certificate(s) end? |  | |
| Your desired period for the audit? |  | |
| In which language should **the audit** be conducted? | German | English |
| In which language is the **QM documentation** available? | German | English |

# Subsidiaries, branch offices, production sites and further sites which are covered by the quality system

*(Please attach an annex if there are more than 5 sites.)*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Location** | Address and legal entity | Employees  (**including Administration**, Freelancers, Service providers, Trainees, Temporary workers (permanent+ non-permanent)) | | | | | | **Shift work** |
| Total Employees  at Location | | Employees without any connection  to the scope (of total) | | Employees in field service (within scope) | |
| Number | FTE\* | Number | FTE\* | Number | FTE\* |
| 1 |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |  |
| 4 |  |  |  |  |  |  |  |  |
| 5 |  |  |  |  |  |  |  |  |
|  | Total |  |  |  |  |  |  |  |

FTE\* = full-time equivalent

# Distribution of employees in organizational areas

(*Please include an attachment if there are more than 5 sites.)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Business area** | Location (Indication in FTE of the Employees  **with activity within the scope of certification**) | | | | |
| 1 | 2 | 3 | 4 | 5 |
| Design and development |  |  |  |  |  |
| Production / Service provision |  |  |  |  |  |
| Warehouse |  |  |  |  |  |
| Quality management / Quality control |  |  |  |  |  |
| Marketing, distribution and field service |  |  |  |  |  |
| Administration and other |  |  |  |  |  |
| Total |  |  |  |  |  |

**Details on shift work** *(If applicable)*

|  |  |  |
| --- | --- | --- |
| Are there any processes that cannot be audited during the regular audit period (9 am - 6 pm)? | Yes | No |
| If so, which processes/shifts are affected? | | |
|  | | |

# Details on outsourced activities

|  |  |  |
| --- | --- | --- |
| Are certain activities outsourced to external parties? (*e.g. part production*) | Yes | No |
| If so, which activities are affected? | | |
|  | | |

|  |
| --- |
| ***NOTES ON DATA PROTECTION:*** *The processing of the personal data provided in this questionnaire is carried out at the request of the signatory/submitting person for the purpose of pre-contractual measures (preparation of offers) and, if applicable, for the performance of a contract coming into existence in accordance with Art. 6 (1) lit. b DS-GVO. For any use of personal data beyond this, the consent of the person concerned is regularly required. You can give such consent in the following section. Further information on data protection can be found in our data protection declaration online at* [*www.mdc-ce.de/privacy*](https://www.mdc-ce.de/privacy.html) *and in our document "Data protection information for customers and interested parties".* |
| **Consent to the use of personal data for purposes of information about services and news from the certification environment**  (If you agree with the purpose of use, please tick this accordingly. If you do not wish to give your consent, tick the field “no”. If you leave the field blank, a previously given consent will remains valid).  Please inform me, independent of the certification procedure, about other aspects and news about the certification environment for medical devices, in-vitro diagnostics and health care as well as about your seminars on the subject:  **Yes, gladly by post**  **Yes, gladly by e-mail (please include your e-mail address)**  **No, currently I have no interest**  According to data protection legislation, you have the right to information, correction, restriction and deletion of your personal data. In addition, you have the right to revoke your consent at any time and without giving reasons. If you wish to exercise any of these rights, or if you have any further questions regarding data protection, please contact us by e-mail at [datenschutz@mdc-ce.de](mailto:datenschutz@mdc-ce.de). |

|  |  |  |
| --- | --- | --- |
| Click here to enter a date. |  |  |
| Place, date |  | Signature or name in the case of electronic transmission |

**Attachments:**

Organizational chart  Previous certificate(s), if applicable Trade register excerpt (not older than 6 months)

1. Under the TCP (Technical Cooperation Programme on Exchange of Medical Device GMP and ISO 13485 Audit Reports) [↑](#footnote-ref-1)