

**FRAMEWORK CONTRACT - INFORMATION
ACCESSIBLE TO APPLICANTS, CERTIFIED
CUSTOMERS AND OTHER INTERESTED
PARTIES**

Name: FRAMEWORK CONTRACT - INFORMATION ACCESSIBLE TO
APPLICANTS, CERTIFIED CUSTOMERS AND OTHER
INTERESTED PARTIES, Code: IAS
Version: 5/03.02.2022

Page. 1/19
Form PS-01-F-01/vers.1

1. PREAMBLE

This framework contract presents the general rules applicable to the supply by S.C. CERTINSPECT REGISTER S.R.L. ("CERTINSPECT"), a Romanian commercial company, with headquarters in Bucharest, district 2, Zambilelor str., no. 96, 1st floor, with order number in the Commercial Register J40/13045/2017, CUI RO37991905, legally represented by administrator Ionescu Mariana, of the contractual services regarding the management system/systems certification process, including specific rules regarding certification, rules regarding the use of the certification mark or logo, the process of handling calls and complaints, obtaining information in order to initiate the certification process, its policies, information about: the geographical areas in which it operates, the status of a certain certification, information about a certain certified client, in accordance with the provisions of the standards SR EN ISO/CEI 17021-1, SR ISO/TS 22003, SR EN ISO/CEI 27006, ISO/IEC 20000-6.

2. SCOPE

2.1 This contract regulates CERTINSPECT's relationship with its clients, being described the certification rules that must be respected by CERTINSPECT's clients in all cases.

2.2 The financial offer is annexed to the Service Provision Contract, having the same evidentiary and binding power as it. The validity period of the *Financial Offer*, if it is accepted, is equal to that of the issued certificate. By accepting and signing the financial offer issued by CERTINSPECT, customers declare that they accept and comply with the contractual obligations, including those shown in this document, for the entire validity period of the issued certificate.

3. TERMS, ABBREVIATIONS AND REFERENCES

3.1 Terms

The terms used in this procedure are the terms stipulated in the reference documents.

3.2 Abbreviations

ADM	Administrator
CAI	Commission for Ensuring Impartiality
CEA	Audit team leader
RCC	Responsible for making the certification decision
CERTINSPECT/body	CERTINSPECT REGISTER SRL
Organization/applicant/client	The CERTINSPECT client who accepts the financial offer, by signing

3.3 Referinces

- SR EN ISO/CEI 17021-1:2015 Conformity assessment. Requirements for bodies performing audit and certification of management systems. Part 1: Requirements
- SR ISO/TS 22003:2016 Food safety management systems. Requirements for bodies auditing and certifying food safety management systems
- SR EN ISO/IEC 27006:2020 Information technology. Security techniques. Requirements for bodies providing audit and certification services for information security management systems
- ISO/IEC 20000-6:2017 Information technology – Service management. Part 6: Requirements for bodies providing audit and certification of service management systems
- EA, IAF documents applicable to the certification activity, in force
- Regulations of the Accreditation Body, in force
- SR EN ISO 9000: 2015 Quality management systems. Fundamental principles and vocabulary

4. OBJECT OF THE CONTRACT

Name: FRAMEWORK CONTRACT - INFORMATION ACCESSIBLE TO APPLICANTS, CERTIFIED CUSTOMERS AND OTHER INTERESTED PARTIES, Code: IAS

Version: 5/03.02.2022

Page. 2/19
Form PS-01-F-01/vers.1

4.1 Contractual conditions regarding the management systems certification process

4.1.1 General

CERTINSPECT maintains and makes available to certification applicants, certified customers and other interested parties upon request information on:

- the status and authority under which the body operates;
- types of management systems for which the body provides certification services and the geographical area in which it operates;
- documents necessary to initiate the certification process;
- own rules on audit and certification processes for granting / maintaining / extending / renewal / restricting / suspending / transferring or withdrawing the certification for each certification scheme;
- the rights and obligations of certified clients;
- requirements that certification applicants must meet;
- how to manage appeals, complaints and recourse;
- certification documents;
- how to use the certification marks of CERTINSPECT;
- the status of a certain certification;
- information about a specific certified customer.

This information is accessible through:

- publishing on the body's website: www.certinspect.ro
- publishing in advertising materials: posters, leaflets, folders and presentation materials or on request.

4.1.2 CERTINSPECT provides certification applicants, certified customers and other interested parties with only up-to-date, accurate and non-misleading information.

4.1.3 CERTINSPECT offers the following certification services:

Management systems:

- Quality according to ISO 9001
- Environment according to ISO 14001
- Occupational health and safety according to ISO 45001
- Food safety according to ISO 22000
- Information security according to ISO/IEC 27001
- Management of services according to ISO/IEC 20000-1
- Business continuity according to ISO 22301
- Anti-bribe according to ISO 37001
- Energy according to ISO 50001
- Medical devices according to ISO 13485
- Health care according to EN 15224
- Social responsibility RS 20000 (own standard)

Note: The current editions of the documents mentioned above apply.

4.1.4 Access to the certification services provided by CERTINSPECT is free and non-discriminatory. It is not conditioned by the size of the organization or its membership in an association or group.

4.1.5 Only the management system specified in the *Certification Application* is subject to evaluation in order to issue the certificate.

Name: FRAMEWORK CONTRACT - INFORMATION ACCESSIBLE TO
APPLICANTS, CERTIFIED CUSTOMERS AND OTHER
INTERESTED PARTIES, Code: IAS
Version: 5/03.02.2022

Page. 3/19
Form PS-01-F-01/vers.1

4.1.6 The certification services provided by CERTINSPECT do not include advice, including internal audit, for the certification applicant.

