# Procedural Guidelines for the Certification of a Quality-Management System

## 1. Introduction

These procedural guidelines describe the procedure for the certification of a quality management system by ECM - Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH (ecm).

This is a voluntary certification in accordance with a reference document specified in the application. The term certification procedure or certification is used below.

The certification procedure is based on the requirements specified in the application and contract.

Any changes to these procedural guidelines will be communicated in writing.
The currently valid version of the procedural guidelines can be viewed on the ecm website.

The following mutual obligations apply.

## 2. Commitments of ecm

**Impartiality**

ecm ensures through its organization and working methods that independence, objectivity and impartiality are maintained in the performance of its activities.

**Competence**

ecm undertakes to implement the applicable requirements for certification bodies with regard to competence. ecm ensures that sufficiently qualified personnel are available for the certification procedure. ecm ensures the qualification of the internal personnel deployed within the scope of the certification activity as well as external personnel or third parties commissioned by ecm.

**Responsibility**

ecm is responsible for reviewing sufficient objective evidence on which to base a certification decision. Based on the audit conclusions, ecm makes a decision to grant certification if there is sufficient evidence of conformity with the applicable normative requirements, or not to grant certification if there is insufficient evidence of conformity.

**Openness and Confidentiality**

Information on the range of services and the basic certification procedures (procedural guidelines) is available to any interested party on request and can be viewed on the ecm website.

Information on the status of voluntary certification procedures is made available to third parties on request, taking into account the legal and normative requirements.

In accordance with the requirements of DIN EN ISO/IEC 17021-1, all parties involved in the certification process are obliged to treat all information obtained in the course of their activities as confidential.

**Exclusion of Consulting Services**

The services offered by ecm do not include consulting services. This refers in particular to involvement in the introduction, implementation or maintenance of a management system, e.g. preparation or creation of manuals or procedures or the provision of specific advice, instructions or solutions regarding the development and implementation of a management system.

The exchange of technical information is not considered a consultancy service. The organization of training courses and lecturing activities are also not considered consultancy services, provided that the training, if it relates to management systems or auditing, is limited to the provision of general information, e.g. the training must not offer solutions tailored to the applicant.

The provision of general information that does not include specific solutions for improving the applicant's processes or systems does not constitute advice in this respect. Such information may include:

- Explanation of the meaning and purpose of the certification requirements;
- Identification of improvement;
- Explanation of the associated theories, methods, techniques or tools;
- Sharing non-confidential information on related best practices;
- other aspects of management not covered by the audited management system.

## 3. Obligations of the Applicant

The applicant undertakes to comply with the assurances contained in the application and to fulfill the obligations arising from these procedural guidelines. The applicant undertakes in particular to

- comply with applicable legal and regulatory obligations and applicable guidance and/or best practice documents (e.g. MDCG),
- maintain the quality management system in the certified form and to fulfill all obligations arising from the certification procedure and extending to the agreed surveillance period of the certificate,
- provide ecm and its authorized representatives access to all business premises and, if necessary, to the business premises of relevant suppliers / subcontractors,
- ensure on the consistency of the information in the management system documentation with the actual circumstances and the information in the questionnaire (customer information query),
- where necessary and after notification: to allow persons to participate in audits (e.g. for accreditation assessment, for training purposes or to observe auditors) .

## 4. Certification Process

The certification process can be divided into 4 phases. At the end of phase 3, the procedure begins again with the phase 0 as recertification, if applied for.

The 1st certification cycle begins with the certification decision and ends with the audit for recertification. The 2nd certification cycle begins with the recertification decision.

Certification process:

Phase 0 Preparation for the certification process
- Optional information meeting
- Application review

Phase 1 Document review, audit stage 1
- Evaluation of the quality management system documentation
- Possible evaluation of contracts with and qualifications of subcontractors to determine the need to include subcontractors in the audit)

Phase 2 Audit stage 2
- Audit of the quality management system on site
- Audit of relevant suppliers / subcontractors, if applicable

Phase 3 Issue of certificates and monitoring
- Certification decision (start of certification cycle)
- Monitoring of the applicant until recertification after three years

**Phase 0: Preparation of the Certification Process**

Information meeting

The certification process can be preceded by a free information meeting. The content of this information meeting is the presentation of the procedural requirements as well as the procedure and the associated costs.

Questionnaire

ecm provides access to the digital data exchange platform. The applicant first receives a questionnaire (customer information request), which must be completed in full and returned to the data exchange platform with the documents requested.

