SYSTEMA CERTIFICARI SRL
Tîrgu Mureş

CERTIFICATION BODY
ACCREDITED FOR MANAGEMENT SYSTEMS CERTIFICATION

FOLDER OF INFORMATION DOCUMENTS FOR MANAGEMENT SYSTEMS CERTIFICATION

Code: M- IMS

Copy no.:
Edition: 1/05.03.2018
Revision: 4/20.06.2023

DRAFTED BY	**VERIFIED BY**
Quality Manager	**Certification Manager**
VLAS CRISTINA	**SZOVERFI BOTOND**

The distribution of this copy is controlled **YES ☐** **NO ☐**

1. OVERVIEW OF SYSTEMA

SYSTEMA - a body providing management systems certification
- operates under the provisions of the standard ISO/IEC 17021-1:2015 Conformity assessment. Requirements for bodies providing audit and certification of management systems.
Requirements and rules set in its own procedures representing the basis of the activity of certification of an organisation.

SYSTEMA conducts activities of certification for:

- quality management system; environment management system; occupational health and safety management system; food safety management system, information security management system and medical device quality management system;
- any combination thereof, in an integrated system.

Through its policy, SYSTEMA aims to provide services of management systems certification under the requirements of the standards of reference, with professionalism, ensuring our clients's trust by observing the principles of impartiality, competence, responsibility, transparence of activities and confidentiality of client-related data and information.

2. REFERENCE DOCUMENTS FOR THE CERTIFICATION ACTIVITY

2.1. SYSTEMA Documents:

SYSTEMA Management System Manual – certification body for Management Systems;

SYSTEMA Regulations and procedures of certification.

2.2. Standards, Guidelines:

- ISO/IEC 17021-1:2015 Conformity assessment. Requirements for bodies providing audit and certification of management systems. Part 1: Requirements
- ISO 9001:2015 Quality Management Systems. Requirements
- ISO 14001:2015 Environment Management Systems. Requirements with a user's guide
- ISO 45001:2018 - Occupational health and safety management systems — Requirements with guidance for use
- ISO 22000:2018- Food safety management systems- Requirements for any organization in the food chain
- ISO/ TS 22003:2013 Food safety management systems. Requirements for the bodies that perform the audit and certification of food safety management systems
- ISO 19011: 2018- Guideline for Quality and/or environment management systems audit
- ISO/IEC 27006:2015- Information technology- Security techniques- Requirements for bodies providing audit and certification of information security management systems
- *IAF MD 9:2023- Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485)*
- *ISO/IEC 27001:2022- Information security, cybersecurity and privacy protection — Information*
- *security management systems – Requirements*

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

2.3. Terms and Definitions

-corrective action – action of elimination of the cause of identified nonconformities or of other undesirable situations;

-appeal – a request by the supplier of the element contemplated in the conformity assessment submitted to the certification body in order for such body to review the decision made in relation to the respective element;

-audit - a systematic, independent and documented process of seeking audit evidence and the objective assessment thereof in order to establish to what extent the audit criteria are met;

-audit conclusions - the outcome of an audit provided by the audit team after having considered the audit goals and all the audit findings;

-conformity – fulfilment of a requirement;

-audit team - one or more auditor who conduct an audit with technical expert suport, as necessary;

-conformity assessment – demonstrate the compliance with the specific requirements concerning a product, process, system, person or body;

-technical expert - a person who provides the audit team with specific knowledge or specific professional experience;

-nonconformity - non-compliance with a requirement;

-major nonconformity - noncompliance with a requirement which may result in the blocking or failure of the quality management system, which can me resolved through corrective actions;

-minor nonconformity- a partial non-compliance with a requirements, which does not result in the blocking or failure of the quality management system and which is resolved through corrective actions;

-policy – document that sets out principles (concerning the certification activity), establishes corresponding goals and sets out means and methods of practical achivement thereof;

-procedure of management system certification - a document which details the activities required for the performance of different works and operations within the process of certification/ analysis/ supervision of the management system;

-observations – deficiencies which may cause nonconformities, if not managed properly and which must be handled carefully by the organisation. The observations may pinpoint aspects which if handled properly may lead to improvments of the management system.

3. PRINCIPLES UNDERPINNING THE CERTIFICATION ACTIVITY

SYSTEMA applies a clear and efficient system for management system certification, in compliance with the fundamental principles of a certification body such as:

SYSTEMA 's impartiality - is provided by its organizational structure, management system and policies established.

