



SYSTEMA CERTIFICARI SRL
Tîrgu Mureş

GENERAL REGULATION FOR THE CERTIFICATION OF MANAGEMENT SYSTEMS

Code: R-SCS-06

APPROVED
General Assembly of Shareholders

.....
General Manager
Aiftimiei Claudiu

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PREPARED BY
The Quality Manager
Vlas Cristina

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Certification Manager
Szoverfi Botond

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INDEX OF REVISIONS AND APPROVALS

| S. no. | Date | Ed./ Rev | Brief description of the amendment | Name, surname, signature | | |
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1. PURPOSE

1.1 The regulation was prepared with reference to the requirements in standard ISO/IEC 17021-1:2015 and defines the requirements of the certification entity *SYSTEMA CERTIFICARI SRL – SYSTEMA*, which must be met by an organisation that requires:

- **the certification of the management system (MS)** applied to:
 - quality management systems, ISO 9001

Other than the condition to observe the requirements specified in this regulation "General regulation for the certification of management systems", code: R-SCS-06, a quality management system is considered fully operational when actions have been implemented to guarantee the consistency in the application of production methods and in the maintenance of quality parameters for products and provided services.

Specifically, in order to obtain the certification of the Quality Management System, the organisation must:

Have implemented a Quality Management System, which must be maintained active and fully operational, with the complete observance of requirements of the reference standard and regulatory documents in that field. The Quality Management System is considered fully operational when:

- it had been implemented for at least three months;
- the internal audit process had been implemented integrally, and its effectiveness can be demonstrated;
- at least one assessment of the management system had been performed and documented - the management analysis;
- there has been a definition of the goals and processes necessary to reach the results, according to the requirements of the client and the policy of the organisation;
- the risk-based evaluation is present;
- there has been an identification of the processes and elements of the system and interactions between them and includes or refers to the appropriate documented procedures; description of processes and their interactions must be extended to all processes identified by the organisation (even with regard to the outsourced processes) necessary for the performance of a product/service, determinant in order to provide the capacity of the product/service to meet the applicable requirements;
- monitoring and measurement of processes and products have been performed and registered according to the established policies, objectives and requirements;
- actions have been implemented for the continuous improvement of processes;
- it includes an appropriate description of the company organisation, the Organisational Schedule;
- it has the registration certificate together with its annexes or a valid legal document of confirmation to indicate clearly the activity, locations and related addresses (for the head office and for each location in the scope of certification);

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- identifies the list of main laws and/or rules applicable to the provided product/service or which are necessary for the appropriate implementation of the quality management system;
- identifies the reasons for exclusion of some elements included in the standard of reference considered inapplicable or which require interpretation or adaptation;

All information received from the client's organisation is dealt with as confidential.

- environment management systems, ISO 14001

Outside the condition of observing the requirements specified in the "General regulation for the certification of management systems", code: R-SCS-06, in order to obtain the certification of the Environment Management System, the organisation must:

- hold a copy of the registration certificate with the Chamber of Commerce and the Confirmation of Company Details or an equivalent document to certify the existence, a description of the type of activities performed on the locations with regard to which the certification of the Environment Management System is requested;
- have documents and registrations to indicate the identification of environment issues associated with the activities of the organisation and the related impact;
- have prepared a documentation to redefine the scope of application of the Environment Management System, the main elements of the system and their interactions, and include or refer to the associated procedures, a document to describe the environment policy, the goals and the schedule (schedules)
- consider the requirements of the standard and provide a description, not necessarily a detailed one, of resources and procedures used to provide compliance with these requirements;
- include an appropriate description of the company organisation.
- include an Organisational Chart
- include the lists with environment issues and impacts generated by the activities, products and services of the organisation;
- include the list of relevant internal procedures for environment management;
- include the list of environment authorisations held by the organisation and the list of legal requirements and other requirements adhered to by the organisation.

- The Environment Management System is considered fully operational when:

- it had been implemented for at least three months;
- the internal audit system had been implemented integrally, and its effectiveness can be demonstrated;
- at least one assessment of the management system had been performed and documented by the management;
- the environment issues and impacts have been identified and evaluated;

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- environment objectives and related environment programmes have been established and documented;
 - significant environment impacts and controls applied to associated activities have been monitored and registered;
 - actions have been implemented for the continuous improvement and prevention of pollution.
- occupational health and safety management systems, ISO 45001. Outside the condition of observing the requirements specified in the "General regulation for the certification of management systems", code: R-SCS-06, in order to obtain the certification of the Occupational Health and Safety Management System, the organisation must:
- hold a copy of the registration certificate with the Chamber of Commerce and the Confirmation of Company Details or an equivalent document to certify the existence, a description of the type of activities performed on the locations with regard to which the certification of the Occupational Health and Safety Management System is requested;
 - have documents and registrations to indicate the identification and assessment of OH&SMS risks and other risks related to the OH&SMS management system;
 - have prepared a documentation to redefine the scope of application of the Occupational Health and Safety Management System, the main elements of the system and their interactions, and include or refer to the associated procedures, a document to describe the environment policy, the goals and the schedule (schedules)
 - consider the requirements of the standard and provide a description, not necessarily a detailed one, of resources and procedures used to provide compliance with these requirements;
 - include an appropriate description of the company organisation.
 - include an Organisational Chart
 - include the list of relevant internal procedures for the management of Occupational Health and Safety;
 - include the list of authorisations held by the organisation and the list of legal requirements and other requirements adhered to by the organisation.
 - include the list of current mobile production units, with the description of the activities performed in such sites, if applicable.
- The Occupational Health and Safety Management System is considered fully operational when:
- it had been implemented for at least three months;
 - the internal audit system had been implemented integrally, and its effectiveness can be demonstrated;

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- at least one assessment of the management system had been performed and documented by the management;
 - risks have been identified and evaluated;
 - environment objectives and related environment programmes have been established and documented;
 - the measures proposed for significant risks are monitored and registered;
 - the organisation obtained compliance with applicable legal requirements by its own assessment of compliance.
- food safety management systems, ISO 22000. Outside the condition of observing the requirements specified in the "General regulation for the certification of management systems", code: R-SCS-06, in order to obtain the certification of the Food Safety Management System, the organisation must:
- the system must have been implemented for at least three months;
 - it has the registration certificate together with its annexes or a valid legal document of confirmation to indicate clearly the activity, locations and related addresses (for the head office and for each location in the scope of certification); it registration documents with Sanitary-Veterinarian and Food Safety Department for the activity, locations and related addresses for which the certification is required;
 - it includes an appropriate description of the company organisation, the Organisational Chart;
 - the internal audit process had been implemented integrally, and its effectiveness can be demonstrated;
 - at least one assessment of the management system had been performed and documented - the management analysis;
 - The organisation identified PRP appropriate to the activity (e.g., regulatory requirements, legislative requirements, requirements related to the client and to the certification scheme);
 - FSMS includes processes and methods that are appropriate for the identification and assessment of hazards regarding food safety within the organisation, as well as for the selection and subsequent classification of control measures (combinations);
 - have implemented the relevant legislation regarding food safety;
 - FSMS must be designed to perform the policy of the organisation related to food safety;
 - validation of control measures, verification of activities and programmes for the improvement are according to requirements of the standard related to FSMS;
 - documents and directives of the FSMS are implemented to communicate on internal level with the suppliers, clients and relevant parties;

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- identify the hazards related to the category in the food chain;
- must have documented procedures on the traceability of the system and on the control of the nonconforming product.