Offer

Based on the information obtained via the questionnaire, ecm creates an individual offer / audit program. This includes the initial audit and a complete certification cycle (initial certification, surveillance and recertification). If the applicant agrees to the offer, ecm sends the application documents: application, contract, price list and these procedural guidelines.

Application

To apply, the applicant submits the signed application and contract documents to ecm. On the basis of the aforementioned documents, ecm first checks whether the requirements for carrying out the requested certification procedure are met. However, no claims of any kind for a further procedure can be derived from the application.

Scheduling

ecm plans the activities required for the implementation of phases 1 and 2 and appoints the necessary personnel. The dates for the audit stage 1 and audit stage 2 are agreed with the applicant.

Consent via External Employees of ecm

In order to exclude potential conflicts of interest with regard to external employees of ecm, ecm will inform the applicant in writing if external employees are planned for the implementation of the certification procedure.

The applicant shall inform ecm in writing on the "Declaration of consent" form of their consent to the use of external staff. In the event that the applicant rejects the external personnel, ecm will endeavor to find an appropriate replacement. As the selection of external, qualified and independent auditors/experts is limited, ecm reserves the right to reject the application/continuation of the requested procedure in this case. Internal employees of ecm will not be named in advance.

## Phase 1: Document Review, Audit Stage 1

The stage 1 audit serves to check the management-system documentation against the requirements of the underlying management standard. In the case of recertification, phase 1 can be omitted if there have been no relevant changes to the underlying requirements or the previously certified management system.

Submission of the QM-System Documentation

Prior to the stage 1 audit, the applicant completes the audit stage 1 checklist provided by ecm and submits it digitally to ecm together with the relevant management system documentation via the data exchange platform.

Care must be taken to ensure that all documents submitted are digitally searchable.

Audit Stage 1

The review of the management-system documentation takes place as part of the stage 1 audit by one or more persons appointed by ecm.

The stage 1 audit can be carried out remotely. Depending on the circumstances, however, the stage 1 audit may require an "on-site audit", e.g.

- for the production or manufacture (placing on the market) of medical devices with a higher risk class (according to the classification rules of Annex VIII of the MDR Class IIb or III)
- at the request of the applicant, e.g. for reasons of special confidentiality interests

If on-site activities are carried out by ecm as part of a stage 1 audit, there is no direct transition to the stage 2 audit.

Audit Findings

The audit findings from audit stage 1 are documented by ecm.

Nonconformities must be remedied by the applicant by means of suitable corrective measures before the stage 2 audit is carried out. The corrective actions must have been positively assessed by ecm before the stage 2 audit is carried out.

Areas of concern (weaknesses) that could be classified as a nonconformity during stage 2 will also be communicated to the applicant.

Impact of the Result of Audit Stage 1 on Audit Stage 2

ecm reserves the right to postpone the stage 2 audit if appropriate corrective actions to the nonconformities identified in the stage 1 audit have not been implemented and submitted to ecm for evaluation in due time.

For this reason, it may be necessary for ecm to revise the planned specifications (in terms of content and time) for the stage 2 audit, e.g. to give the applicant sufficient time to find solutions to the nonconformities identified in the stage 1 audit. It may also be necessary to repeat the stage 1 audit or parts thereof. The applicant will be informed by ecm if the results of the stage 1 audit may lead to a postponement or cancellation of the stage 2 audit. Otherwise, the applicant will receive results of the stage 1 audit with the report on the stage 2audit.

Note: Postponements or repetitions lead to additional costs for the applicant (see price list).

## Phase 2: Audit Stage 2

After completion of phase 1, ecm conducts an on-site audit at the relevant production site(s) or offices: Audit Stage 2. ecm's designated auditors take part in an on-site audit. The aim is to check the practical implementation and application of the management system procedures or the applicant's quality assurance measures on site.

Audit Scope and Time Required

The audit scope (e.g. locations, processes) and the audit time are determined on the basis of ecm's internal procedures, taking into account the applicable accreditation rules. The audit time required for all audit types includes both the time spent on site at the applicant's premises and the time required for planning, document review, interaction with the applicant's staff and report writing.

In this context, the audit duration corresponds to the part of the audit time spent performing audit activities on site from the opening meeting up to and including the closing meeting.

Audit Plan

ecm sends the applicant an audit plan in advance of audit stage 2. The applicant is given the opportunity to further coordinate the proposed audit data with ecm.

