|  |  |
| --- | --- |
| **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 |       |

# Short description of the company’s activities and branch

|  |
| --- |
|       |

# Applied for certification

|  |  |
| --- | --- |
|  | Norm  |
| [ ]  | EN ISO 13485 |
| Desired scope: [Activities, e.g. *development, production and distribution, service, etc.]* + [Manufactured medical devices]  |       |
| [ ]  | ISO 13485 with additional acceptance in Taiwan [[1]](#footnote-2)  |
| [ ]  | ISO 13485 MDSAP with recognition in Australia / Brazil / Canada / Japan / USA 2(*Please also complete the „Questionnaire MDSAP (Basic Data) – DQS“ which you will find including instructions in the download area on our website* [*www.mdc-ce.de/en*](https://www.mdc-ce.de/en/service-portal/downloads/)*.*) |
| [ ]  | EN ISO 9001 |
| Desired scope: [Activities, e.g. *development, production and distribution, service, etc.]* + [Manufactured (medical) products]  |       |

# Area of aimed certification

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

# For multiple sites:

# EN ISO 13485 - Desired scope of application at the respective site

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

|  |  |  |
| --- | --- | --- |
| Site | *Address and, if applicable, different company name* | EN ISO 13485 Scope of application at the site  |
| 1 |       |       |
| 2 |       |       |
| 3 |       |       |
| 4 |       |       |
| 5 |       |       |

#

# EN ISO 9001 - Desired scope of application at the respective site

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

|  |  |  |
| --- | --- | --- |
| Site | *Address and, if applicable, different company name* | EN ISO 9001 Scope of application at the site  |
| 1 |       |       |
| 2 |       |       |
| 3 |       |       |
| 4 |       |       |
| 5 |       |       |

# 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 | **of total:**all Employeesin field service(within scope) | **of total:**all Employees without any connection to the scope |  |
|  |  | Number | FTE\* | Number | FTE\* | Number | FTE\* |  |
| 1 |       |       |       |       |       |       |       |[ ]
| 2 |       |       |       |       |       |       |       |[ ]
| 3 |       |       |       |       |       |       |       |[ ]
| 4 |       |       |       |       |       |       |       |[ ]
| 5 |       |       |       |       |       |       |       |[ ]
|  | Total |       |       |       |       |       |       |  |

FTE\* = full-time equivalent

# Distribution of employees in organizational areas

(*Please add 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 or within a group structure? | [ ]  Yes | [ ]  No |
| * Manufacturing / Production
 | [ ]  Yes |  |
| * Warehouse
 | [ ]  Yes |  |
| * Development and/or management of technical documentation
 | [ ]  Yes |  |
| * Other, such as personnel, procurement, etc.
 | [ ]  Yes |  |
| If so, which activities / processes are affected? |
|       |

# 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 |

# 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) |
|       |

# For the application review and offer preparation, the following attachments must be submitted with this questionnaire:

**Attachments:**

* Organizational chart
* Information on the scope of the QMS - if applicable, an extract from the QMH - with regard to the activities/services/production areas and locations to be included in the certification;
as well as information on standard chapters that are not applied or excluded
* previous certificate(s), if available
* Registration of the company by means of an extract from the national register;
for Germany: commercial register (if not available, business registration); for Austria: commercial register; for Switzerland: commercial register
(Excerpt from the commercial register or company register not older than 6 months)

and additionally for multiple sites:

* for independent branches or companies with a different name than the applicant: contractual provisions for implementing the QMS, in particular regarding the management and administration of the QMS for the location by the defined head office
* mdc new customers (initial certification, transfer): for dependent branches (not listed in the commercial register or similar): proof of official registration of the location; e.g. in Germany, business registration; if not available, a rental agreement or similar document

|  |
| --- |
| ***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 DSGVO. 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 document “Data protection information for customers and interested parties” in the download area at* [*www.mdc-ce.de/en*](https://www.mdc-ce.de/en/service-portal/downloads/)*.* |
| **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.  |

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

1. Under the TCP (Technical Cooperation Programme on Exchange of Medical Device GMP and ISO 13485 Audit Reports)

2 In co-operation with DQS Medizinprodukte GmbH [↑](#footnote-ref-2)