- The Food Safety Management System is considered fully operational when:

- it had been implemented for at least three months;
- the internal audit system had been implemented integrally, and its effectiveness can be demonstrated;
- at least one assessment of the management system had been performed and documented by the management;
- the organisation identified PRP appropriate to the activity;
- related FSMS objectives have been established and documented;
- the measures proposed for significant risks are monitored and registered;

- information security management systems, ISO/IEC 27001

Specifically, in order to obtain the certification of the Information Security Management System, the organization must:

Have implemented a Information Security Management System, which must be maintained active and fully operational, with the complete observance of requirements of the reference standard and regulatory documents in that field. The Information Security Management System is considered fully operational when:

- it had been implemented for at least three months;
- the internal audit process had been implemented integrally, and its effectiveness can be demonstrated;
- at least one assessment of the management system had been performed and documented - the management analysis;
- there has been a definition of the goals and processes necessary to reach the results, according to the requirements of the client and the policy of the organisation;
- the risk-based evaluation is present;
- there has been an identification of the processes and elements of the system and interactions between them and includes or refers to the appropriate documented procedures; description of processes and their interactions must be extended to all processes identified by the organisation (even with regard to the outsourced processes) necessary for the performance of a product/service, determinant in order to provide the capacity of the product/service to meet the applicable requirements
- monitoring and measurement of processes and products have been performed and registered according to the established policies, objectives and requirements;
- actions have been implemented for the continuous improvement of processes;
- it includes an appropriate description of the company organisation, the Organisational Schedule;

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- it has the registration certificate together with its annexes or a valid legal document of confirmation to indicate clearly the activity, locations and related addresses (for the head office and for each location in the scope of certification);
- identifies the list of main laws and/or rules applicable to the provided product/service or which are necessary for the appropriate implementation of the management system;
- identifies the reasons for exclusion of some elements included in the standard of reference considered inapplicable or which require interpretation or adaptation;
- ensures that information receives an adequate level of protection in accordance with its importance to the organization
- prevents the unauthorized disclosure, modification, deletion or destruction of information stored on the media;
- prevents unauthorized access to systems and applications;
- ensures the correct and efficient use of cryptography to protect the confidentiality, authenticity and integrity of information.


- medical device quality management systems, ISO 13485

Outside the condition of observing the requirements specified in the "General regulation for the certification of management systems", code: R-SCS-06, a medical device quality management systems is considered fully operational when actions have been implemented to ensure consistency in the application of production methods and in maintaining the quality of medical devices provided.

Specifically, in order to obtain the certification of the Medical Devices Quality Management System, the organization must:

Have implemented a Medical Devices Quality Management System, which must be maintained active and fully operational, with the complete observance of requirements of the reference standard and regulatory documents in that field. The Medical Devices Quality Management System is considered fully operational when:

- it had been implemented for at least three months;
- the internal audit process had been implemented integrally, and its effectiveness can be demonstrated;
- at least one assessment of the management system had been performed and documented - the management analysis;
- there has been a definition of the goals and processes necessary to reach the results, according to the requirements of the client and the policy of the organisation;
- the risk-based evaluation is present;
- there has been an identification of the processes and elements of the system and interactions between them and includes or refers to the appropriate documented procedures; description of processes and their interactions must be extended to all processes identified by the organisation (even with regard to the outsourced processes) necessary for the performance of a product/service, determinant in order to provide the capacity of the product/service to meet the applicable requirements;

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- monitoring and measurement of processes and products have been performed and registered according to the established policies, objectives and requirements;
- actions have been implemented for the continuous improvement of processes;
- it includes an appropriate description of the company organisation, the Organisational Schedule;
- it has the registration certificate together with its annexes or a valid legal document of confirmation to indicate clearly the activity, locations and related addresses (for the head office and for each location in the scope of certification);
- identifies the list of main laws and/or rules applicable to the provided product/service or which are necessary for the appropriate implementation of the management system;
- identifies the reasons for exclusion of some elements included in the standard of reference considered inapplicable or which require interpretation or adaptation.

- **supervision of certified MS;**
- **recertification, extension, restriction, termination, suspension or withdrawal of certificates.**

1.2 The certificate awarded by SYSTEMA confirms that the certified organisation:

- documented and implemented in an effective manner a management system according to the requirements of reference standard 9001/14001/45001/22000/27001/13485 or integrated and the additional requirements specified by accreditation entities;
- is able to achieve in a systematic manner the policy and established goals.

1.3 Access to the certification services of SYSTEMA free and non-discriminatory. It is not conditioned by the size of the organisation or by the membership thereof to an association or group.

1.4 SYSTEMA certification services do not include any form of consulting for the applicant for certification (preparation of documents of the management system or implementation of the system).

1.5 *SYSTEMA CERTIFICARI SRL* - SYSTEMA is registered with the Trade Register as a legal entity with legal responsibility.

1.6 The correct application of the present regulation is checked by all interested parties in the activities for certification, without having a single interest prevail.

1.7 The following principles are implemented and represent the guidelines for the decision-making process:


- **impartiality:** decisions are made based on objective conformity (or nonconformity) evidence and are not influenced by other interests or other parties;

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- competence: the ability demonstrated by the SYSTEMA personnel to apply knowledge and abilities in all levels;
- responsibility: SYSTEMA has the responsibility to evaluate sufficient objective evidence using an appropriate sampling within the organisation management system, to justify the certification decision;
- transparency: SYSTEMA provides appropriate access to or distribution of non-confidential information related to audit and certification processes, as well as those related to the certification status (respectively the award, extension, maintenance, renewal, suspension, restriction of the field or withdrawal of the certification) to provide the confidence in the integrity and credibility of the certification;
- confidentiality: SYSTEMA maintains the confidentiality of any information that represents the property of the client, providing an appropriate balance between the principles of transparency and confidentiality;
- answer to complaints: the claims of the interested parties are always investigated and processed in an appropriate manner.

2. REFERENCE DOCUMENTS.

- 2.1. ISO/IEC 17021-1:2015 - Compliance assessment. Requirements for entities that perform audit and certification of management systems
- 2.2 ISO 9001:2015 - Quality management systems. Requirements
- 2.3 ISO 14001:2015 - Environment management systems. Requirements and utilisation guidelines
- 2.4 ISO 9000:2015 - Quality management systems. Fundamental principles and vocabulary
- 2.5 ISO 14050:2009 - Environment management. Vocabulary
- 2.6 *IAF MD 1:2023- IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization*
- 2.7 ISO 19011:2018 - Guidelines for the audit of management systems.
- 2.8 MSM-SCS-01 - Management System Manual of SYSTEMA
- 2.9 ISO 45001:2018 Occupational health and safety management system. Requirements and guidelines for use
- 2.10 ISO 22000:2018 Food safety management systems. Requirements for any organisation in the food chain
- 2.11 ISO/TS 22003:2013 Food safety management systems. Requirements for entities that perform audit and certification of food safety management systems
- 2.12 *IAF MD 5:2023- Determination of audit time of quality, environmental, and occupational health & safety management systems*
- 3.13 ISO/IEC 27006:2015- Information technology- Security techniques- Requirements for bodies providing audit and certification of information security management systems
- 3.14 IAF MD 9:2023- Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485)
- 3.15 *ISO/IEC 27001:2022- Information security, cybersecurity and privacy protection — Information security management systems – Requirements*

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3.16 ISO 13485: 2016- Quality management systems for medical devices. Requirements for regulatory purposes

3. DEFINITIONS

Definitions in standards specified under chapter 2 shall apply.

4. STAGES OF THE COMPLIANCE ASSESSMENT PROCESS

The compliance assessment process is presented in the Flow diagram in Annex 1.

