1. Subject

The present certification rules are a component of the General Terms of Business of mdc medical device certification GmbH (referred to in the following as "mdc"). They apply to the operation as Notified Body (identification number 0483) under Regulation (EU) 2017/745 (referred to in the following as "MDR") and also include the surveillance of legacy devices certified under Directive 93/42/EEC according to Article 120 (3e) MDR.
The operation is always based on the current version of the MDR, including the corresponding delegated acts and implementing acts.
It is acknowledged that mdc furthermore applies Common Specifications, harmonised and other standards as well as regulations of the authorisation-granting bodies (in particular designation authorities). It is furthermore acknowledged that in the certification procedure, mdc uses guidelines, recommendations, drafts of standards and working papers which are based on a broad national, European or international consensus. The present certification rules shall also apply to procedures under Article 16 with the conditions laid down in section 3.6.

2. Impartiality

The principle of impartiality, to which mdc fully commits itself, is a fundamental requirement to be met by the assessments, evaluations, tests and certifications to be performed by mdc. The independence of the personnel is verified both when hiring employees and when selecting and commissioning external auditors, technical experts or testing facilities. A mechanism for ascertaining impartiality has been established. Processes for avoiding and handling conflicts of interest are in place.

3. Description of the process

Each certification procedure as per the MDR is subdivided into the following phases:
– Preparation
– Assessment
– Certification
– Surveillance
– Re-certification

Only the following phases are relevant for the surveillance of legacy devices according to MDR Article 120:
- Preparation
- Surveillance

3.1 Preparation

3.1.1 Quote and preliminary check

Interested persons are provided with a questionnaire for preparation of a quotation with a corresponding product list, and a written certification quote is then submitted on the basis of the complete information and attachments. The quotes are based on the assumption that all documents are available in German or English.
The expenditure offered for the assessment of the technical documentation is based on use of a document structure specified by mdc.
A personal preliminary talk or other information provided should outline the course of the procedure and explain the requirements. This does not replace own procurement of information about relevant regulations, appropriate training and/or seeking advice where required.

3.1.2 Application

Application is made exclusively by the manufacturer in writing on the forms provided by mdc. If the quote is accepted, the manufacturer sends the completed and legally signed application forms with the corresponding product list in duplicate to mdc.
With submission of the application, the manufacturer makes the declarations and affirmations contained in the application form. These declarations likewise apply in the scope of subsequent change notifications and product extensions, even if no additional formal application is made.
In the product list belonging to the application for certification, the scope is specified by indication of the products, the binding classification as per Annex VIII of the MDR from the manufacturer's point of view, the corresponding conformity assessment procedures and a timetable for the submission of the associated technical documentation.
With the application the manufacturer declares in particular that all technical documentations are at a stage of preparation which permits submission in accordance with the schedule agreed with mdc
After the signing of the provisory acceptance by mdc, the application is deemed a preliminary commercial contract. At this stage, mdc carries out detailed planning of the procedure and allocates resources for the audits and assessments of technical documentations. It is mandatory that the following documents are submitted by the manufacturer in German or English together with the application: components of the technical documentation as per Annex II of Regulation (EU) 2017/745 for all products or product groups covered by the application:
– Section 1. (all subsections): Device description and specification, including variants and accessories.
– Section 3. c.) Identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed.

With the application, an application fee specified in the offer is to be paid, the amount of which depends on the complexity of the procedure (see price list). The application fee is not refundable even if the procedure is abandoned. If the aforementioned parts of the technical documentation are not submitted within 2 weeks after submission of the application, the application will be rejected.
A preliminary commercial contract can be concluded on the basis of these documents.

The availability of the following further documents in German or English is required prior to the start of the assessment and thus before the final certification agreement can be concluded. These can be submitted with the application, or they can be submitted later:
– A draft of an EU declaration of conformity in accordance with Article 19 and Annex IV for the device model covered by the conformity assessment procedure.
– The documentation of the manufacturer’s quality management system (QM manual and all documented procedures that take into account the aspects mentioned in Article 10 (9) of the MDR), including
  – a documented description of the procedures in place to fulfil the obligations arising from the quality management system and required under the MDR and the undertaking by the manufacturer in question to apply those procedures.
  – a description of the procedures in place to ensure that the quality management system remains adequate and effective, and the undertaking by the manufacturer to apply those procedures.
  – the documentation on the manufacturer's post-market surveillance system and, where applicable, on the PMCF plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92.
  – a description of the procedures in place to keep up to date the post-market surveillance system, and, where applicable, the PMCF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92, as well as the undertaking by the manufacturer to apply those procedures, a description of the procedures in place to keep up to date the clinical evaluation plan, taking into account the state of the art.
– Documentation on the clinical evaluation plan.
– The complete technical documentations as per MDR Annex II and III as requested for the assessment.