Free access – is provided by the equal and non-discriminatory treatment of all organizations applying for certification by SYSTEMA.

Compentence of SYSTEMA's personnel– is demonstrated by the critera of selection, evaluation and monitoring of the staff involved in the certification process, set in compliance with the international reference standards.

Responsibility - both of SYSTEMA and of the applicant/certified organization is established through the certification documents.

Transparency of activities conducted by SYSTEMA, as certification body - is ensured by the availability to submit up-to-date information on the certification process within the limits set in the reference standard and with the clients'consent.

Confidentiality of data pertaining to its clients, - is provided by SYSTEMA through the deonthological code signed by every person involved in the assessment process and through the contractual clauses whereby it undertakes to keep confidential the information obtained.

Responsiveness to complaints- is ensured by the organizational structure of SYSTEMA and by the procedures established for handling every type of dispute that may arise in its relations to its clients.

Risk-based approach – the competence, coherence and impartiality in the certification process are ensured by SYSTEMA by identifying the risks that may impact this process and by making all the decisions required for the mitigation thereof.

4. GENERAL RULES FOR MANAGEMENT SYSTEMS CERTIFICATION

These general rules contain besides the general information SYSTEMA's specific requirements for the organizations interested:

-to certify one or several management systems;
-maintain the certification throughout its validity period;
-to have the possibility to renew, extend or waive the certification.

The management systems certified by SYSTEMA shall be consistent with the requirements of the reference documents applicable.

The Certificate of Conformity demonstrates the compliance of a management system with the requirements of a reference document and does not refer to the quality or conformity of products with a certain normative document.

SYSTEMA publishes periodically on its website www.systemaglobal.ro the list of organisation that received the certification of their management system and the list of organisations whose certification was suspended or withdrawn. In order to obtain and maintain the certification, all certified organisations shall strictly comply wiht these general rules.

In order to meet its clients'needs, SYSTEMA set up and implemented the policy of certification for integrated management systems IMS and other systems, as necessary.

5. REQUIREMENTS FOR INITIAL CERTIFICATION

The certification process, with the corresponding stages and activities, is described below and includes:

- 5.1 Pre-certification activities;
- 5.2 Audit planning;
- 5.3 Initial certification – conducting audits:
  - -audit stage 1 -initial system management assessment;
  - -audit stage 2 – management system certification;
  - - surveillance audit (if any);
- 5.4 Certification decision;
- 5.5 Maintaining of certification;
- 5.5 Supervision activities;
- 5.6 Recertification;
- 5.7 Special audits;
- 5.8 Appeals and complaints.

5.1 PRE-CERTIFICATION ACTIVITIES

The organization interested in the certification of a management system may contact SYSTEMA:
-directly, at the headquarters of the certification body or by post:
address: Madach Imre, no. 8 Street, Tg-Mures, Mures County, Romania;
by phone – at the phone numbers:
+4 0365 882 352, phone / fax: +4 0365 882 352 and 0728 909.637
e-mail: office@systemglobal.ro
or through the website de www.systemaglobal.ro

The process of management system certification shall only be initiated after the submission by the organization of a Call for proposal where it indicates specifically:

- the field (s) and/or activity(ies) for which the certification is sought (as per CAEN code);
- number of employees and number of shifts within the organization;
- number of venues – secondary offices, subsidiaries etc;
- details concerning the documented information they can provide;
- other data deemed important by the organization (if any).

This information shall be structured and clearly presented in the Questionnaire for identification and preliminary assessment for certification.

The list of documents required for the certification of management systems, the SYSTEMA forms that are available either through direct submission to the organization or through direct downloading from the website www.systemaglobal.ro.

SYSTEMA provides any interested organizations with the Folder of informative documents for management system certification, M- IMS together with all the information and forms mentioned above.

If the applicant desire further information concerning the certification process, such information shall be provided by the personnel of SYSTEMA, in order to solve any potential misunderstanding before starting the certification process.

The activity of initiation of the certification shall be conducted according to the SYSTEMA certification procedure 'Information and preliminary assessment', code POG-SCS-01

Information regarding the activities organization specific data (personnel, venues/offices, process characteristics, number of shifts, process complexity) and those relating to the identification of management system(s) for which certification is sought shall represent the fundamentals for the execution of the Certification Agreement.