4.1.1 General


4.1.1 The organisations that require certification for their management systems can contact the SYSTEMA secretariat in the following manners: by phone, in writing, via e-mail or by the internet.

4.1.2 Following the acknowledgement of the intention of an applicant to obtain the certification of the management system, SYSTEMA submits the applicant via e-mail, on the website or directly the "Questionnaire for identification and preliminary assessment" according to the requested certification.

4.1.3 The organisation fills in all applicable columns of the certification/recertification application.

4.1.4 Following the receipt of the certification application filled in by an authorised representative of the applicant organisation, SYSTEMA performs the analysis of the application and establishes the duration of the audit based on the information provided by the organisation:

- requirements of the applicable standard of the management system;
- size and complexity of the organisation;
- general data of the applicant organisation, including the name, address (addresses) of the physical location (locations);
- the required field of certification, including general information on its activities, human and technical resources, positions and relationships within a larger organisation (if applicable);
- issues related to processes and activities;
- the technological and regulatory context;
- any subcontracting of any activities included in the field of application of the management system;
- the number of locations and all specifications of multiple locations (including the size of production units and geographical area);
- number of production groups;
- result of any previous audits;
- presence or absence of another certificate management system;

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- risks associated with the performed activity.

4.1.5 SYSTEMA submits to each organisation that applies for certification a customised offer based on the fees approved by the General Assembly of Shareholders - GAS.

4.1.6 Once the SYSTEMA offer is accepted, the organisation must submit a firm commitment on the basis of which the certification agreement is executed. By the return of a counterpart of the signed certification agreement, the organisation undertakes to observe the specifications and general conditions of the agreement, as well as the present regulation for the certification of management systems and the regulation for the use of the SYSTEMA mark, enclosed to the agreement.

4.1.7 In order to commence the certification, the organisation must submit in stage 1 of the initial audit the documents of the management system for which it required the certification, as follows:

For all management systems:

- a) the registration certificate together with its annexes or a valid legal document of confirmation to indicate clearly the activity, locations and related addresses (for the head office and for each location in the scope of certification);
- b) the organisational chart;
- c) the documentation according to the standard of reference;
- d) evidence of internal audit and review performed by the management upon the management system intended for certification.

4.1.8 The contractual conditions maintain their validity if the organisation commences certification within a 6-month period following the date of the certification application. If this period expires, a new application will be filled in for the certification/recertification, also considering the amendments (if any) SYSTEMA is entitled to amend the terms of agreement.

4.1.9 Multi-site certification applies to organisational that meet the following criteria:

- There is a central head office that manages a unitary management system, which plans, coordinates, controls and audits the relevant activities in locations and orders the necessary corrective actions, including on their level;
- The locations provide products/services mainly similar, relying mainly on similar procedures;
- In case that the organisation is not a single legal entity, the locations have a legal or contractual relationship with the central head offices and have a common management system established, prepared and subject to continuous assessment and improvement from the central head office.

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4.2 Eligibility criteria for sampling

4.2.1 General and specific issues for ISO 9001

4.2.1.1 All locations or the group of locations selected as population for sampling must perform substantially the same type of activities, and the products and/or services supplied by each location must be substantially similar.

4.2.1.2 The management system must be structured and administered in a centralised manner and must be subject to regular internal audits in all locations/production units, as well as to a management analysis on central level. All locations, including the central head office must be subject to a complete internal audit programme prior to the SYSTEMA assessment.

4.2.1.3 The organisation must be able to demonstrate that it collects and reviews data from all locations, including the central head office, and has the authority and possibility to initiate organisational amendments, if necessary, at least with regard to:

- the system documentation and system amendments;
- management analysis;
- complaints;
- assessment of corrective actions;
- scheduling of internal audit and assessment of results;
- various legal requirements.

4.2.1.4 The organisation shall appoint the Management Representative(s) with general responsibility for the maintenance of the management system.


4.2.1.5 Limited variations are permitted in local work practices caused by differences in available equipment or the size of the local organisation (e.g., in small production units, one person may be responsible for multiple tasks).

4.2.2. Specific issues related to ISO 14001

4.2.2.1. In case of organisations with multiple locations, sampling can be applied if there are: comparable environment issues (as quality and quantity) in the respective locations (input materials, waste, waste water, emissions); similar technical equipment intended for the environment technology.

4.2.3 Specific issues for ISO 45001

4.2.3.1 In case of an OH&SMS system operated on multiple sites, it must be established whether it is allowed to take on-site samples according to the assessment of OHS risks associated to the activities and processes performed in each location included for certification purposes.

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4.2.4 Specific issues for ISO 22000

4.2.4.1 The certification entity may certify an organisation with multiple production units within a management system, provided that the following conditions are met:

- a) All production units operate according to a single FSMS controlled and administered centrally,
- b) An internal audit had been performed on each production unit during one year prior to certification;
- c) The findings of the audits in individual production units must be considered as an indication of the entire system and corrections must be implemented accordingly.

4.2.4.2 The use of sampling in multiple production units is possible only for categories A, B, E, F and G and for organisations of more than 20 production units where similar processes from these categories are performed. The same applies to the initial certification, supervisory audits and recertification audits. The certification entity must justify its decision on sampling in case of certification for multiple production units.

After certification, in case sampling is allowed for multiple production units, the annual internal audit schedule must include all the production units of the organisation.

4.2.4.3 In case the certification entity proposes the sampling for multiple production units, the certification entity must use a sampling schedule to guarantee an effective audit of the FSMS to apply the following:

- a) For organisations with 20 or less production units, all production units must be audited. Sampling for more than 20 production units must be performed compared to 1 production unit for 5 production units. All production units must be selected randomly and, after the audit, none of the sampled production units can be nonconforming (meaning that it must not reach the certification limits for ISO 22000).
- b) At least once a year, there must be a FSMS audit in the central office by the certification entity.
- c) At least once a year, the certification entity must perform supervisory audits upon the necessary number of samples production units.
- d) The findings of the audits in sampled production units must be considered as an indication of the entire system and corrections must be implemented accordingly.

Table with examples of the number of production units to be audited when sampling is used for more production units

| | Total number of production units | | | | | | | | |
|---|---|----|----|----|----|----|----|----|----|
| | Number of production units to be audited between 1 and 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 |
| Number of production units more than 20 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Additional number of production units to be audited | 0 | 1 | 1 | 1 | 1 | 1 | 2 | 2 | 2 |
| Number of production units to be audited | X | 21 | 21 | 21 | 21 | 21 | 22 | 22 | 22 |

Note: paragraphs from 4.2.4.1 to 4.2.4.3 are intended for application exclusively to the operations that affect directly food safety instead of production units with administrative destination.

4.2.5 Specific issues for ISO/IEC 27001

4.2.5.1 Where a client has a number of sites meeting the criteria from a) to c) below, certification bodies may consider using a sample-based approach to multiple-site certification audit:

- a) all sites are operating under the same ISMS, which is centrally administered and audited and subject to central management review;
- b) all sites are included within the client's internal ISMS audit programme;
- c) all sites are included within the client's ISMS management review programme.