Manufacturers located outside the Union: draft mandate for the designation of an authorised representative and a declaration of intent by the authorised representative to accept the mandate. If there are several authorized representatives, the assignment per product group must be clearly specified. Only one authorized representative may be listed on a certificate; in the case of several authorized representatives (for different products), several certificates must be issued.

In order to conclude a final contract, the technical documentation for each product applied for must be available at the manufac-

turer. Should not all requested documents be made available to mdc 6 months after submission of the application, mdc may grant a one-time grace period of 3 months maximum. If not all documents are made available to mdc within this grace period, the application will be rejected.

Special regulations for legacy devices according to Art. 120 (3c) MDR:
By way of derogation from the general requirements set out in the previous paragraph, the following applies: Legacy devices are understood to be devices that either have or have had a certificate in accordance with Directive 93/42/EEC or for which a declaration of conformity (exclusively Class I MDD devices) is available. For legacy devices, an application had to be submitted by May 26, 2024.
For the conclusion of a final contract by September 26, 2024, at least the MDR-compliant QM documentation to the extent specified above and the following components of the technical documentation in accordance with Annex II of Regulation (EU) 2017/745 for all products or product groups covered by the application will be submitted:
- Section 1 (all subsections): Device description and specification including variants and accessories.
- Section 3. c.) Identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed.

On the basis of a schedule for the submission of technical documentation accepted by mdc and binding for the manufacturer, this final contract covers all products applied for. The manufacturer commits to submitting the technical documentation on time in accordance with the accepted schedule. If the technical documentation for individual products is not available on time or incomplete, the application for the products concerned may be rejected. The preparation of the technical documentation with regard to timely submission can be monitored, e.g. as part of an on-site audit.
The surveillance of legacy devices in accordance with MDR Article 120 requires that a separate application has been submitted and accepted as a contract by mdc.
Furthermore, reference is made to the deadlines of Art. 120 MDR (Regulation (EU) 2023/607) in order to be able to continue placing legacy devices on the market.
For a timely transfer of legacy devices which have or have had a certificate according to Directive 93/42/EEC, the latest submission dates for the technical documentation are accepted, subject to the availability of corresponding assessment capacities:
- 31 December 2025 for devices of MDR classes III and IIb implantable (with the exception of devices referred to in MDR Article 52 (4) second paragraph).
- 31 December 2026 for devices of MDR classes IIb (non-implantable and devices referred to in MDR Article 52 (4) second paragraph), IIa and Is/Im/Ir).

This does not constitute a guarantee of punctual delivery on the part of mdc.
The latest possible date for the first technical documentation depends on the number of technical documentation and classification of the products and is determined individually by mdc.
The initial audit in accordance with the MDR will take place for all legacy devices in 2025 at the latest.

The notification of rejected or withdrawn applications is made to EUDAMED or according to national requirements.

3.1.3 Certification contract
Only when all aforementioned documents and the payment of the application fee have been received mdc will make a final examination of the application. The designation and classification of the devices is also reviewed in the scope of the examination. However, no legally binding confirmation of the designation or classification can be derived from acceptance of the application. Only by means of a second signature by mdc the application is finally accepted and the actual certification contract comes into force.
If an application cannot be accepted by mdc, then mdc will initiate measures for clarification within one month after receipt or will refuse acceptance.

3.1.4 Surveillance contract for legacy devices
A surveillance contract for legacy devices is concluded if the corresponding application is submitted in full and all other requirements set out in Article 120 of the MDR are met. The manufacturer receives a corresponding confirmation letter after conclusion of the surveillance contract. A detailed listing of all devices affected of this surveillance has to be provided by the manufacturer. Additionally, the manufacturer submits a manufacturers declaration confirming that the conditions for the extension are fulfilled, stating the end date of the transition period. Such self-declaration shall clearly identify the devices covered by the extension and the certificates concerned.

3.2 Assessment phase
After acceptance of the application, the manufacturer receives a written order confirmation.
The audit team (auditors and, if applicable, experts) or the experts for the assessment of the technical documentation are communicated to the manufacturer in the form of personnel profiles. The audit team normally consists of a lead auditor and one or more other auditors. If the auditors/experts are not permanently employed at mdc, the manufacturer must confirm in writing either his consent or rejection of the proposed persons within one week after receipt. The audit team and the experts are then commissioned by mdc. The lead auditor usually coordinates the details of the audit with the manufacturer.
The manufacturer agrees that the bodies granting designation to mdc may observe announced and unannounced assessment audits and ensures their access to his premises and those of the suppliers or subcontractors.

3.2.1 Two-stage auditing
Initial certification procedures of quality systems are audited in a 2-stage process. This procedure comprises an up-front quality management document assessment and - particularly in the case of companies who are not in possession of a quality management certification from an accredited Certification Body or a Notified Body - a stage 1 audit on site in order to ascertain the certification maturity and provide basic proof of implementation of the quality management system, as well as the actual certification audit (audit stage 2). The audit plan for stage 2 is provisional until conclusion of stage 1 and must then be updated where necessary. The manufacturer shall provide the audit team with access to all persons, premises and documents necessary for the audit and shall assist the audit team in carrying out their activities.