Activities During the Audit

The audit activities usually include

- Conducting the opening meeting;
- Review of documents during the audit;
- Communication during the audit;
- Allocation of roles and responsibilities among the persons participating in the audit;

- Gathering and verifying information through interviews, observation of processes and activities, evaluation of documents and records;
- Creation of audit findings;
- Preparation of audit conclusions;
- Conducting the closing meeting.

When conducting the audit, only question lists / checklists authorized by ecm are to be used. The checklists form a guideline for the auditors and are only binding in their application with regard to the minimum requirements to be verified. The auditors may ask further questions beyond the ecm question lists / checklists to clarify specific issues.

Nonconformities

A nonconformity is the non-fulfillment of a requirement . All nonconformities are explained during the audit and recorded in writing in a findings report.

Nonconformities are weighted as follows in the findings report:

*a) Major Nonconformity*:

Nonconformity that impairs the ability of the management system to achieve the intended results.

In the following cases, nonconformities could be classified as major:

- if there is significant doubt that effective process control exists or that products or services meet the specified requirements;
- several minor nonconformities relating to the same requirement or problem could constitute a systemic nonconformity and thus result in a major nonconformity.

Examples:

- an unjustifiable exclusion of a section or process of the applicable normative or legal requirements;
- Lack of implementation of applicable sections or processes of the applicable normative or legal requirements;
- Insufficient evidence regarding the suitability of relevant product realization processes;
- a number of minor nonconformities relating to a standard section or process of the QM system

*b) Minor Nonconformity*

Nonconformity that does not affect the ability of the management system to achieve the intended results.

Findings Report

The nonconformities identified during the audit are documented in a findings report. In principle, the applicant is obliged to analyze the causes that led to nonconformities and to describe the specific corrections and corrective actions implemented or planned to eliminate the nonconformities within a specified period of time. The time frame for submitting the root cause analysis and, if applicable, corrections or corrective actions is specified in the findings report.

Closing Meeting

The audit ends with a closing meeting. The purpose of the closing meeting is to present the conclusions drawn from the audit, including the recommendation regarding certification.

Certification Recommendation

The lead auditor informs the certification body whether it recommends the issue or maintenance of a certificate.

Depending on the weighting of the nonconformity and the attributes of the corrective actions, the auditor documents the following recommendation on the audit checklist:

a) Positive certification recommendation (initial certification / recertification);
b) Maintenance of certification;
c) Suspension / withdrawal / restriction necessary;
d) Re-audit required;
e) Immediate action necessary on the part of ecm.

Note:

According to EK-Med 3.5E11, a significant nonconformity that prevents the granting of a certificate is also the non-fulfillment of elementary requirements, such as

- the introduction of all procedures required by the standard,
- defining the sequence and interaction of the processes,
- the validation of all relevant production and service provision processes,
- the measurement and analysis of processes,
- the definition of measurable quality targets,
- the existence of the records and documented requirements required by the standard,
- the consideration of risk management during the entire product realization process.

Dealing with Major Nonconformities

If major nonconformities are identified during an audit (initial audit, surveillance audit, recertification audit), the lead auditor cannot issue a general positive certification recommendation.

A certificate can only be issued if the corrective actions required on the basis of a root cause analysis have been successfully implemented by the applicant, the evidence of the implementation and effectiveness of the corrective actions has been submitted by the applicant and assessed by the certification body with a positive result.
The certification body shall be able to verify the implementation and effectiveness of corrections and corrective actions to any major nonconformity within 6 months of the last day of stage 2. If this is not possible, the certification body must repeat the stage 2 audit. In addition, immediate actions may be initiated by ecm (see recommendation of the audit management). This also applies to recertification.

Dealing With Minor Nonconformities

For all minor nonconformities, the applicant must submit a root cause analysis and an action plan to ecm, which must be evaluated and accepted by ecm prior to a positive certification decision.

Verification of Corrections and/or Corrective Actions

Depending on the type of nonconformity, corrections and/or corrective actions must either be submitted to ecm in writing or will be assessed by ecm as part of a follow-up audit. The applicant will be informed about the assessment of the submitted corrective actions and the associated lifting or continuation of the nonconformity.

Audit Report

The audit management prepares a written final report on the audit (audit report) on the basis of specified report templates. In the case of an initial or recertification audit, this is submitted to the certification committee for a final decision no later than four weeks after the audit, together with the audit question lists, the findings reports, the information in accordance with DIN EN ISO /IEC 17021-1 and the recommendation of the lead auditor. Exceptions to this are possible in justified cases . Irrespective of this, the applicant receives the audit report.