4.1.7 Certification consists in verifying the compliance of the management systems with the reference standards and not with the legislation in force, the implementation and observance of which rests exclusively with the organization. It is solely responsible for legislative compliance. CERTINSPECT refuses to assume any responsibility in this regard or any obligation to issue guarantees.

4.1.8 The certificate of conformity, issued on the basis of the reference standard indicated by the applicant in the *Application for certification*, does not extend and cannot be used to the products/services offered by it. This Certificate of Conformity will not be used in a way that induces a third party to believe that those products or services are certified.

4.1.9. CERTINSPECT may carry out conformity assessment, as appropriate, both as an accredited body and as a non-accredited body, for those areas for which it does not have accreditation. If the body subsequently obtains accreditation, the certificate shall be issued again in an accredited manner.

CERTINSPECT cannot be held liable in case of loss, change, suspension, withdrawal of accreditation held, for any reason or for any loss or non-recognition of its certificates.

4.1.10 During the on-site assessment, CERTINSPECT auditors consider the employees. If the organization wants the presence of other people (e.g. consultants) in the audit, it has the obligation to ensure that their role is only as observers.

4.1.11 Due to the fact that there may be a possible conflict of interest in the relationship with the applicant for certification, which may make it impossible for CERTINSPECT to provide its services, the name of the consultant must be provided in the *Application for certification* submitted to the body; of his team members. The applicant must inform CERTINSPECT of any changes to this effect.

4.1.12 A conflict of interest in the CERTINSPECT-Client relationship may occur during the period of validity of the certification, in which case CERTINSPECT has the right to cancel the contract with immediate execution, with the client's responsibility to pay for all services provided by the body until at the time of cancellation.

4.1.13 The issuance of the certificate does not necessarily imply that each element of the organisation's management system, deployed at each point of work, is continuously compliant with the audit criteria.

CERTINSPECT performs the audit to assess the conformity of the management system using the sampling method, unless the reference standard provides otherwise. This involves a certain risk regarding the full compliance of the certified management system with the audit criteria.

As a result, CERTINSPECT cannot be held liable if the customer's services, products or processes are defective or the customer receives complaints, fines, cancellations of operating licenses.

4.1.14 The existence of a certification order (*Financial offer accepted*) does not take the place of registration with the authorities, and audits and certificates issued do not replace official inspections and controls performed by the authorities.

4.1.15 The duration of the certification order begins with the acceptance of the *Financial Offer* by signing by the client and ends with the expiration date of the certificate or with the moment of its withdrawal, regardless of the reason. During this period, either party may withdraw by requesting termination at least 30 days before it becomes effective, the notification being sent by registered letter with acknowledgment of receipt. In case of termination requested by the certified organization, it will pay to CERTINSPECT 30% of the total value of services remaining to be performed until the contract expires, based on the invoice issued by CERTINSPECT.

4.1.16 CERTINSPECT performs the services provided in the accepted *Financial Offer*, either with its own employees or with specialized external staff who carry out their activity on behalf of the body on the basis of a contract. They will respect all commitments undertaken by CERTINSPECT, including those relating to confidentiality and impartiality.

4.1.17 The fees related to the stages of the certification process are mentioned in the *Personalized Financial Offer*. For any additional activity or modification of the initially issued certificate, which are not explicitly mentioned in the offer, the following fees will be charged:

- a) issuance of a certificate in English: 50 EURO/certificate and 30 EURO/Annex to the certificate
- b) issuance of a duplicate of the certificate originally issued: 50 EURO/certificate and 30 EURO/Annex to the certificate
- c) issuance of a new certificate as a result of the change of the name of the organization and/or the addresses of the locations (does not apply in case of extension to new locations for which a specific offer is issued): 70 EURO/certificate and 30 EURO/Annex to the certificate
- d) inclusion of a company logo (not products) on the certificate: 100 EURO/certificate and 70 EURO/Annex to the certificate
- e) carrying out an additional 1-day audit to close the major non-conformities found: 300 EURO

4.1.18 For the services performed, CERTINSPECT issues invoices, which must be paid within a maximum of 30 days from their issuance. If payment is delayed, interest for late payment of 0.05%/day of delay on the invoice amount shall be applied. The costs of the activities carried out will be paid even if the certificate is not issued due to non-compliance by the organization with the compliance requirements.

4.1.19 If the body decides to terminate or suspend the certification activity, CERTINSPECT will make every effort to transfer certified clients to other accredited certification bodies at no cost.

4.1.20 In the event that the customer invokes any damage caused by CERTINSPECT, its value may not, in any case, exceed the value of the amounts already paid by the customer under the ongoing contract concluded with that customer.

4.2 Information on the requirements to be met by certification applicants/certified clients

In order to obtain and maintain certification, the organization must:

- a) make all necessary arrangements for the evaluation (make available to CERTINSPECT the documentation relating to the management system for which certification and related records were requested and access to CERTINSPECT auditors, who shall carry out, where appropriate, evaluation, supervision, special audits or resolving possible complaints, in all areas);
- b) to comply with the requirements of the reference standard that constitutes the audit criterion and of the applicable legislation;
- c) to observe the present rules;
- d) to comply with the requirements regarding the use of the certificate and the certification mark;