The information shall also include results of internal audits, management reviews, complaints and their handling, as well as information on reportable incidents, corrective actions and other regulatory reporting requirements. Verification of the manufacturer's compliance with its obligations to report to the authorities is part of the auditing process.

3.2.1.1 Review of the quality management documentation (as part of stage 1)
In stage 1, the lead auditor performs an assessment of the quality management documentation prior to the audit. This documentation must be submitted by the manufacturer at least 4 weeks prior to the scheduled audit date, even if a stage 1 audit is conducted on site. The results of the assessment are documented in a review report and are provided to the company in a timely manner prior to the audit on site. The assessment comprises the documentation of the quality management system specified in section 3.1.2. If major nonconformities are found in the scope of assessment of the quality management documentation, then the client is granted sufficient time for correction.

3.2.1.2 Audit (stage 1 on site)
After the review of the quality management documentation, the stage 1 audit is conducted on site in order to be able to verify the basic implementation in the company and hence the certification maturity. In this audit, unless a stage 2 audit is conducted directly afterwards, remaining major nonconformities, if any, from the review of the quality management documentation are clarified and the readiness for audit is ascertained on the basis of a tour of the premises and interviewing of the employees. The

audit includes procedures required by the MDR as well as the following requirements:
- Area of validity and scope of the quality management system
- Quality management documentation with document control
- Resource management, human resources and infrastructure/work environment
- Management commitment, quality policy, quality objectives and management review
- Process performance, planning and results of internal audits
- Applicable statutory and regulatory requirements

If major nonconformities from stage 1 (quality management documentation or audit on site) have not been rectified, then the audit must not be continued with stage 2, and the company must be granted sufficient time for correction. The stage 2 audit must only be commenced after successful conclusion of the stage 1 audit without major nonconformity.
The time interval between the stage 1 audit (conclusion of the audit) and implementation of the stage 2 audit must not exceed 6 months. Otherwise, a new stage 1 procedure becomes necessary.
In special cases, such as for instance small businesses or if travel to the site is particularly difficult, the stage 2 audit may be commenced immediately upon successful conclusion of the stage 1 audit. It should be noted that any major nonconformities from the review of the QM documentation must have been corrected in advance.
The stage 1 audit may be carried out by either one or several members of the audit team, depending on the overall scope of the procedure.

3.2.1.3 Audit (stage 2 on site)

A stage 2 audit only takes place after stage 1 has been concluded without remaining major nonconformities, and after at least one technical documentation has been assessed. If the results of the assessment of the technical documentation do not indicate any fundamental deficiencies in the QM system, the audit can be performed on site. Prior to the audit, the audit plan is drawn up in consultation with the manufacturer and is confirmed in writing by the manufacturer. The audit at the company-'s premises and, where applicable, at subcontractors/suppliers, is carried out in accordance with a defined schedule, from which the audit team may deviate when necessary. In the audit, the audit team systematically examines the quality management system with regard to implementation of the normative base and the quality management documentation.
Audits at suppliers or subcontractors may become necessary if relevant design, production or testing/inspection steps are not carried out at the manufacturer's site. This requirement arises in particular if the manufacturer cannot provide adequate proof of the subcontractors' competence or if the subcontractors' activities are not adequately verified by incoming inspections at the manufacturer's establishment.
The audit is recorded in writing. If it is found in the course of the audit that requirements of the normative base are not met, the audit team is obliged to inform the manufacturer immediately. Nonconformities identified in the scope of the audit are recorded by the auditors in nonconformity reports. A time frame is specified by the audit team for the implementation of required corrective actions. The nonconformity reports are countersigned by the applicant.
The following options exist for eliminating nonconformities:
– Immediate implementation of the corrective actions defined by the manufacturer during the audit
– Determination of corrective measures and short-term proof of the implementation of these measures in writing.
– Agreement of corrective measures by the manufacturer and verification of the implementation of these measures in a follow-up-audit.

For the elimination of major nonconformities, a time limit of 2 months maximum applies.
A follow-up audit has to be conducted if:
– the company fails to support proper audit performance (e.g. with regard to the provision of competent and authorised interview partners, inspection of documentation, inspection of workplaces).
– the functionality of the quality management system must be fundamentally put into question due to the nature and quantity of nonconformities.
– a proof of the implementation of corrective actions cannot be adequately provided in writing.

The assessment of the effective implementation of the approved corrective actions on nonconformities shall be carried out as part of the next surveillance audit.
At conclusion of the audit, the auditors report on the audit results in a closing meeting. This oral summarization does not comprise a certification decision, but merely a recommendation of the audit team to the Notified Body.
The manufacturer receives a written report on the audit that has been conducted. This report also includes the recommendation with regard to granting of the certification. In special cases, an earlier surveillance audit can be recommended by the lead auditor.

