# 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 |  |
| Distributor acc. art.22 |  |
| 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 |  | Place |  |
| 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 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) | | |
|  | | |

# Branch, activities and processes (please describe)

|  |
| --- |
|  |

# Area of aimed certification

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

# Aimed scope of certification

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Regulation/Standard | | | | Accreditation/Acceptance |
|  | Regulation (EU) 2017/745 – Medical Devices:  Annex IX, Chapter I & III  Annex IX, Chapter II  Annex XI, Part A  additionally Annex XVI  Procedure packs article 22(3) Annex IX, Chapter I  Procedure packs article 22(3) Annex XI, Part A  *(Please also complete Annex I (see below) and, if required, Annex II.)* | | | | ZLG[[1]](#footnote-2) |
|  | Surveillance according to Art. 120 (3c) MDR of certificates according to Directive 93/42/EEC | | | | ZLG1 |
|  |  | as part of a MDR certification. | | Number of MDD certificates enclosed: |
|  |  | without certification according to MDR  *(a confirmation can only be issued until 26 May 2024)* | |
|  | EN ISO 13485 | | | | DAkkS[[2]](#footnote-3) |
| Desired scope of the certificate(s): [Activity, e.g. development, manufacturing and distribution, maintenance, etc.] + [manufactured 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 do 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 |
| Desired scope of the certificate(s):  [Activity, e.g. development, manufacturing and distribution, etc.] + [(medical) devices] | |  | |

# Information on the quality management system

|  |  |  |
| --- | --- | --- |
| Is your quality system 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) 2017/745, 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 syste *(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 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 the group structure? | Yes | No |
| * Manufacturing / production | Yes |  |
| * Warehouse | Yes |  |
| * Development and / or control of the Technical Documentation | Yes |  |
| * Other matters, such as personnel, procurement, etc | Yes |  |
| If yes, which activities / processes 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 are attached to the questionnaire:**

Organisation chart Previous certificate(s), if applicable

Clinical evaluation plan  if possible Clinical evaluation report

Certificates of critical subcontractors

Trade register excerpt (not older than 6 months)

Current certificates acc. to Directive 93/42/EEC the surveillance in accordance with Art. 120 (3c) MDR is applied for

**ANNEX I**

Please attach to the completed questionnaire the duly completed “List of medical devices (MDR)” as Annex I. You will find it in the document “Questionnaire for a quotation - Medical devices - Attachment I: List of Medical Devices (MDR)” on [www.mdc-ce.de/en](https://www.mdc-ce.de/en/service-portal/downloads/).

Please also enclose detailed product information such as instruction(s) for use, detailed product description(s), additional item list(s) etc. with the completed questionnaire.

If it is a recertification procedure, a “Summary of changes and scientific findings for the device” shall also be submitted in accordance with Annex VII, 4.11.

**ANNEX II**

Manufacturers of class Ir devices are also requested to attach the completed “Questionnaire for a quotation - Medical devices - Attachment II: Questionnaire Medical Devices class Ir (if applicable)”. You will find the document on [www.mdc-ce.de/en](https://www.mdc-ce.de/en/service-portal/downloads/).

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)