CERTINSPECT REGISTER

- e) to pay in advance the invoices issued by CERTINSPECT for services, except for state institutions;
- f) to agree on the audit periods and the audit team designated for evaluation within three days from the date of notification. If no response is received within this period, it is considered that the audit period, the audit plan and the team have been accepted by the client.
- g) to agree, in agreement with CERTINSPECT, on the participation of observers from the certification/accreditation body in the evaluation process for the purpose of monitoring the auditing staff or for the purpose of mandatory evaluations from the accreditation body; the client has the obligation that, if the accreditation body requests CERTINSPECT to perform an audit under assistance, to accept its performance within a period established by mutual agreement and at its expense, otherwise the refusal may lead to withdrawal of the accredited certification if the reasons presented are not accepted by the customer;
- h) to inform CERTINSPECT on any irregular situation found by the control authorities as well as on the suspension or withdrawal of authorizations, etc. related to the aspects regarding the object of the certificate;
- i) if changes occur during the period of validity of the certification that affect the validity of the certificate (for example: modification of the information specified in the certification application, interruption of activity, suspension or withdrawal of authorizations, concessions, bankruptcy, insolvency, etc.), the organization must send in advance a written communication to the body, which may accept the changes or request additional assessments or even measures to suspend/withdraw the certificate, depending on the severity and impact of the event in question. The organization may or may not accept this situation and may waive certification by sending a written address to CERTINSPECT, within 30 days of receipt of the communication from the body;
- j) to maintain its structure and organization in accordance with the requirements contained in the standard reference document during the period of validity of the certification;
- k) if the organization intends to modify the scope of certification, mentioned in the certificate, it must send a written request to CERTINSPECT, which is the only one able to decide whether it is necessary to perform a new analysis of the documentation or a new audit;
- l) provide CERTINSPECT, where applicable, with complete and detailed information on the specific risks in the work areas where auditors are required to operate and provide protective equipment for them in the work areas;
- m) if during the period of validity of the certification there are changes in the reference standard (s) or the rules of the accreditation body, which may influence the certification rules of CERTINSPECT, it will notify the certified organizations in writing about its transition policy and associated costs analysis of documentation or on-the-spot audit activities generated by making such changes. In this situation the organization may accept, in which case it will pay these costs, or may waive the certification by sending a written address to CERTINSPECT, within 30 days of receiving the communication from the body;
- n) to present CERTINSPECT information and real documents regarding the evaluated activities, based on which the decision of certification, maintenance, suspension, withdrawal, transfer is taken. CERTINSPECT cannot be held liable if it is subsequently found that this information was incorrect;
- o) exclusively for the audit and certification services of the information security management systems according to SR EN ISO/CEI 17021-1 and SR ISO/IEC 27006, to allow CERTINSPECT to carry out special audits in case the organization has had security incidents of information or in the case of any other major changes that call into question the effectiveness of the information security management system. In this case the costs of these audits will be borne by the client.
- p) exclusively for the certification of occupational health and safety management systems, the certified client must immediately announce the occurrence/registration of a major incident or

Name: FRAMEWORK CONTRACT - INFORMATION ACCESSIBLE TO
APPLICANTS, CERTIFIED CUSTOMERS AND OTHER
INTERESTED PARTIES, Code: IAS
Version: 5/03.02.2022

Page. 6/19
Form PS-01-F-01/vers.1

violation of legal requirements and which required the involvement of the competent regulatory authorities.

r) exclusively for the certification of food safety management systems, the client has the obligation to notify CERTINSPECT immediately, if the following significant incidents occur: food incidents that have caused illnesses; suspension of the sanitary-veterinary authorization due to violation of legal requirements or for other reasons; withdrawal of products/lots of products from the market due to a potential food safety risk.

s) exclusively for the certification of anti-bribery management systems, the client has the obligation to notify CERTINSPECT immediately, in the event of proven cases of bribery involving the client's employees and/or the client's organization. In these cases, CERTINSPECT reserves the right to carry out special audits, the costs of which will be fully borne by the client, in order to decide whether or not to continue the validity of the certificate issued for the anti-bribery management system.

t) exclusively for the certification of the quality management system of medical devices, if information is requested by the Regulatory Authority in the field of medical devices, CERTINSPECT will provide information regarding the client's status regarding the granting, suspension or withdrawal of certification.

4.3 Documents required to initiate the certification process

4.3.1 The necessary documents for the initiation of the certification process are the *Application for certification* for bidding, form P-01-1-F-01, Annex to the certification application for ISO/IEC 27001, form P-01-1-F-02, Annex to certification application for ISO 13485, form P-01-1-F-09.

These documents are available on the body's website, where they can be accessed directly by certification applicants or are made available to them by the body's staff upon request.

4.3.2 In order to start the certification, the organization must send to CERTINSPECT the acceptance of the submitted *Financial Offer* and the following documents:

- a) Copy of the Registration Certificate with its annexes or copy of a valid legal Notary Certificate that clearly shows which activities and locations where they are carried out are included in the scope of certification
- b) Organization chart
- c) The management system documents specified in the standards against which certification is requested, as mandatory (can also be analyzed during stage 1, upon request)
- d) List of internal documents relevant to the management system (can also be analyzed during stage 1, upon request)
- e) List of locations, for organizations with multiple locations only
- f) Authorizations/licenses held for the activities carried out issued by the authorities including the environmental authorization, in the case of certification according to ISO 14001
- g) The notice of operation from the Ministry of Health/National Agency of Medicines and Medical Devices in Romania, regarding medical devices
- h) Other licenses and mandatory approvals issued by the authorities for carrying out the activity (IGP, ANRE, etc.)

NOTES:

-All documents received from the client are considered confidential.

-CERTINSPECT may request from the organization other documents necessary for evaluation.

4.3.3 The contractual conditions remain valid if the organization starts the certification process within 6 months from the date of the *Application for Certification*. If this interval is exceeded, the organization will complete a new *Application for certification*, in which case CERTINSPECT, taking into account the changes, may change the initial contractual terms.

Name: FRAMEWORK CONTRACT - INFORMATION ACCESSIBLE TO APPLICANTS, CERTIFIED CUSTOMERS AND OTHER INTERESTED PARTIES, Code: IAS

Version: 5/03.02.2022

Page. 7/19
Form PS-01-F-01/vers.1

4.4 General rules for certification of management systems

CERTINSPECT issues certifications for organizations whose management system (s) has been recognized as complying with the requirements of the reference standard (s).

