RULES FOR GMED CERTIFICATION OF

QUALITY MANAGEMENT SYSTEMS

Revision 9

Application date: July 15th, 2022

CONTENTS

1. OBJECT AND SCOPE

The object of the present Rules is to specify the terms and conditions for the certification of Quality Systems by GMED, a notified body, in accordance with the national and international regulations applicable to quality assurance for the design, production, distribution or provision of a service in the field of health and medical devices.

Certification is established in accordance with one of the following standards:

- ISO 9001 – Quality management system - Requirements
- NF EN ISO 13485, ISO 13485 – Medical devices – Quality management system – Requirements for regulatory purposes

These rules cover the certification issued by GMED under COFRAC accreditation and within the Medical Device Single Audit Program (MDSAP).

2. TERMS OF SERVICE

Company certification is subject to prior signature of a contract between the applicant and GMED. This contract specifies the reference(s) against which certification is established, the Company's activity to be covered by certification as well as the mutual obligations of the parties.

This certification contract also states the practical and financial terms and conditions of the certification process.

Upon signing the aforementioned contract, the Company undertakes to apply the G-MED Rules of Company Certification, which have a contract value.

To allow the signature of the aforementioned contract, the Company is previously requested to provide GMED with any information relating to certifications obtained or under way which falls within the field of activity due to be covered by the certification contract with GMED.

GMED issues certificates of conformity with the reference(s) mentioned by the contract. The issuance of this certificate entitles the Company to include references to the certification and to use the G-MED mark in accordance with its Rules of Use.
Observance of the Rules of Use of the G-MED Mark and of the terms of reference to the certification, mentioned in § 7 of these regulations, is part of the Company’s contractual commitments.

Quality Management System certificates should not be confused with certificates and attestations of CE marking of medical devices established in pursuance of European Directives concerning medical devices.

Obtaining a certificate or an attestation within the framework of the CE marking does not authorize the applicant to use the G-MED mark.

3. CERTIFICATION PROCESS

Certification process is performed with respect to the requirements of ISO 17021-1:2015 – Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1:Requirements.

The certification procedure comprises the following six steps:

- preliminary stage,

- application for certification,
- initial certification audit,
- decision on certification,
- surveillance of the Company,
- renewal.

The certification process is subject to the diagram attached to the present Rules.

The purpose of audits is to ensure the audited company's management system is compliant with the reference standard, to assess the management system effectiveness and to identify areas for improvement of the management system.
Provisions made within the framework of an application for extension of certification may also be examined during surveillance audits.

A certification renewal audit is performed before the certification period runs out with an overall assessment of the company's management system.

For each audit, the company is informed of the audit team composition and may disapprove the proposed auditors, specifying the reason, thus resulting in a new proposal.

An audit plan is established and submitted to the company for approval 10 working days before the audit. The plan is drawn up in accordance with the provisions of ISO 17021-1.

Each on-site audit includes:

- An opening meeting with the company management aimed at confirming the scope of certification and specify the audit plan ;
- An assessment of compliance of the Quality management system with the baseline reference(s) and of its effectiveness,
- A closing meeting during which the lead auditor delivers his/her conclusions.

3.1. PRELIMINARY STAGE

Further to the first contact with the company, GMED provides the Company all the information relating to the certification process, including a questionnaire to be filled in by the company.

This questionnaire should allow:

- Identification of the company, the persons to contact and its activities,
- Definition of the scope of the application for certification,
- Information retrieval on the quality management system and related documentation.

GMED analyses the questionnaire and may suggest a diagnosis audit or pre-audit to better appreciate the extent to which the company's management system is developed.
This preliminary audit is optional and is not an integral part of the certification process.

Following this first contact, the company receives a certification offer which contains all the information required for a formal application for certification. This offer is made on the basis of the defined audit schedule of the certification cycle, and using information supplied by the company. The audit schedule may be subsequently amended according to changes to the company or the scope of the requested certification, following the results of audits or after modifications in the certification standards.

3.2. APPLICATION FOR CERTIFICATION

The application is made on the basis of the standard documents that the company received and results in a contract being drawn up. This contract lists the applicant's and GMED's obligations and commitments.
Upon signature of the said contract, the Company undertakes to apply the present certification rules, which have a contractual value.