By signing the Certification Agreement, SYSTEMA informs its clients over:
- the activities contemplated in the agreement and the stages of the certification process;
- description of the certification activity, maintaining the certification, expanding or reducing the scope of certification, suspending, total or partial withdrawal of certification;
- the obligation to comply with the stages of certification procedure, indicating that the execution of the Agreement does not lead automatically to obtaining the Conformity Certificate.
- the activities to be conducted throughout the validity of the Certificate and the frequency of surveillance audits;
- performance of audit in a language other than Romanian;
- fees for every stage – set according to the own rules of procedure and to the requirements of the standards applicable to the management system (SYSTEMA reserves the right to amend the certification fees if after the first stage of the certification audit significant differences are found between the data communicated by the Organization and the findings of the audit team).

The contracting activity shall be conducted under the SYSTEMA procedures 'Contract Analysis' and 'Preliminary actions for management system assessment'.

5.2 PLANNING AUDITS

Based on the information resulting from the activity presented at point 6.1. and after clarifying all the aspects with the applicant organization, the stages of the certification procedure to be carried out shall be planned through the Audit programme established when the certification procedure is initiated.

The audit planning shall take into account the size and limits of audit, number of management systems, number of locations and processes to be audited, complexity of processes and number of shifts in order to meet the whole scope of audit.

SYSTEMA shall establish the members and the competences of the audit team depending on the above data. If the auditors do not have enough competences, technical experts may be co-opted. The audit time and fees shall not be influenced by their presence. The audit team shall be led by an audit team leader, referred to as the Lead Auditor within SYSTEMA.

SYSTEMA shall also provide translators, as necessary, in order not to impact on the audit time (extensions, unjustified interruptions etc).

Before every planned or unplanned audit, SYSTEMA establishes an Audit Plan. The Lead Auditor shall taken into consideration the documented information received from the organization, concerning the number of locations, conducted activities, equipment/devices/technologies used, personnel working in shifts, in order to be able to adequately plan the working time of the team.

After receiving the Audit plan the organization may request modification which may prove necessary throughout the audit depending on the existing situations. Any modification to the audit plan shall be agreed by the lead auditor with the organization during the audit opening meeting.

Furthermore, SYSTEMA shall communicate to the organization the names of the audit team members. The organization shall be entitled to challenge, in justified manner, one or more members of the audit team (as necesary).

In case the appeal proves to be well-grounded SYSTEMA shall change the structure of the audit team.

Throughout the performance of the audit, the audit team shall communicate on a regular basis with the organization when it identifies any issues.

5.3 INITIAL CERTIFICATION - performance of audits

The certification procedure shall be initiated after signing the Certification Agreement. It shall include the following stages:

5.3.1 Audit stage 1 - initial management system assessment;
5.3.2 Audit stage 2 – management system certification;
5.3.3 Follow-up audit (if any).

5.3.1 AUDIT STAGE 1 - on-site assessment of management system.

In the audit stage 1, the SYSTEMA audit team shall assess:

- documented information – existence and availability thereof;
- review the client's status compared to the requirements of the standard;
- functioning of the management system – through discussions with the client's personnel;
- collecting the necessary information concerning the scope of the management system, processes and location (s) of the organization and the relevant legal and regulatory matters and fulfilment

thereof (e.g. quality, environment, occupational health and safety, food safety, information security and medical device quality legal matters concerning the client's activities, related risks, etc.);
- the manner of providing the process control;
- how the internal audits program and the management review are planned and conducted;
- review the client's head office, secondary offices (if any) and the specific conditions, according to the sample established through the Audit plan;
- client's allocation of resources for the peformance of the process (es);
- verification of the level of integration of the management system documentation, in case the certification was requested based on two reference standards (if any);
- any other information necessary for the preparation of the audit stage 2.

The audit stage 1 shall end with the findings, which shall be sent to the client together with the Report of audit stage 1. To this end, the organization shall establish a program of measures containing the corrective actions and shall present it to SYSTEMA.

The time span between the audit stage 1 and stage 2 shall be mutually agreed with the client depending on the findings of the audit stage 1 but no more than 6 months. The measures established by the client shall be reviewed by SYSTEMA and depending on such measures a it may be decided either to repeat all or part of stage 1, as necessary. In this case, the Audit program may be reviewed, including all the contractual requirements for stage 2.