Special procedure for the certification of legacy devices according to Art. 120 (3c) MDR:
In accordance with the by mdc accepted schedule for the submission of technical documentation, an initial certification audit can also be carried out if no technical documentation is yet provided. A certificate can only be issued after positive completion of the review of the technical documentation and the audit.

3.2.2 Assessment of the technical documentation

In the case of Class III devices and in the case of implantable Class IIb devices, with the exception of those referred to in MDR Article 52 (4) second paragraph, an assessment of the technical documentation is made for each product in the scope of procedures according to Annex IX. For all other products of Class IIb and Class IIa, a review of the technical documentation in the scope of procedures according to Annex IX and Annex XI Part A is performed on the basis of a sampling plan drawn up by mdc. The sampling plan shall be drawn up, inter alia, on the basis of the dates for submission of the technical documentation as agreed upon within the application. Specific devices will only be included in the certification after availability of the technical documentation and positive assessment or confirmed coverage by previous sampling.

In the case of medical devices of Class Is (sterile), Class Im (measuring function) and Class Ir (reusable surgical instrument), a complete technical documentation for the respective sample selected by mdc is submitted in accordance with the MDR. In the scope of the assessment, the aspects specific to the respective products (sterility, measuring function or reprocessing) are subjected to a full assessment. The other parts of the technical documentation are assessed for formal completeness, even though the MDR does not explicitly stipulate this. All reports on the review of the technical documentation are provided to the manufacturer.
Requested technical documentations are submitted electronically by the manufacturer in due time and complete for all relevant products via the "mdc secure space" (mss) online platform provided by mdc.
Should the necessity of a review of further specific aspects arise in the scope of the assessment of the technical documentation, then mdc is entitled to commission additional experts. Should the necessity of product tests arise in the scope of the assessment of the technical documentation, then mdc is entitled to implement these tests. In that case, the manufacturer provides the required number of test samples, and also bears the costs for the performance of the tests, test samples, transport and disposal.

3.2.3 Summary reports on safety and clinical performance (SSCP)

According to MDR Article 32, the manufacturer compiles a summary report on safety and clinical performance that is comprehensible for the public for Class III products and implantable products. mdc is obliged to validate these reports and in the scope of the validation verifies the existence of the required documents and agreement of the statements with the technical documentation. The manufacturer receives a report on the

results. If the validation is successful, mdc uploads the SSCP to EUDAMED.

3.2.4 Procedure for products as per Annex XVI

Products without medical intended purpose which are listed in Annex XVI are by definition treated like comparable medical devices, with the following peculiarities applying:

- Compliance with the published Common Specifications for these products is mandatory.
- The requirement to demonstrate a clinical benefit in accordance with this Chapter and Annexes XIV and XV shall be understood as a requirement to demonstrate the performance of the device. Clinical evaluations of those products shall be based on relevant data concerning safety, including data from post-market surveillance, PMCF, and, where applicable, specific clinical investigation. Clinical investigations shall be performed for those products unless reliance on existing clinical data from an analogous medical device is duly justified.
- The general safety requirements set out in Sections 1 and 8 shall be understood to mean that the device, when used under the conditions and for the purposes intended, does not present a risk at all or presents a risk that is no more than the maximum acceptable risk related to the product's use which is consistent with a high level of protection for the safety and health of persons.

3.2.5 Procedure for custom-made devices

3.2.5.1 Custom-made devices produced serially in industrial processes

Custom-made devices which are mass-produced by means of industrial manufacturing processes are not deemed custom-made products and are treated like serial products (CE marking obligation).

3.2.5.2 Implantable custom-made devices of Class III

In the case of implantable custom-made Class III devices, a conformity assessment procedure as per Annex IX, Chapter I, or as per Annex XI Part A is implemented.

3.2.6 Consultation procedures

3.2.6.1 Medical devices containing medicinal substances

If a device contains a substance as an integral part that taken on its own can be deemed a medicinal substance as defined by Article 1, Number 2 of Directive 2001/83/EC and that has an auxiliary action to the medical device, then mdc conducts a consultation procedure with a competent authority of a member state or the European Medicines Agency (EMA) in accordance with Annex IX, Section 5.2 of the MDR. If the substance falls under the scope of application of the Annex of Directive (EC) No. 726/2004, then the consultation procedure is always to be conducted with the European Medicines Agency (EMA).
In this procedure, a scientific assessment on the quality and safety of the substance, including the benefit and risk of use of the substance in the medical device, is obtained.
The manufacturer provides the required data in the scope and format stipulated by the respective authority.
When deciding whether to grant or renew a certificate, mdc shall take due account of this scientific opinion and inform the competent authority consulted of its decision. If the assessment is negative, mdc does not issue a certification.