4.4.1 Initial certification

The initial certification audit of a management system is carried out in two stages: stage 1 and stage 2.

Stage 1

The objectives of stage 1 are:

- a) analysis of the documented information of the client's management system/systems;
- b) the evaluation of the conditions specific to the client's location and the development of the discussions with the client's staff in order to determine the level of preparation for stage 2;
- c) analyzing the client's situation and the client's understanding of the requirements of the standard (s), in particular regarding the identification of key performances or significant aspects, processes, objectives and operations of the management system (s);
- d) obtaining the necessary information regarding the scope of the management system/systems, including: the client's location(s); processes and equipment used; established control levels (especially for customers with multiple locations); applicable legal and regulatory requirements;
- e) analyzing the allocation of resources for stage 2 and agreeing with the client the details of stage 2;
- f) focusing on stage 2 planning by obtaining a sufficient understanding of the client's management system(s) and on-site activities in the context of the management system standard(s) or other normative document;
- g) assessing whether the internal audits and analyzes performed by the management are planned and performed at all work points and whether the level of implementation of the management system(s) demonstrates that the certification applicant is ready for stage 2.

In order to achieve the objectives of stage 1, the performed verifications, specific to each certification standard, comply with the procedures of the CERTINSPECT audit process.

If critical observations or non-conformities were identified (in the case of food safety management system certification) at stage 1, they must be resolved until the initial certification audit stage 2. The postponement of stage 2 will be possible for a maximum period of 6 months, and if they are not fixed within this interval, the certification process will restart with stage 1 or end.

The findings of the initial certification audit stage 1 may generate changes in the *Financial Offer* if it is found that the audit area was not requested correctly, if there are more work points than those specified in the *Application for Certification* or a larger number of staff than declared initial.

If the audited is an organization with multiple locations, the initial certification audit stage 1 is carried out only at the headquarters, and in stage 2 the sampled locations will be evaluated, according to the sampling plan.

Stage 2

The objectives of stage 2 of the initial certification audit are:

Name: FRAMEWORK CONTRACT - INFORMATION ACCESSIBLE TO
APPLICANTS, CERTIFIED CUSTOMERS AND OTHER
INTERESTED PARTIES, Code: IAS

Version: 5/03.02.2022

Page. 8/19
Form PS-01-F-01/vers.1

CERTINSPECT REGISTER

- a) the evaluation of the conformity and effectiveness of the management system/systems with the reference standard(s) and/or of another normative reference document, in the client's location(s);
- b) identification of areas for potential improvement of the management system/systems;
- c) evaluating the ability of the management system to meet the applicable legal and regulatory requirements within the organization;
- d) assessment of the ability of the management system(s) to meet the applicable requirements and to obtain expected results.

In order to achieve the objectives of stage 2, the verifications performed, specific to each certification standard, comply with the procedures of the CERTINSPECT audit process.

The certification audit stage 2 is carried out only at the client's premises, based on an audit plan sent to the client 3 days before the scheduled date.

When establishing the activities to be audited in stage 2, it is taken into account that at the initial certification audit and at recertification the entire certification scope is audited and at the Surveillance audits these activities are sampled so that during a certification cycle all activities included in the scope of certification.

Stage 2 can take place immediately after stage 1 in the following situations:

- no critical comments were recorded at the initial certification stage 1 audit;
- the audit team as a whole meets the necessary competence for the audit of the certification area
- the team is fully available during that period.

This stage includes at least the evaluation of:

- a) the organizational context and the risk management process;
- b) organizational processes and their documentation according to importance;
- c) information and evidence regarding compliance with all requirements of the applicable standard(s) of management system (s) or other normative document;
- d) monitoring, measuring, reporting and analyzing the performances in relation to the established performance objectives and targets, in accordance with the expectations from the applicable standard(s) of management system(s) or other normative document;
- e) the capacity of the client's management system/systems and its performance in terms of meeting the applicable legal, regulatory and contractual requirements;
- f) operational control of customer processes;
- g) planning and performing the internal audit and the analysis performed by the management;
- h) the process of investigating the complaints and notifications made by the authorities;
- i) allocation of resources for the proper functioning of the management system/systems;
- j) the responsibility of the management for the declared policy and the establishment and pursuit of the objectives.

If the client does not provide CEA with evidence of the implementation of the system(s) within the organization or poses threats to the audit team, CEA has the authority to discontinue the audit.

At the end of the audit, the client is presented with the audit conclusions and, where applicable, the non-conformity sheets. The customer must complete in these sheets corrections, the cause of non-conformity, corrective actions and implementation deadlines. The non-conformity forms must be signed by the client after completion and must be sent to the CEA for validation, within a maximum of two weeks from the completion of the audit.

Name: FRAMEWORK CONTRACT - INFORMATION ACCESSIBLE TO
APPLICANTS, CERTIFIED CUSTOMERS AND OTHER
INTERESTED PARTIES, Code: IAS
Version: 5/03.02.2022

Page. 9/19
Form PS-01-F-01/vers.1

If there are no non-conformities or non-conformities are minor, the verification of the implementation of corrections and corrective actions and their effectiveness is verified at the next audit, and the audit team's recommendation is to certify whether CEA validates the adequacy of actions proposed by the client.

If the identified non-conformities are major, the organization has 6 months from the last day of the initial certification audit stage 2 to resolve the non-conformities by applying corrections and corrective actions. If this period is exceeded, the initial certification audit will be repeated including stage 1, at the expense of the client.

The verification of the implementation of corrections and corrective actions and their effectiveness is done in this case, through an additional follow-up audit at the client's premises in the areas where major non-conformities have been identified. The duration is recommended by the CEA depending on the extent of the actions implemented by the client and established by the body. The additional audit is invoiced to the client, based on this document and the initial *Application of Certification*.