4.2.5.2 The certification body wishing to use a sample-based approach shall have procedures in place to ensure the following:

- a) The initial contract review identifies, to the greatest extent possible, the difference between sites such that an adequate level of sampling is determined.
- b) A representative number of sites have been sampled by the certification body, taking into account:
 - 1) the results of internal audits of the head office and the sites;
 - 2) the results of management review;
 - 3) variations in the size of the sites;
 - 4) variations in the business purpose of the sites;
 - 5) complexity of the information systems at the different sites;
 - 6) variations in working practices;

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- 7) variations in activities undertaken;
- 8) variations of design and operation of controls;
- 9) potential interaction with critical information systems or information systems processing sensitive information;
- 10) any differing legal requirements;
- 11) geographical and cultural aspects;
- 12) risk situation of the sites;
- 13) information security incidents at the specific sites.

c) A representative sample is selected from all sites within the scope of the client's ISMS; this selection shall be based upon judgmental choice to reflect the factors presented in item b) above as well as a random element.

d) Every site included in the ISMS which is subject to significant risks is audited by the certification body prior to certification.

e) The audit programme has been designed in the light of the above requirements and covers representative samples of the scope of the ISMS certification within the three year period.

f) In the case of a nonconformity being observed, either at the head office or at a single site, the corrective action procedure applies to the head office and all sites covered by the certificate.

The audit shall address the client's head office activities to ensure that a single ISMS applies to all sites and delivers central management at the operational level. The audit shall address all the issues outlined above.

4.2.6 Specific issues for ISO 13485

4.2.6.1 In the case of a multi-site MDQMS system, it must perform substantially the same type of activities, and the products and / or services provided by each location must be substantially similar.

4.3. Audit for initial certification of the MS. Stage 1.

4.3.1 Audit includes the following activities:

1. Review of the MS stage and assessment of the MS documentation of the applicant;
2. Assessment of location(s) and discussions with the representatives of the applicant regarding the level of preparation for stage 2;
3. Review of the MS stage compared to the requirements of the reference standard and their level of comprehension, with regard to the identification of key performance or issues, processes, MS objectives from the applicant organisation, etc.;
4. Collection and assessment of information and objective evidence regarding the basic issues of the MS: the MS field, processes, locations, legal and regulated requirements and their observance, identification of environment issues and their impact;

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5. Establishment of conditions for the performance of Stage 2 and review of the assignment of resources for the performance thereof, notification of the client with regard to the types of information and records that can be requested during the stage 2 of the audit and specifications related to the issues upon which the audit will focus - stage 2;
6. Assessment of planning and performance of internal audit and review performed by the management, in order to see whether the implementation of the MS is according to the approach of Stage 2;
7. Preparation of the audit report Stage 1.

4.3.2 Findings (documented and supported) of the audit Stage 1 can generate amendments of the agreement between SYSTEMA and the client (if it is found that the audit field has not been requested correctly, if there are multiple production units, if there is a significantly higher number of personnel, etc.).

4.3.3 If the results of the audit of Stage 1, documented in the Audit report Stage 1, allow the continuation to Stage 2, SYSTEMA prepares and distributes to the client the Audit Plan for Stage 2.

4.3.4 In case of multi-site certification in Stage 1 of the audit, the assessment of the management system is performed at the central head office and/or a location with a high number of employees and/or (if applicable) with a high level of relevance upon the environment. All requirements of relevant standards must be considered. In addition, the chief auditor, as part of the system analysis, checks if the management system covers in reality all locations and if it is implemented accordingly upon the assessment moment. If applicable, there will be an additional analysis performed for the management system in the organisation locations that are not covered by the sampling procedure.

4.3.5 Assessment of internal audits by the certification audit must confirm that all production units have been audited as part of the internal audit procedure.


4.3.6 If the management analysis and internal audits have not been completed upon the performance of audit Stage 1, they must be performed prior to the Stage 2 audit.

4.3.7 If there are any nonconformities found during the performance of an internal audit or performed by partners (second party), this must also be considered with regard to the other locations. As a general rule, corrective rules must be implemented within the entire organisation. The central head office shall make sure that the corrective actions are implemented and effective. The chief auditor shall check whether the organisation applies these regulations internally.

4.4. Audit for initial certification of the MS. Stage 2.

4.4.1 Goals of the audit.

4.4.1.1 The goals of the audit are:

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- a) Assessment of conformity and effectiveness of the management system/systems with the standard of reference;
- b) Assessment of the capacity of the management system to ensure that the organisation of the client meets the applicable legal requirements, regulated and contractual.

4.4.1.2 Assessment of conformity and effectiveness of the management system/systems with the standard of reference includes the following:

- a) information and evidence related to compliance with requirements of the applicable standard of the MS;
- b) monitoring, measurement, reporting and review of performance compared to objectives and established goals;
- c) consistency between the results of the assessment of environment issues and impact, hazards and associated risks related to occupational health and safety, the measures established by management programmes or plans for prevention and protection;
- d) assessment of the level of compliance with applicable legal and regulated requirements, as well as with other requirements adhered to by the organisation;
- e) operational control of processes identified by the organisation;
- f) Management responsibility.

4.4.2 Preparation of the audit.

4.4.2.1 The preparation of the audit team is performed based on the following documents:

- a) certification file, with updated documents;
- b) records resulting from the performance of the initial certification audit – stage 1;
- c) criteria for the assessment of the implementation of MS;
- d) nonconformity reports and corrective actions for the recording to nonconformities during the audit;
- e) the file made available by the Certification Manager which includes: MSM-SCS-01, and the reference standard/standards;
- f) the file with the specific regulations of the respective field;
- g) number and geographical area of locations, as well as their size and complexity;
- h) outsourced processes included in the field of MS.

4.4.2.2 Preparation of the audit plan: prepared by the chief auditor, together with the team. Signed by the chief auditor (on the last page) and approved by the Certification Manager (on the first page).

4.4.3 Performance of Stage 2 audit at the client's head office/offices

4.4.3.1 This stage of the audit includes the following:

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- a) **The Client receives from the chief auditor the "Audit Plan - Stage 2"**. Performance of the initial certification audit, Stage 2, takes place according to the audit plan, accepted by the client;
- b) **The reunion of the audit team, at the head offices of the audited organisation** - the client must make available to the audit team an appropriate space for that purpose;
- c) **Performance of the opening meeting**, which is chaired by the Chief Auditor and attended by the management of the audited organisation and is intended to provide a brief description of the manner to perform the audit activities and must include the following elements. The level of detail must consider the client's familiarity with the audit process.
- d) **Communication during the audit**
The chief auditor notifies periodically the client with regard to the assessment of the audit and any of the occurred problems. When the audit evidence available indicates that the objectives of the audit are not achievable or suggest the presence of immediate and significant risk (e.g., for safety), the leader of the audit team must report this to the client and, if possible, to the certification entity, to determine the appropriate actions.
Such actions may include:
- reconfirmation or amendment of the audit plan - amendment is performed directly on the audit plan with the signature of the CEA and of the audited organisation;
 - amendments of the audit objectives or of the scope of audit - the Chief Auditor must review together with the client any necessity for the amendment of the scope of audit which occurs as the on-site audit activities progress. The amended scope of audit, recommended for certification will be mentioned in the audit report signed by the management of the organisation;
 - stop of the audit - when the Chief Auditor notifies the client with regard to the occurred issues that do not allow the audit to continue and prepares an audit report which specifies the number of audit days performed until the stop of the audit, with the signature and stamp of the representative of the organisation. Notifies the client that under such circumstances it will be necessary to perform the audit again, therefore an addendum to the agreement will be executed to that end.
- e) **Observers and guides**
The presence of observers throughout the audit activities must be agreed between the certification entity and the client prior to the performance of the audit. The audit team must ensure that observers do not influence or intervene in the audit process or the results of the audit.
- f) **Collection and verification of information**
Throughout the audit, the information that is relevant to the objectives, scope and criteria of the audit (including information related to the interfaces between functions, activities and processes) are collected by appropriate sampling and verified to become audit evidence.
The methods to collect information used by the audit team include, without being limited to:
- interviews;
 - observation of processes and activities;
 - review of the documentation and records.