## Phase 3: Issue of certificates and monitoring

The Certification Decision

The certification committee of the certification body makes the certification decision on the basis of the audit documents submitted by the audit management. The decision of the certification committee is made taking into account the certification recommendations of the persons involved in the audit. The certification committee verifies whether the information provided by the audit team is sufficient with regard to the certification requirements and the scope. The status of all major nonconformities or the assessed, accepted and verified corrections and corrective actions as well as the status of all minor nonconformities or the assessed and accepted action plan of the applicant with regard to corrections and corrective actions shall be taken into account.

Records are kept of the certification decision, the persons involved and the reasons for the decision.

The applicant will be notified in writing of the decision to grant/suspend/withdraw/restrict/extend certificates.

The applicant has the right to appeal against ecm's decision in writing within 4 weeks of receipt. If no agreement can be reached between ecm and the applicant, both parties may take legal action.

The Certification Committee

The certification committee consists of one or more persons who are authorized internally by ecm. They must not have been involved in the audit.

The Certification Committee is not responsible for:

- Decisions on formal changes to certificates (e.g. address changes);
- the suspension of certificates due to commercial issues (insolvency, payment arrears).

In these cases, the decision is made by the management of the certification body.

Multi-site Organizations

With regard to multi-site organizations, the requirements of IAF MD 1 apply.
Certificates issued must include the scope of certification and the locations (sites) covered by the multi-site certification. The name, address and the scope of certification valid for each site must be stated for the individual sites.
If the applicant states that individual sites are no longer relevant and/or the scope of

validity previously valid for a site is restricted, the certificates will be reissued in accordance with this information and the existing certificates will be withdrawn.

If the applicant has temporary locations, these will be marked as temporary locations on the certificates.

Certificates for individual locations (location certificates) are not issued.

If an applicant with multiple sites is found to have a major nonconformity at one site, the certificate will be restricted, suspended or withdrawn unless the responsible party takes appropriate corrective action to ensure compliance with the requirements.

Changes to Existing Certifications

Requests for changes to existing certifications on the part of the applicant must be submitted in writing and will be handled in the same way as the certification procedure described above.

Duration of Certificate Validity

If ecm issues a certificate, ecm also determines the period of validity. Certificates are issued with a maximum validity period of 3 years.

Monitoring Intervals

The first surveillance audit must be carried out within 12 months of the certificate being issued and corresponds to a stage 2 audit. The second surveillance audit is carried out the following year.

Major Nonconformities in the Surveillance Audit

In the case of an existing certification, a certification recommendation by the lead auditor to maintain a certificate in the event of identified major nonconformities is generally only possible if the corrective measures required on the basis of a root cause analysis can be implemented immediately and successfully.
The lead auditor must determine in each individual case whether a recommendation for maintenance of certification can be issued.

Maintenance of certification is only possible on the condition that the company has implemented corrective measures or corrections with regard to the major nonconformity and N evidence of the implementation and effectiveness of these measures is available.

Notification of Change by the Applicant

Applicants are obliged to inform ecm in writing without delay of any matters that could affect the ability of the management system to continue to meet the requirements of the standard used for certification. Such matters are e.g. changes regarding:

- the legal, economic or organizational status or ownership;
- organization and management (e.g. key personnel in management positions, decision-making or specialist personnel);
- contact addresses and locations;
- of the scope covered by the certified management system;
- significant changes to the management system and processes.

Audits Announced or Unannounced at Short Notice

Announced or unannounced audits at short notice may be necessary if:

- external factors such as the following apply:

- available post-market surveillance data known to ecm on the products concerned indicate a possible significant deficiency in the management system.
- ecm obtains knowledge of essential security-relevant information.

- Significant changes have occurred that have been submitted in accordance with the normative requirements or have come to the attention of ecm, and these changes may have an impact on the decision on the status of conformity in accordance with the normative requirements.

## 5. Suspension, Restriction or Withdrawal of Certificates

As soon as ecm is faced with the decision of a certificate suspension, certificate restriction or certificate withdrawal, ecm requests the certificate holder in writing to comment and thereby enables the certificate holder to be heard in order to clarify the facts, unless such a hearing is not possible due to the urgency of the decision to be made.

ecm shall require the certificate holder in writing at to implement corrective measures within a specified period of time to restore the conditions and obligations that existed when the certificate was issued or are associated with it.