The certification dossier consists of a written application, along with the contract signed and the quality documentation in French or in English.

The quality documentation shall include as a minimum:

- the manual of the concerned system, if necessary;
- the list of the system's procedures, or the list of documented information;
- the list of related products and services covered by the management system to be certified.
- any other documents, necessary according to the requested certification rule(s);

GMED processes the application and if admissible, schedules the initial certification audit with the applicant.

3.3. INITIAL CERTIFICATION AUDIT

3.3.1 General

The audit duration and the number of auditors are set by GMED according to the company staff roll, the size and complexity of the organisation, the selected baseline reference(s) and of GMED's possible familiarity with the management system set up within the framework of other certification processes (ex.: regulatory certification).

When the company is already a GMED certificate holder, for all or part of the field of activity concerned, the initial certification audit may be conducted jointly with an audit relating to the certificate issued and it takes elements already audited within that context into account.

The initial certification audit contains two stages:

3.3.2 Stage 1

The first stage of the initial certification audit aims at ensuring that the company fully understand the requirements of the applicable standards, identifying and collecting information relating to the scope of the management system, to the sites concerned, the regulatory and legal aspects that the company should comply with. It aims at assessing the preparedness of the company for the second stage, at verifying that the internal audits and the management review are being planned and performed, and at confirming the procedure defined for conducting the stage 2 audit.

This first stage consists of a review of the documentation submitted by the company liaising with the member of staff appointed by the latter, and of an on-site visit. In some case (i.e.: company already known by GMED, geographical distance of the location), this first stage may be remote using techniques such as teleconferences or videoconferences.

The results of the stage 1 audit are compiled into a report that is submitted to the company. This report gives details on any identified areas of concern that could be considered as a non

conformity during the stage 2 audit. It specifies if the stage 2 audit can be carried out with the arrangements already scheduled or if these arrangements need to be reviewed.

The results of stage 1 may lead to the postponement or cancellation of stage 2. In the case of significant changes that could affect the management system, it may be necessary to repeat all or part of stage 1.

If need be, the arrangements for conducting the stage 2 audit may be modified in agreement with the company.

3.3.3 Stage 2

The audit is made up of an assessment of the compliance of the management system operated by the company with the baseline reference(s) defined, an assessment of its implementation and its effectiveness.

This audit is carried out on the Company's premises, in accordance with the guidelines of ISO 17021-1, by an auditor or a team of qualified auditors appointed by GMED. Auditors are qualified in conformity with the criteria set forth in ISO 17021-1 and the criteria defined by GMED.

The audit report is drawn up by the Lead auditor and accounts for:

- Significant elements of the management system contributing to inspiring confidence in the company achieving compliance with the baseline reference(s),
- Non conformities and relevant observations with respect to the defined baseline reference(s),
- Areas or opportunities for improvement of the management system.

Non-conformities are classified according to a rule defined in a specific document drawn up by GMED. They must be the subject of correction and corrective actions suggested by the company.

Insomuch as they put into question the system's ability to achieve the intended results, or the compliance of the delivered product or service, they are identified as major and must give rise to correction and corrective actions duly specified and documented by the company so as to verify their implementation before any certification decision is made.

Within 15 working days of the end of the audit, the Company communicates to the Lead Auditor its possible comments, the cause's analysis, and the plan of correction and corrective actions it decides to apply as to the nonconformities noticed.

The audit report is analysed by a GMED-appointed representative and submitted to the GMED comité de lecture (internal "comité de lecture"), defined in section 6.

The committee sets out to examine the audit report. Depending on the nature and the seriousness of the non conformities identified and the correction and corrective actions suggested by the company, it issues one or more of the following recommendations:

- Request for further information;
- Request for corrective actions with or without additional documentary assessment;
- Request for corrective actions with or without additional on-site audit;
- Granting of certification, with or without observations.

These recommendations must be based on elements from the audit report or G-MED certification rules.

A time limit is given for any request for corrective actions.