If, after performing the additional follow-up audit, it is found that the non-conformities have not been resolved or other major non-conformities have occurred, then in the case of initial certification/recertification/extension audits it is necessary to perform a new full audit, based on a new order from the client's side.

If the follow-up audit has a positive result, the CEA's recommendation will be to grant the certification. If not, the recommendation will be for non-certification.

Before making the recommendation to the audit team, the CEA verifies the corrections and corrective actions established for the identified non-conformities.

In the case of multi-site organizations, if there is a major non-conformity at only one workplace, which raises significant doubts about the ability of the customer management system to achieve the intended output, certification is not granted until when the customer does not resolve the closure of this non-conformity.

4.4.2 Surveillance

During the period of validity of the certification, two Surveillance audits are scheduled to take place:

- the first surveillance audit (S1) must be carried out within a maximum of 12 months from the date of the certification decision
- the second surveillance audit (S2) must be carried out no later than 24 months from the date of the certification decision

Surveillance audits are carried out only at the client's premises and are not complete system audits but sample processes, certification areas and locations.

The surveillance audit must assess at least:

- a) internal audits and analysis performed by management;
- b) analysis of the actions taken for the non-conformities identified during the previous audit;
- c) handling complaints;
- d) the effectiveness of the management system/systems regarding the achievement of the objectives of the certified client;
- e) the evolution of the activities planned for continuous improvement;

Name: FRAMEWORK CONTRACT - INFORMATION ACCESSIBLE TO
APPLICANTS, CERTIFIED CUSTOMERS AND OTHER
INTERESTED PARTIES, Code: IAS

Page. 10/19
Form PS-01-F-01/vers.1

Version: 5/03.02.2022

- f) continuity of operational control;
- g) analysis of any changes;
- h) the use of marks and/or any references to certification;
- i) analysis of any actions established and/or implemented for: notification of adverse events, withdrawals from the market of medical devices, other notifications to and/or from customers/the regulatory authority.

Two months before each surveillance audit, CERTINSPECT notifies the client that it is scheduled in date for the audit and is asked to specify the period and to send to the body any changes that have occurred in the last year in organization, documentation, management, etc. The notification to the client must request information on significant changes to the quality management system in the client's medical devices, which could affect compliance with applicable legal and regulatory requirements.

Surveillance audits are scheduled so that the activities to be assessed are carried out at the time of the audit. In cases where activities are carried out seasonally, it is permitted to postpone the audit to periods other than the scheduled one provided that they are carried out at least once in a calendar year and given that the first Surveillance audit does not need to be carried out no later than 12 months from the date of the certification decision.

In duly justified exceptional cases, Surveillance audits may be postponed for up to three months, with the certificates remaining valid. Exceeding this deadline entails the suspension process.

Surveillance audits can be combined with other types of audits (initial for other management, extension/restriction, transition systems).

If, as a result of the Surveillance audit, minor or major non-conformities result, they are communicated in the closing meeting to the client and proceed as in the case of the initial certification audit, stating that if the additional audit to follow the implementation of corrective actions these have not been resolved, or other major non-compliances appear, the certificate is withdrawn, and the certification cycle will be resumed.

4.4.3 Recertification audit

The recertification process must be started by the organization at least 3 months before the expiration of the certificate by sending to CERTINSPECT a new *Application for certification*, which will be the basis for a new *Financial Offer* for the next 3-year cycle.

The recertification audit does not include step 1 unless there have been significant changes in the management system(s) implemented by the client or there have been major changes in the regulatory requirements applicable to the certified scope.

The recertification audit usually involves performing an audit at the client's premises.

The objectives of the Surveillance audit are:

- a) the evaluation of the effectiveness of the management system/systems as a whole, taking into account the internal and external changes and its relevance and continuous applicability to the scope of certification;
- b) evaluation of the demonstrated commitment to maintain the effectiveness and improvement of the management system(s) in order to increase overall performance;
- c) evaluating the effectiveness of the management system regarding the fulfillment of the objectives and the intended results of the management system.

d) verifying the effectiveness of the implementation of corrective actions as a result of non-conformities from the previous audit, if applicable.

If the recertification audit results in minor or major non-conformities, they are communicated in the closing meeting to the client and proceed as in the case of the initial certification audit, except for the fact that for any major non-conformities identified the deadline for implementation of corrections and corrective actions by the client and the verification of their implementation by the CEA must not exceed the expiry date of the existing certificate(s).

When the recertification audit is successfully completed before the expiry date of the existing certification, CERTINSPECT issues the new certificate on the date of the recertification decision or at a later date, with the expiry date based on the expiry date of the existing certification.

If the recertification audit has not been completed before the expiry date of the existing certification CERTINSPECT does not recommend recertification and the validity of the certification shall not be extended. CERTINSPECT will inform the customer about this situation.

CERTINSPECT may re-establish a new certification cycle within a maximum of 6 months from the expiry of the validity of the existing (previous) certification, provided that the recertification audit activities are successfully completed, the date of entry into force of the certificate being in this case the date of the decision recertification and the expiry date is calculated from the validity date of the existing (previous) certification. If the recertification audit is performed in these 6 months, this audit will be considered as a stage 2. If the 6 months are exceeded, a full audit will be performed.

4.4.4 Special audits

4.4.4.1 Audit to extend the scope of certification

In order to extend the scope of an already granted certification, CERTINSPECT performs an analysis of the application and determines all the activities necessary to carry out an audit on the basis of which it can be decided whether or not to grant the extension. The audit may be performed in conjunction with a Surveillance audit or between Surveillance audits through a stand-alone audit based on a new *Appication for Certification*.

