**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) |  |
| SRN (Single Registration Number) – if known |  |
| Company VAT (TVA) ID number |  |

**Main contact person**

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

**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) | | |
|  | | |

**Information on the language**

|  |  |  |
| --- | --- | --- |
| In which language is the **technical documentation** available? | German | English |

**Description of products or product groups**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Intended use/short description of the product** (Please enclose detailed product documentation: e.g. instructions for use, product/article list, detailed product description, ...) | Risk class when considered separately as a medical device | Classification rule with bullet | MD-Codes[[1]](#footnote-2) |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |
| 4 |  |  |  |  |
| 5 |  |  |  |  |

**Information on subcontractors/suppliers, if applicable**

(Please add copies of the suppliers’/subcontractors’ certificates!)

|  |  |  |
| --- | --- | --- |
|  | Name and address of subcontractors / suppliers | Subcontracted activity |
| 1 |  |  |
| 2 |  |  |
| 3 |  |  |
| 4 |  |  |

**Please copy this page if more than 4 subcontractors / suppliers are involved**

|  |
| --- |
| ***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 do not forget to 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) |

|  |  |  |
| --- | --- | --- |
| Klicken Sie hier, um ein Datum einzugeben. |  |  |
| Place, Date |  | Signature or full name for electronic transmission |

1. Full details of the MD codes from the implementing regulation EU 2017/2185 that apply to the product. At least one MDA or MDN code and the applicable MDS or MDT codes must be specified for each product; these codes are used to check whether the request falls within the scope of the mdc notification and serve to plan the assessment. [↑](#footnote-ref-2)