1. Scope

These regulations, which belong to the general terms of business of mdc medical device certification GmbH (in the following mdc) cover the following certification activities:

– certification of medical devices according to Directive 93/42/EEC,
– certification of in vitro diagnostic medical devices according to Directive 98/79/EC,

mdc acts as Notified Body (EC identification number 0483) on the basis of the aforementioned Directives in their currently valid version as well as the German Medical Device Law including the respective Decrees in their valid versions. Furthermore it is understood that for the duty as a Notified Body mdc applies the relevant accreditation and designation regulations mdc is subject to as well as European and national recommendations and guidance documents.

2. Due to the fact that the medical device legislation is a constantly changing field, mdc uses in the certification process for interpretation of the state of the art beside harmonized standards other published standards, draft standards, literature and working documents. Application

The applicant declares:

– that he did not apply at any other Notified Body for certification of the same quality system regarding the products mentioned,
– that he assures to fulfill all obligations resulting from the approved quality system and to keep the quality system adequate and efficient,
– that he will institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and implement appropriate means to apply any necessary corrective action. Furthermore he is obliged to notify the competent authorities of the following incidents immediately on learning of them:
  I. any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health,
  II. any technical or medical reason connected with the characteristics or performance of a device leading to the reasons referred to in subparagraph I) to systematic recall of devices of the same type by the manufacturer.
– that according to the regulations of the certification contract, which was signed between him and mdc, and the general terms of business of mdc he will comply continuously with the requirements for the certification and make all relevant information available.
– giving employees or subcontractors of mdc during working hours access to all sites of the company without the necessity of a prior notice.
– having agreed this right of access for the Notified Body with all subcontractors involved in design control, manufacturing, testing and storage as well as with critical suppliers for their sites.

In case of certification of medical devices according to Directive 93/42/EEC the application contains the manufacturer's binding classification of the medical devices according to Annex IX of this Directive.

In case of certification of in vitro diagnostic medical devices according to Directive 98/79/EC the application contains the manufacturer's binding categorization of the in vitro diagnostic medical devices according to Annex II of this Directive.

For the assessment of the technical files during certification or surveillance the manufacturer submits the documents in the number requested by mdc. A technical file review will be only ensured, if all documents are available in English or German language. The possibility of submitting parts of the documentation in in other official languages of the EU has to be clarified by the manufacturer with mdc prior to filing the application.

In case it turns out during a technical file review that product tests are required, mdc is entitled to perform these test. The manufacturer will supply the required samples. He covers all expenses for testing, samples, shipping and disposal.

The manufacturer takes all necessary measures in order to allow performance of unannounced audits at his site and at the site of the subcontractors/suppliers. Refusal or hindrance of an unannounced audit is a major violation of the certification rules, which will cause suspension of the certificate. mdc may inform competent authorities as well as the European authorized representative about this fact.

In the course of unannounced audits samples for product testing are taken. If the required tests cannot be performed on the audited site, mdc is authorized to have the tests performed by a subcontracted laboratory. The manufacturer covers all expenses for testing, samples, shipping and disposal. In case of non-availability of samples onsite, they may have to be sampled from the market. The manufacturer will take over the purchasing costs as well.

2.1. Additional requirements to the application for Annex II.4 of MDD 93/42/EEC, Annex IV.4 of IVDD 98/79/EC (Examination of the design of the product)

The applicant declares:

– that he will put documents to the Notified Body's disposal, which describe the design, manufacture and performances of the product in question. It must include the documents needed to assess whether the product conforms to the requirements of this.

The Notified Body examines the application and if the device conforms to the relevant provisions of the respective Directive an EC design-examination certificate will be issued. The Notified Body may require further tests or proof to decide on the conformity with the requirements of this Directive. Mdc is authorized to perform such tests. The manufacturer makes available the requested samples. He covers all expenses for testing, samples, shipping and disposal.