The audit aims to verify the implementation of the management system/systems for:

- other locations, which have not been included in the certification area already granted, but where activities in the area already certified are carried out,
- activities other than those covered by the scope already certified.

If the certification extension audit is performed between Surveillance audits it is performed as an initial certification audit stage 2, at the organization's headquarters.

4.4.4.2 Unscheduled audits

CERTINSPECT may decide to perform unscheduled audits in cases where:

- the client was suspended, the purpose being to lift the suspension
- there are complaints to the certified customer, the purpose being to verify the truthfulness of the complaint and the possible activities and causes that led to the complaint (related to the certified activities carried out by the organization or the misuse of the certificate and certification mark CERTINSPECT)
- there are changes at the level of management, of the organizational structure, of the locations where the activities in the scope of certification are carried out, the purpose being in this case

Name: FRAMEWORK CONTRACT - INFORMATION ACCESSIBLE TO
APPLICANTS, CERTIFIED CUSTOMERS AND OTHER
INTERESTED PARTIES, Code: IAS

Page. 12/19
Form PS-01-F-01/vers.1

Version: 5/03.02.2022

the verification of maintaining the conformity of the management system/systems against the criteria of the standard or other normative documents.

-to the occurrence of significant incidents/accidents (e.g. appeared in the media and/or announced by the certified customer), related to the environment (e.g. environmental accidents), health and safety at work (e.g. occurrence/registration of work incidents or breach of legal requirements), information security (e.g. leakage of sensitive information, dissemination/theft of sensitive data including personal data), food safety or serious breaches of relevant legislation, which has led to the involvement of relevant authorities.

- the organization has been involved in judicial investigations into corruption in the last 5 years and/or CERTINSPECT concluded from the audit that the organization is exposed to a high risk of corruption that impacts the effectiveness of the anti-bribery management system (for specific audits ISO 37001 (anti-bribery management system)).

- CERTINSPECT has information taken from post-sales surveillance regarding the medical device, which indicates a possible deficiency of the customer's quality management system and/or information regarding the safety of the medical device.

CERTINSPECT describes and makes known, through the documents sent prior to the audit, to the certified clients about the purpose of these audits.

In these cases the client cannot challenge the audit team.

4.4.5 Transfer of certification

At the request of customers, CERTINSPECT may perform certification transfer audits only if it has been certified by a certification body accredited by a member signatory to the MLA (EA-MLA, IAF-MLA) and issues a CERTINSPECT certificate for an equivalent period with the remaining one from the previous certification.

4.4.6 Withdrawal, suspension, restriction or withdrawal of certification

In the event of termination of the contract, for whatever reason, the certificate(s) issued under that contract is/are withdrawn by CERTINSPECT and the use of the granted mark of conformity is prohibited.

The customer can cancel the certification at any time by an official notification sent to CERTINSPECT 30 days in advance. In this case, the client will pay to CERTINSPECT 30% of the total value of the services remaining to be executed until the term of the contract, based on the invoice issued by CERTINSPECT.

CERTINSPECT suspends certification in cases where:

- the certified customer management system(s) has repeated and serious failures in meeting the certification requirements, including the requirements for the effectiveness of the management system(s) (major non-conformities) if not resolved within 6 months;

- the certified client does not allow the performance of surveillance or recertification audits at the required frequency;

-the certified client does not pay his financial debts;

- the certified client requests to be suspended voluntarily;

- failure to comply with the dates/periods of transmission of corrections and corrective actions proposed by the organization for the non-conformities identified within the established terms;

- when the client has used the certificate/certification mark incorrectly or abusively and does not take appropriate corrective actions in a timely manner to correct the factual situation;

- the registration by CERTINSPECT of some justified complaints regarding the certified organization and which demonstrate significant irregularities in the operation of the management system of the client organization;

Name: FRAMEWORK CONTRACT - INFORMATION ACCESSIBLE TO
APPLICANTS, CERTIFIED CUSTOMERS AND OTHER
INTERESTED PARTIES, Code: IAS

Page. 13/19
Form PS-01-F-01/vers.1

Version: 5/03.02.2022

- the organization made changes in the certified management system as a result of some organizational changes (establishment/abolition of locations, in the production structure, etc.) which it did not bring to the notice of the body.

During the suspension, the certification of the client's management system (s) is temporarily invalidated CERTINSPECT has set a maximum suspension period of 6 months. If during this period the suspended client does not solve the problems that led to the suspension then CERTINSPECT takes the decision, as the case may be, to withdraw the certification or to restrict the scope of certification.

CERTINSPECT restricts the scope of certification due to:

- the express request of the client;
- following a surveillance audit, on the recommendation of the CEA;
- following the suspension;

The restriction does not affect the operation of the management system(s) implemented in accordance with the reference standard(s).

-If following an unscheduled audit performed as a result of an incident/accident it is found that the organization has failures in demonstrating the maintenance of the effectiveness of the management system, CERTINSPECT may decide to suspend or withdraw the certification.

CERTINSPECT withdraws the certificate/certificates granted in the following situations:

- at the express request of the client;
- breach of contractual clauses;
- violation of the rules of this document;
- the certified client does not pay his financial debts;
- the certified client uses the certificate/certificates and the conformity mark incorrectly or abusively;
- the client dissolves or goes bankrupt or no longer performs the certified activities in the declared locations;
- the client has not taken effective actions to lift the suspension;
- the client defames or damages the certification body;
- the suspension period has expired.

4.5 Information on certification documents

The certification document issued to the client to whom the certification was granted is the *Certificate of Conformity*.

The certificate of conformity shall be valid for a maximum of three years from the date of issue provided that the management system is further maintained, improved and effective and the CERTINSPECT maintenance audits are completed with positive results.

The maintenance of the validity of the certificates issued is conditioned by the performance of the scheduled surveillance audits and the existence on the certificate of the annual visa.