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g) Identification and registration of the audit findings

The audit findings are communicated by the CEA to the representatives of the audited organisation at the end of each day of audit and in the closing meeting.

Nonconformities are discussed with the client in order to make sure that the evidence is correct and nonconformities are understood. However, the auditor must refrain from suggesting the cause of nonconformities or their solution.

The chief auditor must settle any divergent opinions between the audit team and the client, with regard to the evidence or findings of the audit, and the unsettled issues must be registered in the audit report.

h) Closing meeting

This meeting is held by the audit team together with the client's management and, when applicable, with those responsible for the audited functions or processes.

The purpose of the closing meeting is to submit the conclusions of the audit, including the recommendation related to certification. Any nonconformity must be presented so that it is understood and signed by the audited entity, and the proposed deadline for settlement must be agreed by the chief auditor.

i) Preparation of the audit report

The chief auditor prepares the Audit Report also distributed to the client. It includes the findings of the respective audit.

j) Analysis of causes for nonconformities

The client must review the cause and establish the necessary specific correction and corrective actions to eliminate the found nonconformities, within a defined period.

k) Effectiveness of corrections and corrective actions

If following the certification audit there are minor nonconformities and remarks, these are communicated in the closing meeting, and the organisation must review the causes for such nonconformities, establish the corrections/corrective actions and deadlines proposed for their implementation. The organisation has a period of 7 days following the completion of the audit to complete and submit to the chief auditor the identification of causes of nonconformities, corrections/corrective actions established and the implementation deadlines, filled in on the nonconformity and remarks forms of the audit reports.

If following the certification audit there are major nonconformities, they are communicated to the client in the closing meeting. The organisation has 6 months following the date of completion of the audit to settle the corrective actions established by them and accepted by the chief auditor for the settlement of major nonconformities. Otherwise, audit will be restarted from the beginning, including stage 1. In order to evaluate the closure of major nonconformities, an additional audit is needed.

4.5 Complete or limited additional audit.

4.5.1 Additional audit is intended to inspect the closure of major/minor nonconformities and the effectiveness of performed corrective actions.

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4.5.2 The audited organisation will be notified by the chief auditor in the closing meeting if, in order to review the effectiveness of the correction and of corrective actions necessary for the closure of registered nonconformities, it will be necessary to:

- a) perform a complete additional audit (complete repeated performance of audit stage 2);
- b) an additional limited audit (a number of audit days at the client, proposed by CEA/AS in the Audit Summary and established by the person who reviews the file in order to make the certification decision);
- c) or documented evidence (which must be confirmed during the future supervisory audits) by the registration of this issue in the Nonconformity reports prepared by the chief auditor/auditors.

4.5.3 Additional audit that requires a visit to the client's premises takes place within maximum 6 months following the initial certification audit, Stage 2, by a visit to the head offices of the organisation.

4.5.4 Complete additional audit – means the resumption of audit Stage 2, therefore it is performed in the same manner, using the same forms with the specification of the audit type "**complete additional - for initial certification**".

4.5.5 Limited additional audit – includes the following steps:

- **Audit planning** (if the audit visit is necessary) - the chief auditor submits to audit a "Notification letter for additional audit", after the audited entity agrees upon the follow-up audit date;
- **Performance of the audit**, which involves:
 - the chief auditor travels to the audited entity or receives from the audited entity the documents necessary for the closure of the nonconformity;
 - the chief auditor analyses and assesses the information and objective evidence submitted by the audited entity to demonstrate the settlement of the nonconformity and the effectiveness of the performed corrective actions.
 - the chief auditor fills in the Nonconformity reports from the previous Audit report with the results of the inspection.
- **Audit report:**
 - the chief auditor prepares the additional audit report enclosed with the Reports of major nonconformities closed;
 - the chief auditor submits to the audited entity upon the closure of the audit one copy of the additional audit report and of the Reports of major nonconformities with the finding of the performance of corrective actions and of their effectiveness.

5. THE MS CERTIFICATE

5.1 Issue and release of the certificate

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5.1.1 After the end of Stage 2 of the audit for initial certification and agreement upon the corrections/corrective actions and/or inspection of their implementation, as well as following the analysis of the certification file in the Certification Committee, the organisation will be released the certificate with a single registration number.

5.1.2 The SYSTEMA certificate defines:

- the name of the client;
- the address of the registered office and locations;
- reference standard;
- the scope of certification;
- the date of release/expiry of the certificate.

5.1.3 In case of multi-site certification, SYSTEMA

- if that is a certification with multiple production units and the same line of business, both addresses shall be mentioned on the certificate up to the limit of: head offices + 2 production units
- if there are more than 2 production units, the individual certificate will be issued for each address and the adjacent certificates are numbered with 01, 02,.... 0n
- if there are addresses with different lines of business for the same client, the related certificate is issued and the certificates are numbered with 01, 02,.... 0n;

5.1.4 If the activities of the production units represent only part of the much wider scope of the organisation, the scope applicable to all production units will be declared clearly.

5.1.5 SYSTEMA notifies the client to visit and take possession of the certificate for the MS.


5.1.6 The certificate is releases only based on the signature of the client's authorised entity (representative) in the register of issued certificates.

5.1.7 During the validity of the certificate, the organisation receives the right to use the certification mark, according to the regulation for the use of the mark, enclosed to the agreement.

5.2 Maintenance of the certificate validity.

5.2.1 The initial certificate for the MS is valid for a period of three years if the management system continues to be implemented and effective, which will be demonstrated by supervisory audits. Prior to the expiry of the certificate, a recertification audit will be performed and a new certification cycle will begin.

5.2.2 Maintenance of validity of the SYSTEMA certificates is conditioned by the performance of scheduled supervisory audits and by the payment of their value, and is confirmed by the application of the annual certificate visa.

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5.3 Supervisory activities

5.3.1. General

5.3.1.1 Supervisory activities are intended to monitor on a regular basis and consider the changes occurred at the certified client and its management system.

5.3.1.2 Supervisory activities include on-site audits to assess whether the certified client management system meets the specified requirements related to the standard with regard to which the certification had been granted.

5.3.1.3 Supervisory activities may also include other activities, such as:

- requests for information submitted to the certified client on some issues of certification, and to provide documents and/or records (in electronic or paper format);
- the review of any statements of the client on its activities (e.g., promotional materials, website, etc.);
- other monitoring means of the performance of the certified client.

5.3.2 Supervisory audit

5.3.2.1 Supervisory audits are on-site audits, but are not necessarily complete system audits and must be scheduled together with other supervisory activities, so that the confidence is maintained that the certified management system continues to meet the requirements between the recertification audits.


5.3.2.2 The supervisory audit includes the evaluation of the following, as a minimum:

- a) internal audits and management analysis;
- b) a review of the actions taken for the nonconformities identified during the previous audit;
- c) dealing with complaints;
- d) the effectiveness of the MS with regard to the achievement of the certified client;
- e) evolution of the activities scheduled for continuous improvement;
- f) continuity of operational control;
- g) analysis of any amendments, and
- h) use of trademarks and/or of any other references to certification.

5.3.2.3 The schedule of supervisory audits provides the performance of two scheduled audits as follows:

- 11 months from the completion of the certification / recertification audit
- 22 months from the completion of the certification / recertification audit.

5.3.2.4 The date of completion of the certification/recertification audit is considered the last day of the audit stage 2.

