With the following information we would like to give you an overview of the processing of your personal data by mdc medical device certification GmbH and your rights under data protection legislation (basis: Articles 12 to 23 EU Data Protection Regulation GDPR "Rights of the Data Subject" and §§ 32 to 36 Federal Data Protection Act BDSG). Please refer to the following information about which data will be processed by mdc and how they will be used. The following data protection information is particularly addressed to customers, interested parties, applicants and authorized representatives. Therefore not all parts of this information may apply to you.

1. Who is controller of the processing of data and to whom may I refer for questions regarding privacy?

The controller of data processing is:

mdc medical device certification GmbH
Mr. Harald Rentschler (CEO)
Kriegerstraße 6
70191 Stuttgart / Germany
Phone: +49 711 253597 0
E-mail address: mdc@mdc-ce.de

You may contact our internal data protection officer:

mdc medical device certification GmbH
Data protection officer
Kriegerstraße 6
70191 Stuttgart / Germany
E-mail address: datenschutz@mdc-ce.de

2. What kind of data from which resources will be processed?

We collect your personal data when you get in contact with us, e.g. when you visit our booth at a business fair as an interested party, when you contact us through an authorized representative or through the consulting company you have contracted or when you contact us directly as an applicant or customer. In particular, if you complete and submit the questionnaire for the preparation of an offer, submit applications or if you use our products and services within the framework of an existing business relationship, personal data is processed. In addition to that we process personal data as far as they are necessary to provide our services, which we legally obtain from publicly accessible sources (e.g. commercial register, press, and internet).

3. For which purposes do we process your data (purpose of processing) and on on what legal basis?

We process personal data in accordance with the provisions of the European General Data Protection Regulation (GDPR), the Federal Data Protection Act (BDSG) and the existing special legal regulations at national level (federal and state legislation):

a) For the fulfilment of contractual obligations (Art. 6 para. 1 b GDPR)
The processing of data is carried out for the purpose of providing inspection, assessment and certification services, seminar offers in the context of the execution of our contracts with our customers or for the implementation of pre-contractual measures which are carried out on request (e.g. by interested parties in our services). The purposes of data processing are primarily based on the specific product (e.g. certification process according to an internationally recognized standard, assessment services of technical documentation, inspection, assessment and certification within the scope of CE marking, the performance of seminars). Further details on data processing purposes can be found in the relevant application documents and terms and conditions.

b) Within the framework of the balancing of interests (Art. 6 para. 1 lit. f GDPR)
As far as necessary, we process your data beyond the actual fulfilment of the contract in order to protect the legitimate interests of us or third parties. Examples: Examination and optimization of procedures for the analysis of requirements for the purpose of direct customer contact, advertising or market research, insofar as you have not objected to the use of your data, assertion of legal claims and defense in the event of legal disputes, guaranteeing IT security and the IT operation of the company, prevention and clarification of criminal offences, for the collection of evidence in the event of robberies and fraud offences, measures for building and plant security (e.g. access control), measures to secure the building rights, measures for business management and further development of services and products, risk management of mdc medical device certification GmbH.

c) Based on your consent (Art. 6 para. 1 lit. a GDPR)
If you have given us your consent to process personal data for specific purposes (e.g. receipt of advertising e-mails about products and services and information from the certification environment in the areas of medical devices and healthcare), the lawfulness of this processing is based on your consent. Any consent granted can be revoked at any time. This also applies to the revocation of declarations of consent that were issued to us before the GDPR became effective, i.e. before 25 May 2018. The revocation of consent does not affect the legality of the data processed until revocation.

d) Due to legal requirements (Art. 6 para. 1 c GDPR) or in the public interest (Art. 6 para. 1 e GDPR)
In addition, as an accredited certification body and Notified Body for the award of CE markings, we are subject to various normative and legal obligations, i.e. legal and official requirements (e.g. accreditation rules of the ZLG, accreditation rules of the DAkkS, corresponding EU regulations in the field of medical products, the EU 2017/745 Medical Device Regulation, the Medical Products Act (MPG)(national law) and others). The processing also includes the fulfilment of legally and officially prescribed control and notification obligations.

4. Who will receive my personal data?

Within mdc medical device certification GmbH those departments receive access to your data that need it to fulfill our contractual and legal obligations. External service providers we have engaged (auditors and technical experts, co-operation partners) may also receive data for these purposes. In addition, it is possible that data may be passed on to the supervisory authorities within the framework of official reporting obligations or within the framework of branch office assessments by bodies issuing authorizations. We have concluded appropriate written agreements with our affiliated bodies and contractual partners on secrecy, confidentiality and secure handling in the processing of personal data.

These are companies in the categories credit institutions, tax consultancy, IT services, telecommunication services, collection, destruction of data and files, as well as sales and marketing. With regard to the transfer of data to recipients outside of mdc medical device certification GmbH it should be noted that we as a Notified Body and accredited certification body are bound to secrecy and confidentiality with regard to all customer-related facts, data, information and assessments of which we become aware.