3.2.6.2 Implantable Class III devices and active Class IIb devices which are intended to administer and/or remove a medicinal product

In the case of these products, a procedure as per Annex IX Section 5.1 of the MDR is conducted. For this procedure, mdc sends the assessment report issued by the clinical expert to the European Commission along with the manufacturer's clinical evaluation. The European Commission then forwards the documents to an expert panel as specified in MDR Article 106. The expert panel decides within 21 days after receipt, whether it will issue a scientific opinion regarding mdc's report on the assessment of the clinical evaluation. If the scientific opinion is issued, then it is received by mdc within another 60 days. mdc duly takes into account the scientific opinion in its decision on the granting or extension of a certification.

3.2.6.3 Devices which are manufactured using tissues or cells of animal origin as specified in Directive (EU) 722/2012, or which contain such

If a product is manufactured using tissue or derivatives from animal tissue of certain species in accordance with Regulation (EU) No. 722/2012, then mdc conducts a consultation procedure as specified in said regulation. After the assessment, mdc issues a "Summary Evaluation Report" (SER) which is forwarded to the competent authorities of all member states via the ZLG *[Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices]*. Should the member states have comments, then these are taken into account and appropriate corrective actions are initiated.

3.2.6.4 Devices composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body

For devices, or their products of metabolism, that are systemically absorbed by the human body in order to achieve their intended purpose, mdc conducts a consultation procedure as per Annex IX Section 5.4 of the MDR together with a competent authority as per Directive 2001/83/EC or the European Medicines Agency (EMA).
In this procedure, a scientific opinion is issued as to whether the applicable requirements specified in Annex I of Directive 2001/83/EC are adhered to with the product. The manufacturer provides the required data in the scope and format stipulated by the respective authority.
mdc duly takes into account this scientific opinion in its decision on the granting or extension of the certification and informs the consulted authority of its decision.

3.3 Certification phase

The final decision on certification is reached in an evaluation and decision process in which one or more persons permanently employed by mdc are involved, who were themselves not involved in the assessment.
The assessment reports are the primary basis for this assessment and decision, but, if necessary, the submitted documentation as well as all information obtained in the course of the procedure can also be consulted. The manufacturer is informed of the result in writing. This information can, in the case of a rejection, include conditions which must be fulfilled for the granting of a certification.
If the granting of a certification is subject to special conditions, then these are stated as requirements.
The period of validity of certifications according to the MDR is five years maximum. There is no entitlement to the full 5-year period of validity. I.e. if the decision on certification is made more than 6 months after the last day of the initial certification audit, the validity of certifications according to Annex IX, Chapter I or Annex XI Part A is limited to a maximum of 5 years and 6 months after the last day of the initial certification audit.
In the case of Class III devices and implantable Class IIb devices, with the exception of sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, EU quality management system certificates as per Annex IX are valid only in connection with an EU technical documentation assessment certificate for the respective products.
The manufacturer gets an original certificate in German or English, whichever he prefers.
If the granting of a certificate is rejected, the applicant has the option to object in writing in the form of an appeal within four weeks. This appeal is the subject of a renewed review of the procedure. This appeal is subject to a renewed assessment of the procedure. In the event of a renewed rejection, the applicant has the option of appealing to an arbitration procedure of the mdc, provided that the appeal is justified, i.e. it can be assessed as initially comprehensible within the scope of a preliminary examination.
Should no progress be achieved in the scope of an assessment such that after two reassessments still no positive recommendation can be stated, then an evaluation and decision in terms of a finally refused certification can be made. In the event of refusal, the application must be made once more and must be subjected to a fresh assessment and certification procedure.

If the manufacturer withdraws an application for certification or cancels a certification contract, then mdc reviews the reporting situation with regard to the assessments conducted and reserves the right to a reach a decision in terms of a rejected certification and to report this. Reporting is done to EUDAMED or according to national requirements.

3.4 Surveillance phase

3.4.1 Surveillance audits

The successful implementation of surveillance audits is precondition for the maintenance of a certification. These audits must take place at intervals of 12 months maximum. The manufacturer takes precautions to ensure that these audits can be carried out in due time even if key staff members are prevented at short notice from taking part.
mdc may additionally conduct announced or unannounced surveillance audits if induced to do so by special events (e.g. incidents, corrective actions).
According to the provisions of the MDR, unannounced audits are also conducted without any special reason. The manufacturer makes all necessary arrangements to enable these to be conducted in his premises and the premises of the subcontractors/suppliers. The refusal or obstruction of an unannounced audit constitutes a serious violation of the certification rules, which entails the consequence of immediate suspension of the certification. Samples for product tests are taken in the scope of the unannounced audits. Should it not be possible to perform these tests as witness tests at the audited premises, or if there is any special reason for this, then mdc is entitled to perform these tests at laboratories subcontracted by mdc. The manufacturer bears the costs for performance of the tests, test samples, transport and disposal. Should test samples have to be taken from the market due to non-availability at the audited premises, then the manufacturer additionally reimburses mdc for all procurement costs.
Additional surveillance measures may also become necessary if provisions that the devices have to comply with change or if mdc has received information from which it can be concluded that the device no longer meets the requirements of the normative base.
The manufacturer likewise receives a written report on the surveillance audit that has been conducted. In special cases, an earlier surveillance audit can be recommended by the lead auditor. For the elimination of major nonconformities, a time limit of 2 months maximum likewise applies here. If this time limit is not adhered to, then this entails a suspension of the certification.
After every surveillance measure, an internal evaluation and decision concerning the approval of the amendment or maintenance of the certification takes place.