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5.3.2.5 At least 30 days prior to the month when the scheduled audits will be performed, SYSTEMA submits a notification (via fax/e-mail/mail) to the certified organisation to establish the month of the audit and also to request the organisation's agreement to that end.

5.3.2.6 Supervisory audits can be shifted \pm one month. In exceptional circumstances (force majeure), a shift of maximum 3 months is granted and the certificates maintain their validity, and afterwards the suspension process is commenced.

5.3.2.7 Supervisory audits can be combined with other types of audits (initial for other management systems or extension/restriction).

5.3.3 Unscheduled supervisory audit

5.3.3.1 Performed in the circumstances specified in the agreement and is intended to check the maintenance of the MS according to the requirements in the reference standard with regard to which it had been certified and of the amendments made by the certificate holder, in the MS documentation.

5.3.3.2 Performed similarly to the scheduled supervisory audit (para. 5.3.2)

5.4 MS recertification audit

5.4.1 Intended for the recertification of the MS, requested by the certificate holder at least 3 months prior to the expiry of its validity and submission of the recertification application.

5.4.2 Performed following the receipt of the recertification application, according to POG-SCS-06 by an audit team established by the Certification Manager.

5.4.3 The recertification audit (which cannot exceed 3 years following the release of the certificate) considers the following:

- the stage of the management system in its integrity with potential internal or external amendments;
- effective interaction between the MS processes and its improvement to increase its performance;
- the manner in which the operation of the certified MS contributed to the achievement of the policy and objectives established by the organisation.

5.4.4 A certification cycle must include the complete assessment of the scope of application of the certified MS. In case that the recertification audit identifies activities in this scope that have not been covered by the audited entity by works during the 3 years of validity of the issued certificate,

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therefore they could not be assessed by the certification entity, the scope of certification will be restricted by the elimination of these activities.

5.4.5 In case of multi-sites and an integrated system, the audit plan submitted by the certification entity must also identify the areas/locations to be audited, the used audit criteria, the assigned time, etc., thus generating confidence in the effectiveness of the recertification process.

5.4.6 Recertification criteria are:


- a) demonstration of effectiveness of the management system in its entirety, considering the internal and external changes and its continuous relevance and applicability in the field of certification;
- b) demonstration of the commitment in the maintenance of the effectiveness and improvement of the management system to increase the general performance;
- c) demonstration that the activities of the certified management system contribute to the observance of the policy and achievement of objectives of the organisation;
- d) in case of identification of nonconformities and/or remarks, the chief auditor establishes the time limits for the establishment and settlement of corrections and corrective actions, as follows:
 - I. for nonconformities:
 - max. 30 days, for the establishment of corrections and corrective actions, their performance and presentation of objective evidence of their settlement for inspection at the head offices of SYSTEMA;
 - max. 60 days, for the performance of corrections and corrective actions and the submission of objective evidence of their settlement on location by a repeated audit, according to the decision of the chief auditor.

NOTE: 1. The period is established as not to exceed the date of expiry of the certificate validity. 2. If the correction is not performed within the deadline established mutually with the audited entity in the closing meeting (by consideration of the severity of the nonconformity and of the risk that the products and services of the organisation do not meet the specific requirements), the affected scope of certification can be decreased and it can event be decided to deny the extension of the certificate validity.

II. for remarks:

- for the remarks that do not affect the effectiveness of the management system, max. 30 days for the transmission of a plan of measures for the settlement thereof, which must be checked at the following scheduled audit;
- for the other remarks, according to the decision of the chief auditor, max. 60 days for the transmission of a plan of measures for their settlement and evidence for the application of such measures, to be checked at the head offices of SYSTEMA

These terms are established by the chief auditor in the minutes of the closing meeting.

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5.4.7 Completed by the preparation of an audit report.

5.5 Extension or restriction of the scope of certification

5.5.1 If the holder wants to:

- extend/restrict the scope in the certificate upon other offices and/or for other lines of business than those declared initially;
- procure a certificate for the MS applied according to another standard different from the one for which the initial certification had been obtained,

the applicant prepares a new application for certification and submits it to SYSTEMA, which commences the assessment process.

5.6 Waiver of the certificate

5.6.1 In case the holder wants to waive the certificate prior to the expiry of its validity, it will submit SYSTEMA an official application with the grounds for such waiver. The original certificate must be enclosed to the application.

5.6.2 Regardless of the date of preparation of the application, the annual tax paid for the use of the certificate will not be returned. If the tax is not paid, the waiver application must also be accompanied by the tax corresponding to the period when the certificate had been used.

5.6.3 In order to extend the validity of waived certificates, the certification procedure shall apply.


5.7 Suspension of the certificate

5.7.1 The certificate is suspended by SYSTEMA in one of the following circumstances:

1. when the MS of the certified client's registers repeated and severe failures with regard to the achievement of the certification requirements, including the requirements for the effectiveness of MS;
2. when the certified client does not allow the performance of the supervisory audits according to the required frequency;
3. when the certified client requires the voluntary suspension;
4. did not pay the fees established according to the agreement;
5. inappropriate reference to the certified scope.

5.7.2 In case of finding a circumstance according to para. 5.7.1 the following measures are taken, as ordered by the Certification Manager:

1. warning of the holder with regard to the suspension of the certificate;
2. written notification (letter/fax message) of the holder with regard to the obligation that within maximum 30 days following the receipt of the document, the causes leading to the

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suspension must be settled and a written notification is sent to SYSTEMA, in order to inspect and cancel the suspension.

5.7.3 If within 30 days following the receipt of the warning document regarding the suspension, the holder of the certificate settles the causes leading to the suspension of the certificate and provides a written notification as to their settlement, SYSTEMA orders the following measures:

1. inspection of the settlement of causes leading to the suspension of the certificate;
2. cancellation of the suspension;
3. written notification of the holder with regard to the restoration of conditions for the maintenance of the certificate validity, cancellation of the certificate suspension and payment of expenses incurred for the inspection under para. 1.

5.7.4 If within 30 days following the receipt of the warning document with regard to the suspension, the certificate holder does not apply the necessary corrective actions for the cancellation of the suspension, the General Manager of **SYSTEMA** orders the following measures, following the final discussion with the holder:

1. the effective suspension of the certificate;
2. the written notification of the holder with regard to the suspension of the certificate and the obligation to remedy the reasons leading to the suspension and to provide a written notification to SYSTEMA until the expiry of the suspension period;
3. measures to make accessible to the public the status of suspensions.

5.7.5 The effective suspension of the certificate is performed for a period of max. 6 months, and it will not be added to the validity period of the certificate.

5.7.6 Following the suspension of the certificate, the holder cannot make any reference thereto in its activity and can file an appeal.


5.7.7 Upon the expiry of the suspension period, SYSTEMA performs an inspection to make sure that the causes leading to the suspension are remedies and that the conditions are met to restore the validity of the certificate (only if SYSTEMA received a written notification).

5.7.8 If applicable, following the notification:

1. the suspension is cancelled and the certificate becomes valid;
2. the holder is notified and the cancellation of the suspension is published.

Otherwise, SYSTEMA orders the withdrawal or the restriction of the scope of certification.

5.7.9 The expenses incurred due to the inspection of the settlement of causes leading to the suspension of the certificate, potential appeals, cancellation of the suspension, etc., are covered by the holder of the certificate.