5.3.2 AUDIT STAGE 2 - initial certification of management system

In the audit stage 2, the audit team shall assess:
- the level of management system implementation;
- the efficacy of the implemented management system.

During the certification audit, the SYSTEMA audit team shall:
- confirm that the declared management system and processes comply with the reference standards and with the applicable legislation;
- review the performances of the organization against the key objectives and established targets;
- review the control methods applied on the processes in order to maintain the declared management system;
- assess the management system efficacy (internal audit and management review);
- assess the performance of monitoring and measurement, reporting and review of objectives and targets;
- assess whether the management system provided the feedback required for the continuous improvement and performance in fulfilling the applicable legal, regulatory and contractual requirements.

The audit stage 2 may result in nonconformities (major and/or minor) and/or remarks or opportunities for improvement. The nonconformities referred to in the Reports of Corrective Actions (RACs) and are submitted to the client together with the Report of audit stage 2. For nonconformities, the organization shall establish corrective actions and for the observations a Program of measures with corrective actions which shall be submitted to SYSTEMA.

Major nonconformity – identifies the non-fulfilment of the requirements stipulated for an activity, situation raising significant doubts concerning the efficacy and efficiency of the management system put in place and operated within the organization.

Minor nonconformity or Discrepancy – partial fulfilment of the requirements of the reference standard, but which does not affect the efficacy or efficiency of the management system put in place and operated within the organization.

Observations – deficiencies which may generate nonconformities of not properly managed and which shall be handled carefully by the organization. The observations may pinpoint aspects which if handled properly may lead to improvments of the management system.

Opportunity for Improving- suggests that the system element could be improved (efficiency or control).

The certification procedure shall only be completed when all nonconformities identified during the audit activities were rectified and the corrective actions were assessed and accepted by the audit team through follow-up audit (s) (if more than two follow-up audits are required the procedure shall be suspended until the application of corrective actions is completed).

The organizations with declared multi-site locations/subsidiaries:

- In case of organizations with multi-site locations/subsidiaries, SYSTEMA shall use sampling methods, as necessary. The sample size shall be communicated by SYSTEMA to the organization in the Audit plan;
- If the sampling method is employed for the initial certification, throughout the 3-year certification cycle, SYSTEMA shall assess all the sites of the orhanization.

5.3.3 FOLLOW-UP AUDIT (if any)

The follow-up audit – is an additional audit, which is planned and conducted when following the audit of stage 2, the corrective actions related to nonconformities cannot be considered to be closed based on the objective evidence documented and sent to the audit team and require a move to the place for their closure.

In case that the follow-up audit cannot solve the above-mentioned nonconformities, a new follow-up audit shall be established. Any follow-up audit shall be conducted based on an addendum to the Certification Agreement.

In order for the client to be granted the certification, the follow-up audit shall end without nonconformities.

5.4 DECISION OF MANAGEMENT SYSTEM CERTIFICATION– Conformity Certification and Certification Mark by SYSTEMA

The Conformity Certificate is the document whereby SYSTEMA certifies that the management system put in place by the organization to which it was granted complies with all the requirements of the reference standard.

The Conformity Certificate shall only be granted after the examination of the organization's Certification File containing all the documents/Reports resulting from the undertaken certification procedure, together with all the evidence of fulfilment of the requirements in the reference standard and the application of corrective measures for the nonconformitites identified during the conducted audits (if any).

The Conformity Certificate shall have a 3-year validity, as of the date of the Decision, during which two annual surveillance visits shall be established.

The organization which completed the certification procedure shall also be granted the right to use on its promotion documents or in the header of its documents only the symbol of SYSTEMA certification mark which identifies the certified management system; together with the certificate the client will receive the set of logos and trademarks that are appropriate, respectively the regulation of use of the mark.

5.5 MENTIAINING, EXPANSION, RESTRICTION, SUSPENSION, TOTAL OR PARTIAL WITHDRAWAL OF CERTIFICATION

Throughout the period of validity and supervision of the certification of the management system put in place by the certified organization, the following activities may take place:

5.5.1 Maintaining of certification

The decision to maintain the certification shall be made after undertaking the surveillance audits, namely:

- following the annual surveillance audit - in case there are no major and/or minor nonconformities identified or if such nonconformities are rectified (only the observations to be included in the 'Conclusions' chapter of the Report of surveillance audit are accepted).
- following an additional follow-up audit, undetaken after the suspension of the certification, in case the nonconformities which had led to the suspension of the certification were rectified.