3.4.2 Assessment of technical documentations on a random sample basis

In the scope of the surveillance, an assessment of the technical documentation on the basis of a random sample plan is performed for the following products:

- Class IIb products
- Non-implantable Class IIb devices
- The following implantable Class IIb devices: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors

The provisions set forth in section 3.2.2 apply.

3.4.3 Periodic Safety Update Reports (PSUR)

The manufacturers of Class III devices or of implantable devices submit their Periodic Safety Update Reports in accordance with MDR Article 86 to mdc via EUDAMED. mdc reviews the report and records the assessment along with details on measures taken, if any, in EUDAMED. The Periodic Safety Update Reports and mdc's assessment are put at the competent authorities' disposal via EUDAMED.
For non-implantable Class IIb devices, the manufacturer submits the Periodic Safety Update Reports to mdc annually, and for Class IIa devices, he submits it to mdc every 2 years. From this, mdc derives measures, surveillance focuses or surveillance samples where appropriate.

3.4.4 Reporting obligations

Manufacturers holding an EU technical documentation assessment certificate or undergoing a procedure according to Annex IX Chapter II shall report to mdc all planned changes that could affect the safety and performance of the device or the conditions prescribed for use of the device.
All manufacturers shall report to mdc planned substantial changes to the quality management system or the product range covered by this. This concerns e.g. location, organisation, production technologies, relevant suppliers or subcontractors and product range
mdc shall be notified of changes by means of a form* available on the website. Should mdc deem extraordinary surveillance measures necessary due to such notifications, then an additional documentation review or an additional audit may be conducted. The result of these assessments is documented in reports and in a supplement to the certificate concerned. The manufacturer is entitled to implement the notified change only after receiving feedback from mdc. In the event of a change of address or a change of company name, all valid certifications must be newly issued in German or English at the applicant's expense.
Incidents involving devices, particularly serious incidents and field safety corrective action as per Article 87 of the MDR, must, after being reported to the authorities concerned, also be promptly reported to mdc. mdc must furthermore be informed of market restrictions (e.g. due to court decisions or decisions made by authorities). mdc must also be promptly informed of regulatory surveillance measures conducted under medical device legislation, such as inspections or requests of documents, and must be promptly informed of the results of these. The manufacturer furthermore informs mdc of any ongoing investigations or legal disputes regarding non-conforming devices.
The reporting obligations also include notification of any other changes that could have an impact on the fulfilment of the certification requirements.

3.4.5 Surveillance of legacy devices according to MDR Article 120

For the surveillance of legacy devices, the manufacturer shall comply with the obligations arising from the previous contractual relationship with regard to Directive 93/42/EEC, the contractual relationship under MDR with mdc or another Notified Body and, if applicable, the agreement under MDR Article 120 (3e).
Surveillance of legacy devices includes a planned annual surveillance audit and may include other elements in accordance with the mdc's rules and regulations for certification under Directive 93/42/EEC. This concerns in particular the reporting of incidents, field safety corrective actions such as recalls and the regular submission of the PSUR according to MDR Art. 86 as well as unannounced audits.
Notifications of changes shall be made in accordance with the mdc rules for certification under Directive 93/42/EEC, excluding substantial changes in the design or intended purpose of the products.

3.5 Re-certification and contract extension

To extend the certification and thus the contractual period, the manufacturer must obtain a quote for the re-certification at the latest 12 months before expiry of the certification concerned and must make an application at the latest 9 months before expiry of the certification. The procedure for re-certification corresponds to that for initial certification; the on-site audit in this case only has to be conducted as a 2-stage audit if there are substantial changes of the quality management system or if numerous deficiencies have been found in the review of the quality management documentation.
The re-certification audit must be conducted before expiry of the certification. Should this not be possible, then a complete procedure for initial certification with increased audit cost is required.
For renewal of EU certifications on the assessment of the technical documentation, the manufacturer submits a summary of the changes to the product and the scientific findings regarding the product, which includes at least the following:

* „Notification of Change (MDR) “ at www.mdc-ce.de/en

– all changes to the originally approved device, including changes not yet notified,
– experience gained from post-market surveillance,
– experience from risk management,
– experience from updating the proof of compliance with the general safety and performance requirements set out in Annex I,
– experience from reviews of the clinical evaluation, including the results of any clinical investigations and PMCF,
– changes to the requirements, to components of the device or to the scientific or regulatory environment,
– changes to applied or new harmonised standards, CS or equivalent documents,
– changes in medical, scientific and technical knowledge, such as:
  – new treatments,
  – changes in test methods,
  – new scientific findings on materials and components, including findings on their biocompatibility,
– experience from studies on comparable devices
  - data from registries and registration bodies,
  - experience from clinical trials with comparable products.