In the case of organizations with multiple establishments, the certificate issued shall be accompanied by a list of all the establishments and the activities carried out therein. In this case the organization is obliged to inform CERTINSPECT about the closure of the work points or the opening of new work points, whenever such changes occur, otherwise it is considered that the certification is used improperly and will act accordingly, according to point 4.7.

4.6 Notification of changes

4.6.1 Notifications made by the body

Any change in the certification requirements, mainly due to the change in the reference standards against which the certification was made, the change in the requirements of the accreditation standard or the application guidelines, is communicated to each client certified or in the process of certification through a Transition Policy, displayed on the body's website (www.certinspect.ro) and/or sent directly by e-mail to each client.

The organization may waive certification if it considers that it cannot comply with the new requirements. The waiver decision must be notified in writing to CERTINSPECT at least 30 days before the final date of compliance.

In order to increase the confidence of the interested parties and in particular to comply with the applicable legal and regulatory requirements, CERTINSPECT may disseminate the audit report or information about this report to the regulatory authority (eg: Ministry of Health/National Medicines and Devices Agency Medical from Romania) and/or information about the certifications granted, suspended or withdrawn.

4.6.2 Notifications made by the organization

CERTINSPECT requests its customers to notify without delay (within max. 30 days) of any changes made regarding:

- a) modification of the legal, commercial, organizational or property status;
 - b) modification of the organizational structure and/or management;
 - c) contact address and locations;
 - d) the scope of certification within the certified management system;
 - e) major changes to the management system(s) and processes;
- in response to the notifications of scheduled audits, or occurrence of significant incidents (see 4.2 and 4.4.4.2).

4.7 Rules regarding the use of certificates and certification marks

The certification logo is available to CERTINSPECT customers upon request, by sending it by e-mail.

The certified organization may use the certification logo only after obtaining the certificate of conformity and only during its validity.

The CERTINSPECT certification logo may be used on documents, brochures, advertising materials, motor vehicles, advertisements in magazines of the certified organization provided that the specifications in this document are met.

Certified organizations can use the CERTINSPECT compliance mark for a management system free of charge.

All CERTINSPECT certified customers must comply with these rules regarding the use of the certification mark.

CERTINSPECT customers must follow the following rules:

- a) to comply with the requirements of CERTINSPECT when referring to the status of certification in its own means of communication such as: internet, brochures, advertisements or other documents;
- b) not to make misleading statements regarding its certification;
- c) not to use or permit the use of a certification document or part thereof in a manner that may be misleading;

Name: FRAMEWORK CONTRACT - INFORMATION ACCESSIBLE TO
APPLICANTS, CERTIFIED CUSTOMERS AND OTHER
INTERESTED PARTIES, Code: IAS

Version: 5/03.02.2022

Page. 15/19
Form PS-01-F-01/vers.1

CERTINSPECT REGISTER

- d) after the withdrawal/restriction of the certification, not to use in the advertising materials references to the certification, or to modify them, as the case may be;
- e) it is prohibited to use the certification logo for a management system, certified by CERTINSPECT, on a product and/or product packaging, in a place visible to the consumer, which could be interpreted as an indication of the conformity of the product;
- f) not to use the certification logo for a management system, certified by CERTINSPECT for locations outside the scope of certification and/or other entities;
- g) not to use the certification in a way that could harm the certification body and the loss of public trust;
- i) the certification logo is used strictly by the certified organization and may not be transferred to a third party, is not the subject of an assignment or a measure of enforcement;
- j) the certified organization is prohibited from using the mark of the CERTINSPECT accreditation body, the logos of the CERTINSPECT accreditation body, IAF, MLA, EFAC and EA or the use of the CERTINSPECT own logo instead of the conformity mark;
- k) the certified organization is prohibited from reproducing the certification logo without the written consent of CERTINSPECT;
- l) the certification logo for a management system shall not be used, on the reports of the testing, calibration or inspection laboratories, specific to the organization;
- m) the organization must take the necessary measures when the certification logo for a management system certified by CERTINSPECT is used in conjunction with the registered trademark, trade mark or service mark, in such a way that by this use the statement on certification, not be extended beyond the content of the reference standard specified in the certificate granted.

The certified organization must keep records of the documents on which the CERTINSPECT mark appears and submit the CEA on request.

The control of the application of the CERTINSPECT certification logo is performed internally through internal and external audits by CERTINSPECT within the surveillance/recertification audits performed.

For the food safety management system, the external control of the application of the CERTINSPECT certification logo is also carried out through market monitoring actions (visits of CERTINSPECT staff in the food marketing points and by consulting the websites of the veterinary authorities and with attributions in consumer protection - in order to monitor the occurrence of possible food incidents).

The certified organization shall no longer be entitled to use the certification mark for the management system concerned when:

- certification is suspended (suspension or delay in renewal of certification)
- the withdrawal and cancellation of the certification or the waiver by the organization of the certificate, in which case it must be returned to CERTINSPECT.

Failure to comply with these rules, depending on the degree of guilt, entails sanction by:

- a) warning the organization requesting corrections and corrective actions;
- b) suspension of the certification until the solution of the causes that led to the non-observance of the provisions of the present rules;
- c) withdrawal of certification;
- d) publication of the deviation;
- e) legal action.

Name: FRAMEWORK CONTRACT - INFORMATION ACCESSIBLE TO
APPLICANTS, CERTIFIED CUSTOMERS AND OTHER
INTERESTED PARTIES, Code: IAS

Page. 16/19
Form PS-01-F-01/vers.1

Version: 5/03.02.2022

Unlawful use of the certification logo entails civil and criminal liability under the law.

The organization sanctioned for non-compliance with the provisions of these rules can file an appeal within 20 days (from the date of application of the sanction) to the "Commission for handling appeals" of CERTINSPECT.