The implementation of corrections and corrective measures is subject to monitoring by ecm.

If the certificate holder does not fulfill the conditions within the specified period, ecm suspends or withdraws the certificate issued or restricts the scope of the certificate. The certificate holder will be informed of the change in status of the certificate. The rights associated with the certificate are thereby revoked with immediate effect.

**Suspension of the Certificate**

The certification can be suspended by ecm. In the event of suspension, the certification of the certificate holder's management system is temporarily suspended. This occurs, for example, in cases where:

- the certified management system permanently or seriously fails to meet the certification requirements, including the requirements for the effectiveness of the management system;
- the certificate holder is not permitted to carry out the surveillance or recertification audits, which must be conducted at the required frequency;
- there are refusals by the certificate holder during an unannounced audit;
- the certificate holder has voluntarily requested a suspension.

A suspended certification will be reinstated when the problem that led to the suspension has been resolved. If the problems that led to the suspension have not been resolved within a period of time specified by ecm, this will result in the withdrawal of the certificate or restriction of the scope of the certification.

**Restriction of the Scope of the Certification**

ecm will limit the scope of a certification to exclude those parts that do not meet the requirements if the certificate holder has permanently or seriously failed to meet the certification requirements for those parts of the scope of the certification.

**Withdrawal of a certificate**

Reasons for the withdrawal of certificates may include

- misuse of certificates,
- absence (no longer present) of essential requirements for certification,
- opening of insolvency proceedings against the certificate holder or discontinuation due to lack of assets,
- cessation of business operations by the certificate holder,
- noncompliance with legal provisions or official requirements,
- outstanding claims from ecm that the applicant has not settled despite reminders,
- amendments to the contractual conditions / procedural guidelines to which the certificate holder objects in writing within 4 weeks of their entry into force or the opportunity to take note of them,
- any other reasons arising specifically from these procedural guidelines.

**Expiry of the Validity of the Certificate**

No further action is required from ecm when certificates expire.

## 6. Recertification

The application for recertification must be submitted no later than 6 months before the expiry date of the certificates issued (corresponds to phase 0 of the certification cycle) . With the application, the applicant must submit information on whether and to what extent the assessment criteria have changed since the certificates were issued or renewed.

recertification can only take place if a recertification audit has been carried out beforehand.

If the recertification activities are successfully completed prior to the expiry of the existing certification, the expiration date of the new certification may be based on the expiration date of the existing certification.

Provided that the recertification activities have been completed after the expiry of the existing certification, the certification body may restore the certification within 6 months of the expiry of the certificate.

If the recertification audit has not been completed 6 months after the expiry of the certificate or the implementation and effectiveness of corrections and corrective actions for any major nonconformity could not be verified, at least the stage 2 audit must be repeated in order to carry out the recertification procedure.

In both cases, the issue date of the new certificate corresponds to the date of the recertification decision or a later date and the expiration date must be based on the previous certification cycle.

## 7. Appeals Regulations / Complaints Procedure

A distinction is made between appeals and complaints. However in both cases ecm will determine together with the objector or complainant whether, and if so, to what extent the subject matter and its resolution must be made publicly accessible.

ecm ensures that the persons involved in the process of handling appeals and complaints are different from those who conducted the audits and different from those who made the decision to certify and were not otherwise involved in the subject matter of the appeal or the complaint.

ecm shall also ensure that the lodging, investigation and decision of objections or complaints do not result in any disadvantage to the appellant or complainant.

Irrespective of the decision of the complaint committee, both parties have recourse to the courts in the event of the appeal.

## Appeals

Applicants have the right to appeal decisions made by ecm. Appeals are objections by applicants to decisions or procedures of the certification body or its staff. Appeals must be submitted in writing and can only be made by applicants and certificate holder.

Examples of appeals:

- appeals regarding the full or partial refusal, suspension or withdrawal of certificates;
- appeals regarding the incorrect representation, evaluation or interpretation of facts in audits.

For example, the following do not count as objections:

- complaints regarding the cost structure;
- complaints regarding the scheduling of audits or document evaluations.

Appeals must first be sent to ecm in writing within four weeks of receipt of the decisions. ecm will confirm receipt of the appeal to the appellant.

Appeals are recorded by ecm and forwarded to the complaint committee for investigation.

## Complaints

Complaints are negative statements made by applicants, certificate holders or third parties about the certification body or about certificate holders of the certification body or about subcontractors used by the body. Complaints must be made in writing. Complaints may be lodged by applicants, certificate holders and third parties.