mdc evaluates this summary and, depending on the results, requests either the complete technical documentation or parts of the same for assessment.
The certification for re-certification normally includes the expiry date, which is not more than 5 years after the expiry date of the preceding certification.
If the re-certification procedure cannot be completed within 6 months after expiry of the preceding certification, then a follow-up certification can no longer be issued; rather, a procedure analogous to an initial certification must be performed. The period of validity of the follow-up certification is nevertheless adjusted to the expiry of the precursor and has the date of issue and start of the date of validity on which the procedure was concluded at mdc.

3.6 Procedures according to Article 16

Procedures according to Article 16 are only offered in connection with certifications according to EN ISO 13485 by mdc.
The present certification rules apply to the extent applicable to these procedures. The applicant undertakes to make full use of the forms specifically provided for Article 16. This includes in particular an up-to-date list of activities and devices to be submitted in advance of each audit, on the basis of which the respective audit scope will be reviewed and adjusted if necessary.
Contrary to section 3.1., an application can also be submitted and accepted by mdc if the following documentation required for Article 16 is not yet available:
- QM manual
- documented procedures according to EN ISO 13485
- further specific QM documents for the implementation of the requirements of Article 16.

The modalities for the submission of the documents will be communicated together with the order confirmation.
Sections 3.2.2 to 3.2.6 as well as 3.4.2 and 3.4.3 do not apply.
The reporting obligations according to 3.4.4 include, in the case of procedures according to Article 16, in particular the planned inclusion of further product categories (new MDA and MDN codes) and the extension of activities according to Article 16 beyond the certified scope.

4. Enforcement of the certification rules

In the event of violation of the General Terms of Business and/or components of the same by the manufacturer, mdc can take the necessary measures. These measures may be the stipulation of corrective actions, the restriction of the certification, the suspension of the certification for a limited period of time or the withdrawal of the certification. In particular, mdc is entitled to withdraw or suspend the certification if the following states of affairs already existed at the time of the certification:
– The requirements of the MDR, which are a precondition for the certification granted, were not fulfilled.
– A product or category of product which is the subject of the procedure was erroneously placed on the market as a medical device, accessory or product in accordance with Annex XVI MDR.
– The device or device category was assigned to an incorrect class, and an incorrect declaration was accordingly submitted.

The certification can be withdrawn in particular if one of the following states of affairs has arisen after it has been granted:
– The requirements prescribed by law that apply to the certified quality management system or a certified product are no longer fulfilled.
– A device product no longer meets the general safety and performance requirements such that patients, users or third parties are exposed to considerable risk or that products do not fulfil the intended purpose stated by the manufacturer and these deficiencies cannot be eliminated within a reasonable time limit.
– The device or the device category is not or is no longer covered by the MDR.
– The classification of a device has changed and corrections within a reasonable time limit are not possible.
– The certificate, the CE marking or the fact of the certification is misused.
– Declarations on the certification are made for areas or products for which no certification exists.
– The manufacturer applies his certification in such a way as to bring mdc into disrepute.
– Declarations are made which mdc can consider misleading or non-authorised.
– The certification or reports or parts of the same are used in a misleading way.
– The manufacturer fails to subject himself to the surveillance procedure or fails to submit the requested documentation on time.
– Nonconformities found are not eliminated within a time limit specified by mdc.
– The manufacturer terminates his business operation due to bankruptcy or for other reasons or curtails the same in such a form that the normative base can no longer be fulfilled.
– The manufacturer gets into arrears with payment with respect to mdc in spite of reminder notice.
– The manufacturer fails to meet his reporting obligations.
– The manufacturer or his subcontractor or supplier refuses or obstructs the implementation of an unannounced audit or a product test.

In the event of suspension or withdrawal of a certification, the manufacturer is given the opportunity to first explain his position, unless this not possible in view of the special urgency of the measure. Refused or obstructed unannounced audits or product tests associated therewith constitute such an urgency.

5. Reporting and informing obligations concerning certificates issued

mdc reports to the competent authorities via EUDAMED or according to national requirements all required information on the issued certificates of the products for which a conformity assessment procedure has been carried out. For certain Classes III and IIb devices, further information is additionally included as specified in Article 54 (3) and Article 55 (1).
Information on rejected, restricted, suspended and withdrawn certifications is likewise reported by mdc. Additional notifications can be made to the authority in charge of the manufacturer, other competent authorities or other Notified Bodies. Notifications to the authorities may comprise recommendations for risk prevention.
The information on harmonised standards and Common Specifications stipulated according to Annex XII is not stated directly on the certifications but is provided to third parties upon request.