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5.8 Withdrawal or restriction of the scope of certification

5.8.1 The certificate is withdrawn or the scope of certification is restricted when the holder of the certificate:

1. does not pay the fee for the performance of the supervisory audit;
2. does not pay the expenses incurred for the unscheduled supervisory audit;
3. does not pay the fee for the repeated audit;
4. does not pay the annual fee for the use of the certificate;
5. has its certificate suspended and the holder did not remedy the causes leading to such suspension, in the period of effective suspension of the certificate, or the corrective actions have been inappropriate;
6. cannot or will not meet the new requirements in the rules of certification of SYSTEMA, amended according to parag. 8.4;
7. waives the certificate in writing, according to parag. 3.10;
8. does not pay the invoices to be paid for other services provided by SYSTEMA with the suspension;
9. becomes bankrupt or dissolved;
10. does not observe the contractual provisions, respectively the performance of the supervisory audit.

5.8.2 In all such circumstances, the General Manager of SYSTEMA orders - after the final discussion with the holder (as applicable) - the following measures:

1. withdrawal and/or restriction of the scope of the certificate;
2. the written notification of the holder with regard to the withdrawal and/or restriction of the scope of certification and its obligation to return the certificate;
3. publication of the withdrawal and restriction of the certificate.

5.8.3 The expenses generated by the inspection and review of potential appeals of the holder against the decision to withdraw the certificate are covered by the holder of the certificate, regardless of the final decision.

5.8.4 Following the withdrawal of the certificate, the holder cannot make any reference thereto in its activity and can file an appeal.

5.8.5 In renew the withdrawn certificates, the certification procedure shall apply.

5.9 Update of the certificate.

5.9.1 Upon the occurrence of a new edition of the reference standard for the MS, the certificate holder takes the following measures:

1. updates the MS documents and implements the occurred amendments;
2. schedules and performs an internal audit for the inspection of amendments;
3. submits to SYSTEMA a controlled copy of the updated documents, including internal audits and management analysis.

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NOTES:

1. SYSTEMA checks the conformity of the MS with the new edition of the reference standard with the opportunity of the first supervisory audit scheduled following the coming into force of the respective standard.
2. If the holder of the certificate intends to update the certificate sooner, it shall submit a written request to SYSTEMA for the performance of an unscheduled supervisory audit.
3. The date of the unscheduled supervisory audit is established upon mutual agreement with SYSTEMA.

5.9.2 If the performed supervisory audit does not reveal any nonconformities, the certificate can be updated. SYSTEMA issues a new certificate that will have:

1. a new number (only upon the request of the certificate holder);
2. date of the initial edition;
3. the new edition of the reference standard for the MS.

5.9.3 If the supervisory audit reveals nonconformities and the certificate cannot be updated, SYSTEMA will perform a repeated audit on a date established upon mutual agreement with the certificate holder, but not later than 60 calendar days following the date of the performed supervisory audit.

5.9.4 If the certificate cannot be updated following the repeated audit, SYSTEMA withdraws and cancels it.

6. APPEALS


During the process of certification and supervision of the MS, the applicant/holder of certificate can file an appeal on level 1 or 2 as follows:

6.1 Appeals during the process of evaluation of compliance

6.1.1 Appeals in level 1 (Certification Manager or General Manager) - can be filed by applicants against those nonconformities found during the audit, with regard to which there were different opinions and an agreement could not be reached in the audit closing meeting.

6.1.2 Appeals in level 1 are performed as follows:

- the decision to file the appeal is made by the applicant and registered in the minutes of the closing meeting of the audit;
- the appeal of the applicant is enclosed to the respective nonconformity report and submitted to SYSTEMA, for review and decision, within 5 days following the date of the audit closing meeting;

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- The Certification Manager decides with regard to the appeals in case that it is not part of the audit team;
- The General Manager of SYSTEMA decides with regard to the appeals in case that the Certification Manager is part of the audit team;
- accepted appeals are withheld by the chief auditor and included in the audit file;
- rejected appeals are returned to the applicant as an annex to the audit report.

6.1.3 If the appeal in level 1 is denied, the applicant can:

- a) take the appropriate measures to settle the nonconformities within 25 calendar days, to fill in the RNACP with these measures and submit to SYSTEMA a copy of the RNACP, for review and acceptance, and to follow-up on the continued performance of the product; or
- b) file an appeal in level 2 (parag. 6.1.4).

6.1.4 Appeals in level 2 (Appeal Commission) - can be filed by the applicant only in case of appeals denied in level 1. Appeals can be filed within 10 calendar days following the notification.

6.1.4.1 If the organisation is not satisfied with the results of the investigation and the decision received with regard to the settlement of the appeal in level 1, there can be a new appeal in level 2 (Appeal Commission) and submit it within 10 days following the communication.

6.1.4.2 Until the preparation and submission thereof to the Appeal Commission, the applicant notifies via fax/e-mail that there will be an appeal in level 2.

6.1.4.3 The General Manager distributes to the Certification Manager the appeal to be registered in the register. The Certification Manager notifies the president of the Appeal Commission and establish the date for validation and investigation.

6.1.4.4 The Appeal Commission validates and investigates the appeal and decides whether it is accepted or rejected.

6.1.4.5 The final decision for the acceptance/rejection of the appeal is notified in writing to the organisation. In case that the Appeal Commission accepts the appeal, the organisation pays the taxes for the release/ use of the certificate, confirm their payment and receives the right to use the certification documents.

6.1.4.6 Should the Appeal Commission reject the appeal, based on its own review or on the proposal of the nominated team, the applicant accepts the decision and, under such circumstances, acts according to the provisions of para. 6.1.3.1.a).

6.2 Appeals against the decisions to award/extend validity, suspend or withdraw and/or restrict the scope of certification

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6.2.1 Should SYSTEMA decide not to award, not to extend the validity, to suspend the certificate or to withdraw and/or restrict the certification, the applicant/holder of a certificate can file an appeal level 2 (Appeal Commission), within maximum 10 calendar days from the date of the SYSTEMA decision

6.2.2 The next steps are according to the provisions in the procedure "Dealing with appeals, complaints and claims", code: POG-SCS-08.

7. RIGHTS AND OBLIGATIONS OF THE CERTIFICATE HOLDER FOR MS

7.1 The rights of the certificate holder for MS


The holder of a certificate for the MS has the following rights:

- 7.1.1 To make public the fact that it is in the possession of a certificate for the MS issued by SYSTEMA, in any manner deemed convenient for it, in observance of provisions of para. 7.2.3;
- 7.1.2 To agree with SYSTEMA with regard to the documents and activities of common interest (supervisory schedule, supervisory audit, etc.);
- 7.1.3 To be published periodically in the SYSTEMA publications following the procurement of the certificate;
- 7.1.4 To benefit from confidentiality from SYSTEMA, CC-SYSTEMA and the Accreditation Council - IAS, with regard to information provided to them;
- 7.1.5 To have the possibility of hearing by SYSTEMA prior to the making of the decision to suspend or to withdraw and/or restrict the certification;
- 7.1.6 To appeal to the Accreditation Council - IAS against the decisions of SYSTEMA on the suspension, withdrawal and/or restriction of the scope of certification;
- 7.1.7 To be notified with regard to the amendments occurred in regulations or taxes;
- 7.1.8 To provide a written request for the extension/restriction/waiver of the certificate/termination of the agreement.