3.4. DECISION FOR CERTIFICATION

In view of the audit report, the Lead Auditor's conclusions, and the “comité de lecture” recommendation, GMED president or his delegate makes a decision.

The decisions may be to:

- grant the Company immediate certification,
- conduct a documentation assessment before the certification,
- carry out an additional audit,
- deny certification.

The documentation assessment and the additional audit aim at verifying that the corrections and corrective actions suggested are being applied.

For major nonconformities, this verification must be carried out within 6 months from the last day of the stage 2 audit. If this deadline cannot be met, a new stage 2 audit is conducted under the above mentioned provisions.

The decision is notified to the Company and, where applicable, leads to the establishment of a certificate.

It lists at least the following:

- Company identification
- The site(s) covered by certification,
- The certification baseline reference(s),
- The activity covered by certification,
- The certificate validity period (3-year for a normal cycle)

This certificate is maintained every year and renewed at its end of validity on the basis of provision specified in 3.5 and 3.6.

The certificate is registered. GMED transmits all information on the content and status of the certificate and may publish it.

3.5. COMPANY SURVEILLANCE

The certificate is maintained on the basis of commitments made by the company on applying on the one hand, and on observations from a surveillance audit conducted at least once a year on the other hand.

In the event of major modifications, verification of the maintenance of the management system may take place within the framework of additional audits.

3.5.1 Surveillance audit

The date of the first surveillance audit after initial certification is set within 12 months after the certification decision date.

If the company holds a regulatory certificate managed by GMED, the audit performed with respect to this certification may be conducted jointly with the surveillance audit.

The follow-up audit, the preparation of the report and the company's response to any non-compliances identified during this audit are made under the same terms as the stage 2 audit.

Within the framework of the company surveillance, GMED decides whether to carry out surveillance audits or additional audits and on the provisions aimed at ensuring that the compliance of the management system is maintained:

- Request for corrective actions;
- Additional audit;
- Report to the “comité de lecture” for opinion.

If a non conformity considered as a serious hinder to the effectiveness of the audited management system or as jeopardising the expected product compliance is identified during one of these audits, GMED submits the report to the “comité de lecture” for examination and a subsequent opinion on a suspension for a limited period or a withdrawal decision. (see 3.5.2).

In the transition period, GMED may take any conservatory measure that may be needed relating to the certificate validity or the request for corrective actions.

Any application for the extension of the scope of the certification granted may be subject to assessment during the follow-up audit. The duration of the audit is then adapted. Depending on the content of the application for extension, a step 1 audit may be required. (see 3.3.2)

3.5.2 Suspending, withdrawing, reducing the scope of certification

GMED may suspend, withdraw or reduce the scope of a certificate when it is noticed that:

- the contractual requirements are not complied with,
- the Quality System does not conform with the requirements,
- the holder refuses to conduct the follow-up audit within the time allotted by GMED,
- the holder does not fulfill his financial obligations,
- the company requests cancellation of its certification.

GMED then formally notifies the holder of the suspension, withdrawal or reduction by recorded delivery letter, indicating, in the first case, the terms and conditions of the lifting of the suspension, in particular the corrective measures to be taken and the period for which the suspension is pronounced.

GMED undertakes the verifications necessary to restore the certification.
Where applicable, suspension is lifted and certification is back into force and the holder is notified.
Otherwise, GMED withdraws or reduces the certification.

In the latter case, the provisions regarding the use of the certification mark and reference to the certification mentioned in § 7 of these rules must be followed by the company.

3.6. CERTIFICATE RENEWAL

Before the certificate expires, GMED carries out a renewal audit.

The renewal audit aims at confirming the management system as a whole is still compliant and effective, as well as continuously operating within the scope of certification.

In case of major modifications of the management systems or affecting the company, a step 1 audit (see 4.3.2) may be required.

The renewal audit must be completed at least 3 months before the certificate's term date.

The results of the renewal audits are examined following the same rules as for an initial certification audit.
Decision to renew the certificate is made following the same procedure. It takes into account the results of the renewal audit, the company's evolution for the whole certification period as well as possible complaints registered against the certified company.