We may only pass on information about you if required by law and/or official regulations, if you have consented to this or if we are authorized to provide information. Under these conditions, the recipients of personal data may be, for example: public bodies and institutions (e.g. Central Authority of the Federal States for Health Protection with regard to Medicinal Products and Medical Devices (ZLG), German Accreditation Body GmbH (DAkkS), the Federal Institute for Drugs and Medical Devices (BfArM), the Federal Association of Statutory Health Insurance Physicians (KBV), the Federal Association of Statutory Health Insurance Funds (GKV Spitzenverband Bund), tax authorities, criminal prosecution authorities) if there is a legal or official obligation.

Recipients may also be other Notified Bodies or certification bodies or comparable institutions to which we transfer personal data in order to carry out the business relationship within the framework of co-operation procedures for certification.

5. Is data transferred to a third country or to an international organization?

Data will only be transferred to bodies in countries outside the EU area (so-called third countries) if it is necessary to carry out your orders (e.g. to audit a branch office in a third country), if it is required by law or if you have given us your consent.

Furthermore, mdc medical device certification GmbH does not transfer any personal data to third countries or international organizations outside the EU.

6. How long will my data be stored?

We process and store your personal data as long as it is necessary for the fulfilment of our contractual and legal obligations or as long as you are authorized to represent the respective (natural/legal) person to us. It should be noted that our business relationship is a continuing obligation, which is set up for years in accordance with the term of the commissioned certification basis. If the data is no longer required for the fulfilment of contractual or legal obligations, it will be regularly deleted, unless its temporary further processing is necessary to fulfil storage obligations. The German Commercial Code (HGB) and the German Fiscal Code (AO) should be mentioned. The periods of retention or documentation specified there are two or up to ten years. In addition, within the scope of the activities as a notified body, there are official requirements for the archiving of procedural documents which are 10 years (or 15 years for implants) after the end of the validity of the last certificate. Storage could also be necessary for the preservation of evidence within the framework of the legal statute of limitations. According to §§ 195 et seq. of the German Civil Code (BGB), these limitation periods can be up to 30 years, whereby the regular limitation period is 3 years.

7. What data protection rights do I have?

Every data subject has the right of access under Article 15 GDPR, the right of rectification under Article 16 GDPR, the right of deletion under Article 17 GDPR, the right to restrict processing under Article 18 GDPR, the right of objection under Article 21 GDPR and the right of data transferability under Article 20 GDPR. With regard to the right of information and the right of deletion, the restrictions under Articles 34 and 35 BDSG apply. In addition, there is a right of objection to a competent data protection supervisory authority (Article 77 GDPR in conjunction with Article 19 BDSG). You can revoke your consent to the processing of personal data at any time. This also applies to the revocation of declarations of consent that were given to us before the basic data protection regulation came into force, i.e. before 25 May 2018. Please note that the revocation is only effective for the future. Processing that took place before the revocation is not affected.

8. Is there an obligation for me to provide data?

Within the framework of our business relationship, you must provide us with personal data which are necessary for the establishment and execution of a business relationship and the fulfilment of the associated contractual obligations. There is also a legal obligation to collect and process your personal data for identification purposes. Without these data, we will generally not be able to conclude or execute the contract with you.
If you are authorized to represent a company, you must provide us with the personal data that is necessary for the acceptance and implementation of a representation/authorization and the fulfilment of the associated contractual obligations. Without this data, we will usually have to reject you as a representative/authorized representative or cancel an existing representative authorization.
Any changes arising in the course of the business relationship must be reported immediately.
If you do not provide us with the necessary information and documents, we may not commence or continue the business relationship requested by you or we cannot establish or continue the power of representation/authorization requested by the respective person. Your obligations to cooperate in the certification process, which are described in our GTC, remain unaffected by this.

9. Does automated individual decision making take place?

To establish and conduct business relations we do not use any fully automated decision making (profiling) in accordance with Article 22 GDPR

10. Information about your right to object

1. Right of objection in individual cases
You have the right to object at any time to the processing of personal data relating to you, which is carried out on the basis of Article 6 paragraph 1 letter e) GDPR (data processing in the public interest) and Article 6 paragraph 1 letter f) GDPR (data processing based on a balancing of interests) at any time and for reasons arising from your particular situation. This also applies to profiling based on this provision within the meaning of Article 4 No. 4 GDPR. If you object, we will no longer process your personal data unless we can prove compelling reasons for processing that are worthy of protection and outweigh your interests, rights and freedoms, or unless the processing serves to assert, exercise or defend legal claims.

2. Right to object to the processing of data for direct marketing purposes: In individual cases, we process your personal data in order to carry out direct advertising. You have the right to object at any time to the processing of your personal data for the purpose of such direct marketing. If you object to processing for direct marketing purposes, we will no longer process your personal data for these purposes. The objection can be made without form and should be addressed to: mdc medical device certification GmbH, Data protection officer, Kriegerstr. 6, 70191 Stuttgart / Germany, e-mail: datenschutz@mdc-ce.de

Information about your right to lodge a complaint with a supervisory authority

If you believe that the processing of your personal data by mdc does not comply with the requirements of the GDPR and/or the BDSG, you have the right in accordance with article 77 GDPR, to lodge a complaint with a supervisory authority. This can be done without prejudice to any other administrative or judicial remedy.
You will find an overview of the supervisory authorities at federal and state level on the Internet under the following link of the Federal Commissioner for Data Protection and Freedom of Information:
https://www.bfdi.bund.de/DE/Infothek/Anschriften_Links/anschriften_links-node.html