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

|  |  |
| --- | --- |
| Title | Mr.  Ms.  Dr. |
| First and Last Name |  |
| Position |  |
| Direct phone |  |
| Personal E-Mail Address |  |

If the company is based in non-EU countries (except EFTA countries, Switzerland and Turkey)

|  |  |  |  |
| --- | --- | --- | --- |
|  | **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 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) | | |
|  | | |

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 / Directive | Accreditation/Acceptance |
|  | EC- Directive 98/79/EC – In vitro Diagnostic Devices  Annex IV  Annex VII  *(Please also fill in Annex I)* | ZLG[[1]](#footnote-1) |
|  | EN ISO 13485 | DAkkS[[2]](#footnote-2) |
|  | EN ISO 9001 | DAkkS2 |
|  | EN ISO 13485 with additional acceptance in Taiwan | under the TCP[[3]](#footnote-3) |
|  | ISO 13485 MDSAP with additional acceptance in Canada/USA/Brazil/Japan/Australia | In co-operation with DQS[[4]](#footnote-4) |

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 Notified Body/registrar? |  | | | |
| If yes, when does the validity of your certificate(s) end? |  | | | |
| Your desired period for the audit? |  | | | |
| In which languages can the audit be conducted? |  | | | |
| In which language is the technical documentation available? | German | English | | Other |

Subsidiaries, branch offices, production sites and further sites which are covered by the quality system*(Please copy this page in case there are more than 5 sites)*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Location | Address and legal entity | Number of Employees | | | | | | Shift work |
| Full time | Part time | External sales | Marginally employed staff | Temporary workers (permanent + non-permanent) | Trainees |
| 1 |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |  |
| 4 |  |  |  |  |  |  |  |  |
| 5 |  |  |  |  |  |  |  |  |
|  | Total |  |  |  |  |  |  |  |

Distribution of employees in organizational areas   
*(Please copy this page in case there are more than 5 sites)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Business area** *(Please add an organization chart of your company)* | Location | | | | |
| 1 | 2 | 3 | 4 | 5 |
| Design and development |  |  |  |  |  |
| Manufacturing / Production and warehouse |  |  |  |  |  |
| Repair or Reprocessing of medical devices |  |  |  |  |  |
| Quality management / Quality control / Regulatory Affairs |  |  |  |  |  |
| 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 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 data protection declaration online at* [*https://www.mdc-ce.de/privacy.html*](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 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) |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Place, Date |  | Signature or full name |

**ANNEX I**

Certification of In- Vitro Diagnostic Medical Devices according to EC Directive 98/79/EC

**A) Description of products or product groups***(Please provide detailed product documentation, usage instructions)*

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Purpose / product or product group name** | **Class** | **OEM**[[5]](#footnote-5) |
| **1** |  |  |  |
| **2** |  |  |  |
| **3** |  |  |  |
| **4** |  |  |  |

*(Please copy this page if more than 4 products are to be certified!)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **The above mentioned products are classified as follows** | **Device** | | | |
| **1** | **2** | **3** | **4** |
| Devices for self-testing (IVD 0400) |  |  |  |  |
| Devices for self-diagnosis for measurement of blood sugar (IVD 0309) |  |  |  |  |
| Reagents and reagent products, including related calibrators and control materials | | | | |
| for determining the following blood groups: ABO system (IVD 0101), Rhesus (C, c, D, E, e) (IVD 0102), anti-Kell (IVD 0103) |  |  |  |  |
| for the detection, confirmation and quantification in human specimens of markers of HIV infection (HIV 1 and 2) (IVD 0201), HTLV I and II (IVD 0202), and hepatitis B, C and D (IVD 0203) |  |  |  |  |
| for determining the following blood groups: anti-Duffy and anti-Kidd (IVD 0301) |  |  |  |  |
| for determining irregular anti-erythrocytic antibodies (IVD 0302) |  |  |  |  |
| for the detection and quantification in human samples of the following congenital infections: rubella, toxoplasmosis (IVD 0303) |  |  |  |  |
| for the detection of following hereditary disease: phenylketonuria (IVD 0304) |  |  |  |  |
| for determining the following human infections: cytomegalovirus, chlamydia (IVD 0305) |  |  |  |  |
| for determining the following HLA tissue groups: DR, A, B (IVD 0306) |  |  |  |  |
| for determining the following tumoral marker: PSA (IVD 0307) |  |  |  |  |
| And software, designed specifically for evaluating the risk of trisomy 21 (IVD 0308) |  |  |  |  |
| IVDs in sterile condition (MDS 7206) |  |  |  |  |
| IVDs containing or using software, or being controlled by software (MDS 7205) |  |  |  |  |
| IVDs utilising biological active coating and/or material (MDS 7209) |  |  |  |  |
| IVDs utilising material of human origin (MDS 7210) |  |  |  |  |
| IVDs utilising micromechanics (MDS 7207) |  |  |  |  |
| IVDs utilising nanomaterials (MDS 7208) |  |  |  |  |

**B) Information concerning subcontractors / suppliers***(Please copy this page if more than 2 subcontractors / suppliers are involved)*

|  |  |  |
| --- | --- | --- |
|  | **Name and address of subcontractors / suppliers** *(Please add copies of the suppliers’/subcontractors’ certificates!)* | **Subcontracted activity** |
| **1** |  |  |
| **2** |  |  |

1. Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten [↑](#footnote-ref-1)
2. DAkkS – Deutsche Akkreditierungsstelle GmbH - German Association for Accreditation GmbH [↑](#footnote-ref-2)
3. Technical Cooperation Programme on Exchange of Medical Device GMP and ISO 13485 Audit Reports [↑](#footnote-ref-3)
4. DQS Medizinprodukte GmbH [↑](#footnote-ref-4)
5. These are products which are placed on the market under the name of your company, but are sold as ready-to-sell products by an "original equipment manufacturer" ("original manufacturer"). [↑](#footnote-ref-5)