6. Use of the certification, the certificate and the CE marking

If a certification by mdc exists with regard to the manufacturer's products, then the manufacturer is entitled to make use of this state of affairs in accordance with the statutory and contractual stipulations.
The utilisation of the certificates includes:
– Utterances in written, pictorial or oral form concerning the fact of the certification.
– Utilisation of original certificates, photocopies of the certificates and other depictions of the same.

The following general utilisation rules apply in this context:

– In said utilisation, only the actual normative base, the scope of application and the assertion of the certification may be referred to.
– Any utilisation of the fact of the certification and of certificates and marks which mdc could consider misleading or unauthorised is prohibited.
– The manufacturer undertakes to refrain from applying his certification in a way that can contradict mdc's objectives or bring mdc into disrepute.
– The manufacturer undertakes to refrain from issuing any statements concerning the certification which mdc may consider non-authorised.
– If the manufacturer is not sufficiently sure about the present provisions concerning the utilisation of the certification, he undertakes, as a precaution, to obtain the Notified Body's consent for the intended form of utilisation.
– mdc advises against the promotional utilisation of the certification as per the MDR, since this is a matter of fulfilment of a statutory requirement. Should the CE marking nonetheless be used for advertising, then it must, according to MDR Article 20(5), be depicted in full, including the identification number 0483.
– All rights of use of the certification (including the certificates and CE marking) expire with expiration of the validity of the certificate or a premature declaration of invalidity (e.g. cancellation of contract, suspension or withdrawal of certifications). After a declaration of invalidity or expiry, the certification must not be used for any promotional activities, and any appearance of an existing certification must be avoided. If the scope of application of the certification has been reduced, then the promotional materials must be modified if necessary.

The utilisation of the certificates by depiction of the originals, photocopies thereof or other graphic depictions is permissible. The depiction must only be made in the original colours black/white or in grey shades.
It must be ensured that all components are legible or, in the case of a smaller, not fully legible depiction, that all illegible contents are separately explained in full.
When depicting the certificate, the depiction of an annex belonging to it, if there is one, is mandatory. All third parties to whom a certification with reference to an annex is made accessible must also be enabled to access the associated annex.
Certificates which are in the possession of the manufacturer remain the property of mdc. After a declaration of invalidity, they must be promptly returned to mdc or their destruction must be confirmed in writing, unless they have become invalid due to their expiration.
The CE marking is a statutory mark based on EU regulations. It may only be used with the mdc assigned identification number 0483 for products that are declared on a valid certificate from the mdc and provided that all other regulatory requirements for the product are met. No additional marks or explanations are allowed to be used in direct connection with the CE marking. The CE marking is affixed to the product, the labelling and the instructions for use as well as on the commercial packaging.
The requirements of the MDR (in particular Article 20 and Annex V) must be observed. Further information can be found in the "Blue Guide" of the EU Commission.
In the event of suspension, withdrawal or other declaration of invalidity or expiry of the certification, the manufacturer is, from the date of invalidity or of expiry, no longer entitled to place products with CE marking on the market using the identification number 0483. The certification must not thereafter be used for any promotional activities, and any appearance of an existing certification must be avoided. If the certification is taken over by another Notified Body, then the further use of the identification number must be agreed in writing with mdc and the subsequent body.
The use of logos and numbers of mdc's designating authorities is not permissible.
Violations of the present authorisations for use constitute violations of the certification rules and General Terms of Business. In the case of holders of certificates, they can entail measures up to the suspension or the withdrawal of the certification.
If a manufacturer discovers an utilisation of the certification or the CE marking contrary to the rules or if an accusation to that effect is made against him, then he undertakes to inform mdc of this without delay. Personnel who implement the utilisation of the certification or the CE marking in the company (e.g. marketing) should be trained with regard to the significance and the correct utilisation.
mdc can prosecute any abusive utilisation of the certification or the CE marking by the holder of the certification or others by taking legal action. mdc is entitled to publicize the abusive utilisation in any form whatsoever.
The manufacturer undertakes to only make use of his certification in the scope of these regulations and further requirements resulting from laws, standards, guidelines, contracts or other stipulations.

7. Liability

mdc's liability for damages caused by mdc, particularly in connection with infringements of obligations resulting from the contractual relationship or due to impermissible actions, is limited to the three-fold fee for the respective single order in connection with which the damage has arisen. This aforementioned regulation is not applied if a damage is due to fraud or intentional or grossly negligent behaviour on the part of mdc, nor is it applied in the case of such damages as are due to the infringement of obligations or in the case of damages resulting from injury of life, body or health or in the case of damages for which liability is assumed according to the product liability act. mdc has a liability insurance as required by law with a limit of liability of € 5.000.000 for personal injury, property damage and financial loss. mdc assumes no liability for workers provided by the client for support on occasion of the services to be rendered by mdc according to this contract.