2.2. Additional requirements to the application for Annex III.6 of IVDD 98/79/EC (EC design-examination certificate for devices for self-testing)

The applicant declares that he will supply the Notified Body with following documents:

– a comprehensible description of the design of the product which enables the assessment of the conformity with the design-related requirements of IVDD 98/79/EC,
– test reports including, when appropriate, results of studies carried out with lay persons,
– data showing the handling suitability of the device in view of its intended purpose for self-testing,
– the information to be provided with the advice on its label and its instructions for use.

The Notified Body examines the application and if the device conforms to the relevant provisions of the Directive an EC design-examination certificate will be issued. The Notified Body may require further tests or proof to decide on the conformity with the requirements of this Directive for design.

2.3. Additional requirements to the application for Annexes IV.6 or VII.5 of IVDD 98/79/EC (Verification of manufactured products covered by Annex II List A)

The applicant assures the following procedure: The applicant forwards to the Notified Body without delay after the conclusion of the controls and tests the relevant reports on the tests carried out on the manufactured devices or each batch of devices. Furthermore, the manufacturer shall make the samples of manufactured devices or batches of devices available to the Notified Body in accordance with pre-agreed conditions and modalities.

The manufacturer may place the devices on the market, unless the Notified Body communicates to the manufacturer within the agreed time-frame, but not later than 30 days after reception of the samples, any other decision, including in particular any condition of validity of delivered certificates.

Assessment
The applicant agrees that the bodies granting mdc authorization may observe assessment audits and assures their access to his and his suppliers' facilities.
During audits according to EC-Directives mdc verifies that the applicant fulfills his legal notification requirements towards competent authorities.
In cases of certifications according to EC-Directives it may become necessary that subcontractors or suppliers have to be audited by mdc if relevant design, manufacturing or inspection activities are not performed by the applicant. In particular this is required if the manufacturer cannot provide sufficient proof of competence of the subcontractor/supplier or if the activities are not verified sufficiently by incoming inspections.
In cases of certifications according to EC-Directives it may become necessary that specific design, manufacturing or testing aspects may require during the assessment involvement of additional experts or laboratories.

4. Enforcement of the Certification Rules
In cases where an applicant violates general terms of business of mdc and/or parts of them, mdc may take necessary measures. These measures may be the agreement of corrective actions, a restriction in the scope of certification, a timely limited suspension or a withdrawal of the certification. In any case suspension or withdrawal will only occur by decision of the certification board.
In particular mdc can suspend or withdraw certificates according to §18 of the German Medical Device Decree (MPG) if one of the following facts existed at the time of certification:
– the requirements of the Annexes II - VII (as far as applicable) of the Directive 93/42/EEC, Annexes III - VII of Directive 98/79/EC (as far as applicable), which are condition for the granted certification, were not fulfilled,
– a device or a category of devices, which is subject to the certification procedure, was wrongly specified as a medical device pursuant to Directive 93/42/EEC, as an in vitro diagnostic medical device pursuant to Directive 98/79/EC,
– a device or a category of devices was classified wrongly and therefore a wrong declaration of conformity was used,
– the device, which was submitted for EC-type examination, was not in accordance with the devices manufactured later.
Furthermore the certificate can be withdrawn if one of the following facts will occur after granting a certification:
– the legal requirements for the system, device or category of devices covered by the certificate are not fulfilled,
– the device or category of devices is not or not further covered by the Directive 93/42/EEC or Directive 98/79/EC.
– the device or category of devices do not fulfill the Essential Requirements in a way that patient, user or third persons are exposed to major risks or the devices do not fulfill the claim defined by the manufacturer and the fault can not be removed in a planned and adequate time.
Furthermore the certificate can be withdrawn in particular if:
– the certificate or the mdc-Logo are misused,
– the applicant makes statements about certification of scopes which his certificate does not contain,
– the applicant uses the certification in a way that brings mdc into disrepute,
– the applicant makes statements that mdc regards as misleading or not authorized,
– the certificate or reports or parts of them are used in a misleading way,
– the applicant does not accept the annual surveillance audits,
– the applicant, his subcontractor or supplier does not accept or hinders the performance of an unannounced audit or product test,
– the applicant does not eliminate non conformities concerning the normative basis within a given period of time,
– the applicant gives up his business activities because of financial or other reasons,
– the applicant gets into payment defaults despite mdc's reminders,
– the applicant does not fulfill the notification requirements.