4.8 Complaints and appeals management

4.8.1 Appeal

The appeal represents the client's refusal to accept the decisions taken by CERTINSPECT regarding the evaluation and certification activity. The certified customer has the right to make, in justified situations, appeal. The appeal shall be made in writing no later than 30 days from the date of receipt of the CERTINSPECT decision.

Any costs related to the investigation will be borne by the appellant, in case it is found that the appeal was unfounded or by CERTINSPECT if the appeal is justified.

If, following the resolution given by CAI CERTINSPECT, the appellant still considers himself unjustified, he may apply to the courts competent to resolve the dispute.

4.8.2 Complaints

The complaint concerns the dissatisfaction of the certified client with the administrative or technical performance of CERTINSPECT or with regard to the management system of a CERTINSPECT client.

The complaint must be accompanied by supporting evidence.

4.9 Confidentiality

4.9.1 For a clear and complete understanding of the provisions of this clause, confidential information means:

(i) any data (including but not limited to personal data of representatives, employees, contractors or delegates of the other Party), information, documents, technical documentation, procedures or any other documents, regardless of the medium, that come to the notice To the Parties during or in connection with the performance of the Contract;

(ii) information, ideas or materials of a technical nature as a result of research and development, drawings/plans and specifications and other materials or concepts relating to products and production;

(iii) information, ideas or business materials such as non-public financial information, information on costs, profits, products, marketing, sales plans and forecasts, business plans and financial plans and forecasts and development projects and opportunities, products not delivered to the market, other documents representing the market position of the Parties.

4.9.2 Mutual obligations of confidentiality

4.9.2.1 The parties undertake that, for the entire period of validity of the contract concluded between them, as well as for a period of 2 years from the date of termination of the contract, for whatever reason, to:

-exercise at least the same degree of diligence with regard to the Confidential Information of the co-contracting Party which it exercises in order to protect its own Confidential Information of a similar nature; and

CERTINSPECT REGISTER

- at a minimum, adopt, maintain and follow written and comprehensive security practices and procedures that are sufficient to protect Confidential Information against any:

- (a) unauthorized disclosure, access, use or modification;
- (b) misuse, theft, destruction or loss; or
- (c) inability to justify the possession of such Confidential Information.

4.9.2.2 Without limiting the generality of the above provisions, the Parties will use or reproduce the Confidential Information only to the extent necessary to fulfill their obligations under the Contract or any work order or similar provision under the Contract. In addition, the Parties will disclose Confidential Information only to staff (employees) who justify a need to know such Confidential Information (and only to the extent necessary) for the purposes set forth in the Contract.

4.9.2.3 The Parties shall ensure that:

- (a) each employee or collaborator who enters the Confidential Information will be required to comply with the confidentiality obligations set forth in this document; and
- (b) maintain and follow security practices and procedures that are sufficient to detect specific patterns, practices or forms of activity that indicate the possible existence of theft or misuse of Personal Data. The parties will promptly report all such incidents or suspicious activities. The Parties declare that they will conduct regular risk assessments to identify and reasonably assess the foreseeable internal and external risks to the security, confidentiality and integrity of electronic, paper and other records containing Personal Data and will evaluate and improve, where appropriate, the effectiveness of safeguards to limit such risks.

4.9.2.4 The Parties shall not transmit Confidential Information without the prior approval of the other Party. If any Confidential Information is transmitted (by mail, magnetic tape, e-mail transmission or any other means of communication) such Party shall use and ensure that its employees use the highest degree of care to protect such information against intrusion, unauthorized interventions, theft, loss and breaches of privacy.

4.9.2.5 The parties shall promptly notify each other (and in any case no later than 24 hours from the time they become aware) in writing, of any accidental or intentional damage, alteration, destruction, unauthorized disclosure, loss, misuse or theft of or on Confidential Information (including unauthorized access to or use of Personal Data belonging to the other Party, improper handling or deletion of data, theft of information and/or accidental or intentional unauthorized disclosure of Confidential Information) in connection with the Agreement. The parties will cooperate with each other to investigate, remedy and reduce the impact of the effects of the incident.

4.9.3 The confidentiality obligations assumed in this document will not apply to the extent that the Parties can demonstrate, through clear and convincing evidence, that such information:

- (i) are or have become generally known, without any breach by the Parties of the provisions of this clause or any other contract entered into by the Parties;
- (ii) were lawfully in the possession of the Party, without restrictions of confidentiality, before that Party received them in accordance with the provisions of this clause;
- (iii) were lawfully obtained by a Party from a third party who had the right to disclose such information, without restrictions of confidentiality or arising out of ownership;
- (iv) have been developed independently by the Party without the use or reference to the Privacy Information;
- (v) are the subject of a written contract in accordance with which the Party has authorized the Co-Contracting Party to disclose such information.

Name: FRAMEWORK CONTRACT - INFORMATION ACCESSIBLE TO
APPLICANTS, CERTIFIED CUSTOMERS AND OTHER
INTERESTED PARTIES, Code: IAS
Version: 5/03.02.2022

Page. 18/19
Form PS-01-F-01/vers.1

CERTINSPECT REGISTER

4.9.4 The obligations of confidentiality established by this clause shall not apply to the extent that the Parties are required to disclose Confidential Information in accordance with the law or a provision of a court, regulatory agency or other governmental jurisdiction.

The financial offer is an integral part of this framework contract and of the Service Provision Contract, having the same probative and obligatory value.

Name: FRAMEWORK CONTRACT - INFORMATION ACCESSIBLE TO
APPLICANTS, CERTIFIED CUSTOMERS AND OTHER
INTERESTED PARTIES, Code: IAS
Version: 5/03.02.2022

Page. 19/19
Form PS-01-F-01/vers.1