In the event of a major nonconformity being raised during a renewal audit, corrections and corrective actions should be implemented by the applicant within the time frame set by GMED, which must verify the implementation of corrections and correctives actions before the validity of the certification expires.

In the event of a non conformity and on recommendation of the "comité de lecture", GMED makes one of the following decisions:

- Refusal of renewal of the certificate,
- Request for corrective actions within a deadline, and verification of their implementation through documentary assessment;
- Request for corrective actions, within a deadline, and an additional audit.

If the renewal audit or the verification of the implementation of corrections and corrective actions for major nonconformities cannot be completed before the expiry date of the certification, the certificate is not renewed.
GMED may restore the certification within 6 months from the certificate's end of validity, if and only if the actions mentioned above are completed and result in a favourable outcome. After this period, a new stage 2 audit must be conducted, at least. During the period where the company has no certification, the company must give up advertising or making reference to the certification.

Upon renewal of the certificate, the date of expiry is based on the date of expiry of the previous certificate.

4. APPEALS

The applicant or the certification recipient may appeal against any of GMED's decisions as regards quality systems certification activities.

The reasons for appealing must be provided. The appeal should be notified by registered post with acknowledgement of receipt within 15 days of the company's receipt of the notification.

The appeal is processed by GMED within 30 days of receipt and is examined by the “comité de lecture” whenever it relates to the certification decision or the certification rules.
GMED informs the plaintiff, within this time limit, as to whether or not it maintains its decision.

Where the appeal is maintained, the appeal is brought before the Certification Committee, defined in Article 6, which, after examination, offers its conclusions to GMED president.

Final GMED decision is notified to the appealing company.

5. COMPLAINTS HANDLING

Any complaint received by GMED is examined by GMED to ensure and confirm the complaint relates to activities certified by GMED.

When it affects a company holding certification, GMED informs the company concerned to proceed to examine the complaint.

The company concerned should then inform GMED of the outcome and keep records relating to the complaint and the measures taken to solve it at GMED’s disposal.

Verification that the announced actions have been implemented is carried out during the following audit at the latest.

When there is significant doubt on whether the effectiveness of the management system is maintained, GMED can perform additional audit. This audit may be unannounced (without a prior notice to the company).

Within the framework of the company surveillance, GMED examines the records relating to complaints and checks that appropriate corrective actions have been initiated.

6. INTERVENERS AND RESPONSIBILITIES WITHIN THE CONTEXT OF THE CERTIFICATION PROCESS

GMED supervisory board:

- Defines the certification policy,
- Monitors certification activity finances,
- Delegates to GMED’s president decisions relating to the operation of certification and the setting up of certification committees as well as the appointment of their members,
- Entrusts to the certification and safeguarding impartiality committee the monitoring of the certification policy implementation on the basis of an annual report presented by GMED’s president or his/her deputy.

The President:

- Decides on the creation of certification and safeguarding impartiality committee aimed at facilitating the consultation of parties involved in certification ; he also designates the committee members,
- Consults the certification and safeguarding impartiality committee on the respect byGMED’s compliance with impartiality rules,

- Makes certification-related decisions (granting, suspension, renewal and withdrawal), and relies for this purpose on recommendations issued by the internal “comité de lecture” or the certification committee opinion if necessary,
- Plans out the certification body policy and the responsibilities that follow,
- Appoints the staff in charge of certification operations.

The certification and safeguarding impartiality committee is made up of representative members of the interests involved in certification. It is made up, among others, of manufacturers' representatives with an interest in the field of health and medical devices, representatives of “Users-Buyers-Prescribers” and representatives of GMED.
This committee can be joint with the LNE committee.

The certification and safeguarding impartiality committee:

- delivers an opinion on the certification policy which falls within G-MED certification mark,
- approves the Rules of G-MED Certification,
- Issues recommendations on ways to apply these rules,
- examines appeals presented to it after the “Comité de Lecture” has delivered its opinion and suggests courses of actions,
- gives an opinion on GMED's compliance with the rules of impartiality.

The “Comités de Lecture” are committees made up of competent persons of GMED. Upon request of the certification committee, the GMED may schedule the observation of a “Comité de Lecture” by two members. One member is from the manufacturer’s representative, the other is from the “Users-Buyers-Prescribers” representatives.

