# 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) | |  |
| Own SRN (Single Registration Number) in the function as | Manufacturer |  |
| Authorized representative |  |
| SRN of the authorized representative | |  |
| Company VAT (TVA) ID number | |  |

# Main contact person

|  |  |
| --- | --- |
| Title | Mr.  Ms.  Dr |
| First and last name |  |
| Position |  |
| Direct/mobile phone |  |
| Personal e-mail address |  |

# If the company is based in Switzerland or outside the EU (except other EFTA countries)

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Address of the authorized representative based in the EU** | | |
| Company name |  | Legal Entity |  |
| Street |  | Country |  |
| Postal code |  | City |  |
| Salutation | Mr.  Ms. | Title |  |
| First and last name |  | Position |  |
| Direct/mobile phone |  | E-mail address |  |
| The national registration number of the EU representative: | |  | |

# External consulting companies

|  |  |  |
| --- | --- | --- |
| Were or are you supported by an external consulting company in implementing or maintaining the QM system? | Yes | No |
| If yes, please provide all involved consulting companies (company name, location) | | |
|  | | |

# Short description of the company’s activities and branch:

|  |
| --- |
|  |

# Area of aimed certification

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

# Aimed scope of certification

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Regulation/Standard | | | Accreditation/Acceptance |
|  | Regulation (EU) 2017/746 – In vitro diagnostic medical devices:  Annex IX, Chapter I & III  Annex IX, Chapter II  *(Please complete the „List of In Vitro Diagnostic Medical Devices (IVDR)“ to be attached in the document “Questionnaire for a quotation – In Vitro Diagnostic Medical Devices – Attachment: List of In Vitro Diagnostic Medical Devices (IVDR)” to download on our website* [*www.mdc-ce.de/en*](https://www.mdc-ce.de/en/service-portal/downloads/)*.)* | | | ZLG[[1]](#footnote-2) |
|  | EN ISO 13485 | | | DAkkS[[2]](#footnote-3) |
| Aimed scope of the certificate(s): [Activity, e.g. development, manufacturing and distribution, maintenance, etc.] + [manufactured in vitro diagnostic medical devices] | |  |
|  | ISO 13485 with additional acceptance in Taiwan | | under the TCP[[3]](#footnote-4) |
|  | ISO 13485 MDSAP with additional acceptance in Australia/Brazil/Canada/Japan/USA  (*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/)*.*) | | in co-operation with DQS[[4]](#footnote-5) |
|  | EN ISO 9001 | | | DAkkS2 |
| Aimed scope of the certificate(s):  [Activity, e.g. development, manufacturing and distribution, etc.] + [(in vitro diagnostic medical) devices] | |  |

# Information on your existing quality management system

|  |  |  |
| --- | --- | --- |
| Has your QM system already been certified?  *(If yes, please add copies of your certificates)* | Yes | No |
| If yes, by which Notified Body/registrar? |  | |
| If yes, when does the validity of your certificate(s) end? |  | |

# Information on the time schedule

|  |  |
| --- | --- |
| Until when can the technical documentations listed in Annex I be submitted for assessment? |  |
| When is your QM system ready for audit? *Note: before performing the audit according to Regulation (EU) 2017/746, an assessment of the Technical Documentation must be performed.* |  |
| Is there a deadline by which the audit should be completed? |  |

# Information on the language

|  |  |  |
| --- | --- | --- |
| In which language should the **audit** be conducted? | German | English |
| In which language is the **technical documentation** available? | 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 attach an annex 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 operation *(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 yes, which activities are outsourced? | | |
|  | | |

|  |
| --- |
| ***NOTES ON DATA PROTECTION:*** *The processing of the personal data communicated in this questionnaire takes place at the request of the signatory/the submitting person for the purpose of pre-contractual measures (preparation of offers) and, if necessary, for the execution of a coming contract according to Art. 6 Para. 1 lit. b GDPR. For any further use of personal data, the consent of the data subject 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 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  In accordance with 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 have any further questions about data protection, please send an e-mail to [*datenschutz@mdc-ce.de*](mailto:datenschutz@mdc-ce.de) |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Place, Date |  | Signature or full name in case of electronic transmission |

**The following documents have to be attached to the questionnaire:**

* Trade register excerpt (not older than 6 months)
* Organisation chart
* Previous certificate(s), if applicable
* Certificates of critical subcontractors
* Duly completed „**List of In Vitro Diagnostic Medical Devices (IVDR)**“ (*to be attached in the document “Questionnaire for a quotation – In Vitro Diagnostic Medical Devices – Attachment: List of In Vitro Diagnostic Medical Devices (IVDR)” to download on our website* [*www.mdc-ce.de/en*](https://www.mdc-ce.de/en/service-portal/downloads/))
* Performance Evaluation Plan (PEP)
* Instruction(s) for use, detailed product description(s), etc.
* For a recertification procedure: Summary of changes and scientific findings for the device in accordance with Annex VII, 4.11

1. Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten [↑](#footnote-ref-2)
2. DAkkS – Deutsche Akkreditierungsstelle GmbH [↑](#footnote-ref-3)
3. Technical Cooperation Programme on Exchange of Medical Device GMP and ISO 13485 Audit Reports [↑](#footnote-ref-4)
4. DQS Medizinprodukte GmbH [↑](#footnote-ref-5)