In case of a suspension or withdrawal of a certificate the applicant or his representative located in the EEC has the possibility to explain his position in advance. Exceptionally a withdrawal can be performed without this hearing if there is a special urgency for this measure. Rejected or hindered unannounced audits state such a case of special urgency. Information regarding refused, restricted, suspended or withdrawn certificates and written confirmations are reported by mdc via DIMDI. Additional notifications can be made to the competent authority relevant for the manufacturer, other competent authorities or to the other notified bodies according to §18 MPG and IVDD 98/79/EC, MDD 93/42/EEC. The authorities may inform further authorities and the European Commission. Reports for authorities may contain recommendations for risk protection. Certificates which were declared as non-valid by mdc have to be returned in original or their destruction has to be confirmed in writing.
In case of repeatedly negative assessment results mdc may refuse the issuing of a certificate. Information regarding those refused certificates is reported to DIMDI by mdc.
If the customer withdraws a certification application or terminates a certification contract, mdc checks the report on the assessments carried out and reserves the right to decide and report a refused certificate.

5. Use of certification, certificate, CE marking and certification mark
The applicant is obliged to use his certification only according to the conditions mentioned in the rules concerning the "Use of certification, certificate and certification mark".

6. Notification Requirements
Beside the notifications which are requested by mdc in the context of the surveillance audit, planned changes in the location, organization, relevant suppliers, subcontractors, production technologies and/or product range must be notified*. Further the applicant is obliged to inform mdc immediately about incidents or recall of the products in the sense of Article 10 of Directive 93/42/EEC or Article 11 of Directive 98/79/EC. Furthermore limitations regarding market activities (e. g. through verdicts or decisions by authorities) must be reported to mdc. Any actions by competent authorities under the medical device legislation like inspections or requests for documents as well as the results have to reported to mdc timely. Furthermore the manufacturer informs mdc about any disputes or legal investigations regarding non-conforming products.

6.1. Certificates according to Annex II.4 of MDD 93/42/EEC, Annexes III.6 or IV.4 of IVDD 98/79/EC
The applicant informs mdc of any planned significant change to the approved design*. Changes to the approved design must receive further approval from mdc certificate wherever the changes could affect conformity with the essential requirements of the relevant Directive or with the conditions prescribed for the use of the product. This additional approval will take the form of a supplement to the EC design-examination certificate.

7. Class III and IIb medical devices, in vitro diagnostic medical devices covered by List A
An application for conducting a certification process according to Annex II of the Directive 93/42/EEC which contains class III products is deemed to be as application for the EC design examination. To conduct a certification process according to Annexes V and VI of MDD 93/42/EEC which contains class III or IIb products the presentation or the acquisition of a valid EC type examination certificate is necessary.
For in vitro diagnostic devices covered by List A a certification process according to Annex V of IVDD 98/79/EC is necessary in addition to the certification process according to Annex VII.
In vitro diagnostic devices covered by List A may only be placed on the market after a positive examination of the manufactured products according to Annex IV.6 respectively VII.5 of the Directive 98/79/EC.

8. Liability

Liability through mdc is limited to cases of premeditation or gross negligence. The height of the liability is limited to following amounts: € 3.000.000 for personal injury, € 2.000.000 for material damage and for property damage. All further claims are excluded. mdc is covered by a legally required liability insurance covering the above mentioned amounts.

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* form „notification of changes“ in www.mdc-ce.de/downloads/mdc-documents