Examples of complaints:

- complaint regarding the delay of certification procedures;
- complaints from third parties about possible misconduct by an applicant to the certification body.

In the event of a complaint, ecm checks whether the complaint relates to certification activities for which ecm is responsible. If this is the case, the complaint is forwarded to the complaints committee.

If ecm receives a complaint about an applicant or certificate holder, ecm will inform the person concerned within 4 weeks while maintaining confidentiality towards the complainant.

## Complaints Committee

The complaints committee is responsible for processing and investigating appeals and complaints with the aim of mediation. The complaints committee decides on the justification of the appeal and complaint and on any measures to be taken. If the complaint concerns an ecm certificate holder, the investigation of the complaint must take into account the effectiveness of the certified quality management system of the certificate holder.

The complaint committee must also take into account the results of previous similar appeals and complaints.

The complaints committee shall draw up a record of the results of the investigation, the decision and the measures taken. If these measures provide for corrections at the certification body, they must be continued in accordance with ecm's internal procedure for corrective and preventive actions.

The complaint committee may request the certification committee to review the certification decision. However, the complaint committee itself cannot make a decision on the certification. The complaint committee forwards its records to the certification committee for information. The certification committee shall inform the objector or complainant of the outcome of the investigation, the decision, the measures taken and the formal conclusion. The objector or complainant is informed within four weeks with a final report or through regular status reports (every four weeks) until the final report.

## 8. Use of the Certificates / ecm Signets

**Use of the Certificates**

The use of the certificates issued by ecm is only permitted within the regulations made here, within the respective existing scope of the certification and exclusively during the period of validity of the certificates.

The applicant is entitled to use the certificates for business purposes, including advertising, for the duration of their validity.

Misleading information about the certification status or misleading use of certification documents is not permitted.

Certificates based on normative reference documents do not authorize the affixing of the CE marking.

Any use that discredits ecm or the certification system is not permitted.

The applicant is obliged to do the following in particular:

- must comply with the requirements set out in these procedural guidelines when referring to the certification status in communication media, such as the Internet, brochures or advertising materials or other documents;
- must not make any misleading statements regarding certification;
- may not use certification documents or parts thereof in a misleading manner or permit such use;
- must stop using all advertising materials that contain references to the certification status when the certification is withdrawn;
- must change all advertising materials if the scope of the certificate has been restricted;
- shall not allow any reference to management system certification that could tacitly imply that the certification body certifies a product (including a service) or a process;
- must not tacitly imply that the certification applies to activities and locations outside the scope of the certification;
- may not use the certification in a way that brings the certification body and/or the certification system into disrepute and jeopardizes public trust in the certification body.

**Use of the ecm Signet**

References to the certification status can be made using the ecm signet. However, the ecm signet may only be used within the scope, period of validity of the certification and in the form shown here:


The signet may not be altered. Size adjustments are permitted without changing the proportions, provided that this does not impair the legibility of the logo.

Only the use of the logo for advertising purposes is permitted.

The signet may not be used as an indication of product conformity or be interpreted as such. The logo may not be used to identify products, not even in close connection with products, in such a way as to suggest that the products themselves have been certified by ecm. This also applies to product packaging and labeling (labels and instructions for use) of products.

It is expressly forbidden to use the logo on laboratory test reports, calibration certificates, inspection reports or certificates.

The applicant is obliged to establish a procedure to control the use of the label. Among other things, this procedure must guarantee traceability to ecm. There must be no ambiguity in the label itself or in the accompanying text with regard to what has been certified and which certification body has granted the certification.

The use of the logo is restricted to the legal or natural person of the applicant and may not be transferred to third parties or successors without the express permission of ecm. The right to use the logo may not be assigned.

If a certification has expired or is suspended by ecm for whatever reason, the right to use the label expires. In such a case, the existing documents or the media bearing this signet must be withdrawn immediately and no longer used within a period of 14 days from the suspension of the certification taking legal effect.

The above paragraph also applies if the certification is withdrawn or the right to use the label expires for other reasons, in particular for reasons of violation of the provisions of the agreements between ecm and the applicant.

By using the signet, the above regulations are recognized as binding.

Use of the IAF-DAkkS Symbol

The use of the IAF-DAkkS symbol is not permitted for applicants or certificate holders.

## 9. Final provisions

These procedural guidelines replace the version included in 0510_VTR_Vertragssatz_EN16.