The “Comités de Lecture”:

- Examine audit reports, give an opinion and issue recommendations relating to actions to be taken and decisions to grant, suspend, renew or withdraw certification.
- Investigate appeals against GMED’s decisions and forward the elements on to the certification committee for a review and a proposal on decisions to make.

7. THE G-MED MARK OF CERTIFICATION AND REFERENCE TO CERTIFICATION

The G-MED Mark, which verifies that the Company’s quality system has been certified by GMED, is represented below:

This distinctive mark is registered with the I.N.P.I. along with the particular Rules of Use of the G-MED Mark of Company quality systems.

Its use is strictly reserved for LNE and GMED within the context of collective publicity and for the certificate recipient, who received the corresponding notification, in accordance with the terms and conditions defined by particular rules.

When testing, calibration or inspection activities are covered by the certification, the reports or the certificates issued by the company as part of its activities, are considered as products and thus, the certification mark must not be applied on these documents.

A reference to the certification may be displayed on the product packaging or in the accompanying document only under the following conditions:

- The product in question is covered by the scope of the certification held by the company;
- The reference includes:
    - the name and address of the certified site,
    - the type of management system, the certification standard and its year
    - the name of GMED: the entity which issued the certification.
- The statement does not imply that the product, service or process is certified by GMED.

When referring to the certification, the company must meet the following requirements:

a) comply with the requirements of GMED when making reference to its certification status in communication media, such as websites, brochures or advertising and other documents;
b) do not make or permit any misleading statements regarding its certification;
c) do not use or permit the use of a certification document, in whole or in part in a misleading manner;
d) upon withdrawal of its certification, cease all advertising which refers to its certified status;
e) modify any advertisement if the scope of certification is reduced;
f) do not allow any reference to the certification of its management system, which implies that a product, service or process is certified by GMED;
g) do not to imply that the certification applies to activities and sites which are not covered by the certification scope;
h) do not to use the certification in such a manner that would bring GMED's reputation and/or the certification system into disrepute and thus compromise the public confidence.

Any misuse of this mark or improper reference to GMED's certification is subject to legal proceedings, in pursuance of the regulations in force concerning misleading publicity and intellectual property.

The graphic chart is handed over when the certificate is delivered.

8. REFERENCE TO GMED ACCREDITATION

GMED does not authorize companies to use the COFRAC accreditation mark, apart from the full reproduction of certificates issued by GMED.

The company holding a certificate covered by COFRAC accreditation may make reference to GMED accreditation. This reference must clearly indicate that it is an accreditation held by GMED and must be accompanied by the following words: COFRAC Certification of management systems Accreditation No. 4-0608 - List of accredited sites and scopes available on www.cofrac.fr.

Any reference to GMED accreditation must comply with the requirements of the current version of the document " Règles générales pour la référence à l'accréditation et aux accords de reconnaissance internationaux " GEN REf 11 available on www.cofrac.fr.

As soon as the company no longer holds an accredited certification issued by GMED, the company shall cease all advertising that refers to GMED accreditation.

The company shall not place any reference to GMED accreditation on any products (including their packaging).

Any misuse of the COFRAC accreditation mark or improper reference to accreditation detected by GMED will be notified to the company concerned by letter so that it can remedy the situation. If necessary, this misuse will also be notified to COFRAC, which may take any action it deems necessary.

Misuse is defined as (From GEN REF 11 General rules for reference to accreditation and international recognition agreements):

- unauthorized use of the COFRAC logo and accreditation marks,
- the use of marks, textual references or other references to accreditation that are likely to mislead the reader as to the beneficiary of the accreditation, the scope of the accreditation, the validity of the accreditation, the status of the signatory to the international recognition agreements or the activities covered by these agreements

These rules are reviewed on a yearly basis. They may be revised at GMED's suggestion or on request coming from members of the certification and safeguarding of impartiality committee. Modifications must be approved by the committee.

The present revision of GMED certification rules was approved by the certification and safeguarding of impartiality committee on June 3rd, 2022.

Annex
CERTIFICATION PROCESS