7.2 The obligations of the certificate holder for MS

The holder of a certificate for the MS has the following obligations:

- 7.2.1 To observe the requirements in the reference standard with regard to which it had been certified;
- 7.2.2 To be familiar with and observe the requirements of this regulation for certification/agreement;
- 7.2.3 Take all measures necessary so that its publications and documents (letters, catalogues, labels, leaflets, etc.) and the advertising (commercials, etc.) do not generate any confusion with regard to the certificate for the MS (standard of reference, validity, line of business in the certificate, etc.);
- 7.2.4 To not use the certificate in its publications to declare that the certificate covers the quality of offered products or services;

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7.2.5 To make a clear indication of all restrictions and conditions imposed by SYSTEMA, as applicable, on the date of the release of the certificate;

7.2.6 To allow SYSTEMA to perform supervisory/recertification audits, as applicable, to maintain the certificate;

7.2.7 To allow the unconditional access of SYSTEMA:

- to the sites/locations where activities are performed;
- to the MS documents;
- to the records of internal audits and taken corrective actions;
- to the complaints received by the holder with regard to the MS;
- on the manufacturing flow, to installations, processes, locations, etc.

7.2.8 To make available to SYSTEMA the staff and means necessary for the performance of supervisory and recertification audits;

7.2.9 To pay in due time the fees for supervision, recertification, etc., specified in the agreement;

7.2.10 To provide SYSTEMA with a written notification within maximum 3 months with regard to the amendments occurred in comparison with the original situation, such as:

- the legal status, registered offices, other locations;
- organisational and administrative structure (with regard to management);
- the MS documents;
- the management representative.

7.2.11. To apply a system of registration and settlement of all complaints related to the MS and notify SYSTEMA or make such complaints available, on demand;

7.2.12. To update the MS documents in order to make them consistent with the new editions of the reference standard, upon their occurrence, and submit them to SYSTEMA;

7.2.13. To apply the amendments occurred in the regulations for certification and other documents received from SYSTEMA;

7.2.14. To end any reference to or advertising of the certificate, if the certificate is expired, suspended, withdrawn and/or restricted scope of certification or if it waived the certificate.

8. PUBLICATIONS

8.1 Publicity by SYSTEMA

8.1.1 SYSTEMA prepares on a periodical basis and maintains up to date the following documents:

- a) the list of certificates issued by SYSTEMA for the MS;
- b) the list of clients certified with a certificate that is suspended, withdrawn and/or the scope of certification is restricted.

8.2.2 Lists are published to stakeholders, at the offices of SYSTEMA or on the website of the entity, www.systemaglobal.ro.

8.2 Publicity by the certificate holder

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8.2.1 The holder is entitled to announce that it is in the possession of a certificate for the MS issued by SYSTEMA and publish this in any manner deemed convenient for it (see parag. 7.1).

8.2.2 Under all circumstances, the holder must observe the obligations specified under parag. 7.2.

9. FEES

9.1 The services for the certification, supervision and recertification of the MS, performed by SYSTEMA according to this regulation are paid by the applicants/holders of certificates, according to the fees in force as at the respective date, applied by SYSTEMA, without any discrimination.

9.2 The payment method for the fees shall be according to the specifications in the agreements.

9.3 Fees can be amended by the General Manager with the approval of the General Assembly of Shareholders - GAS.

9.4 In case of modifications of the fees, the Certification Manager will notify in writing (address/fax/e-mail) all entities with which it has contractual relationships. If they are not willing to pay the new amended fees, the certificate holders can waive their certificates, according to parag. 7.1.7, within one month following the receipt of the notification.

9.5 All fees specified for the performed services are added with the legal VAT and the travel and accommodation expenses for the personnel involved in the respective services.

9.6 Additional expenses incurred by SYSTEMA due to the default or inappropriate observance by applicants or holders of certificates, of the obligations in the present regulation or in the agreements, will be covered by the respective entities.

10. ANNEXES

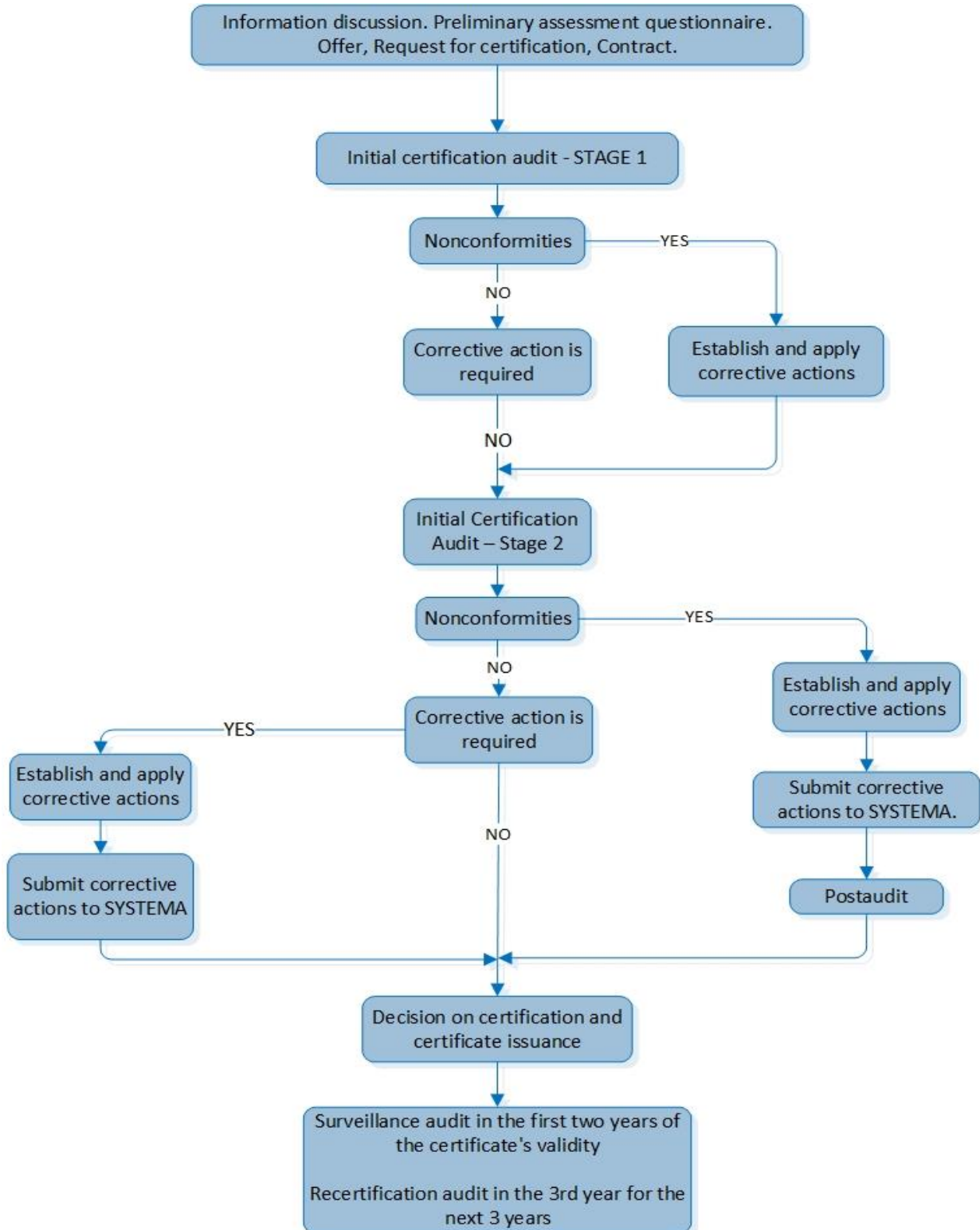
10.1 Annex 1 - Certification scheme for management systems.

10.2 Annex 2 - Certification transfer scheme for management systems

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Annex 1

Certification scheme for management systems



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Annex 2

Certification transfer scheme for management systems