5.5.2 Expanding the scope of certification

- an additional area not included in the initial certification is added;
- an additional area which was subsequently developed;
- for a new site;
- application of certification for another/other management system(s).

The organization shall submit to assessment the specific documentation for the application. Any of these assessments shall be finalized with an Audit Report presenting the conclusions of the assessment. The documentation of the organization together with the Certification File shall be assessed based on the SYSTEMA procedures in order to decide to grant or reject the expasion of the scope of certification.

5.5.3 Restraining the scope of certification

- following the annual surveillance audit - it is established that the system is not maintained for all the processes, according to the initial certification.
- the holder of the Certificate submits a request to restrain the certified scope/activities; or
- in case of establishing that the restraining requested as a result of the modification of certain elements of the initially certified system does not affect the proper functioning of the management system for the other certified areas.

Irrespective of the situation, SYSTEMA shall issue a new Certificate updated according to the real status of the organization.

5.5.4 Total or partial suspension of certification;

- identification during the surveillance audit of major nonconformities, for which the organization cannot apply corrective measures;
- complaints received directly by SYSTEMA regarding the certified organization;
- identification during the surveillance audit of certain infringements of the certification requirements concerning:
- the abusive use of granted certification, for other areas which had not been assessed;
- the failure and/or refuse to present to SYSTEMA any notifications, complaints and corresponding records;
- failure to present the records concerning the undertaken corrective actions,
- following he notification out of its own motion by SYSTEMA regarding the abusive use of the Certification Mark in remote situations.

The suspension shall be valid throughout the period between the two decisions made by SYSTEMA concerning the suspension/withdrawal of suspension of the certification.

5.5.5 Total or partial withdrawal of certification

The certification shall be withdrawn when:

- the nonconformities leading to the decision of suspension were not removed within maximum 60 days from the communication of the official decision of suspension of the certification;
- a second suspension of the certification within 12 months;
- the requirements considered when the certification was granted were not maintained and/or the modifications thereto were not communicated to SYSTEMA, within max. 60 days;
- wrong data are purposefully presented during the surveillance actions;
- the provisions of the certification agreement are abuseively and repeatedly breached;
- the failure to pay the fees at the level and due date agreed in the agreement and/or the addenda for the activities undertaken by the certification body;
- the certified holder voluntarily renounces the certification granted by SYSTEMA.

5.6 SURVEILLANCE ACTIVITIES

The organizations that were granted the certification of the management system by SYSTEMA shall be submitted to a planned surveillance activity (one visit per year, the first 12 months as of the Decision date) throughout the validity of the Certificate -3 years.

The surveillance activities shall be conducted in line with the Surveillance Program developed according to SYSTEMA's 'Surveillance of certified organizations' certification procedure.

During this period, SYSTEMA may conduct additional audits in the following cases:

- following some important modifications to the organizational structure or to the certified management system;
- upon the Certificate holder's request in case of restraining/expanding of the certified scope;
- following complaints concerning the activities conducted in the certified area.

5.7 RECERTIFICATION

The recertification shall apply to organizations which, upon the expirty of the Conformity Certificate, request the renewal therof. The recertification shall take place:

- at the expiry of the validity of the Conformity Certificate - following the client's request to continue the certification activity (SYSTEMA shall notify the organization of the expiry of its certification 3 months before the expiry date);
- in case of modification of the referential – in this case the whole certification process shall be undertaken according to the new referential.

When the recertification activities are successfully completed before the expiry date of the certification in force, the expiration date of the new certification may be based on the expiry date of the certification in force.The date of issue of the new certificate must be the date on which the recertification decision is taken or a later date.

If the certification body did not complete the recertification audit or was unable to verify the implementation of corrections and corrective actions for major non-conformities before the certification expiry date, then the recertification should not be recommended and the validity of the certificate should not be extended. The client must be informed and the consequences must be explained to him.

After the certification expires, the certification body can restore the certification within 6 months, provided that the recertification activities are completed completely, otherwise at least one stage 2 must be performed. The effective date on the certificate must be the date on which the recertification decision is taken or a later date and the expiry date must be based on the previous certification cycle.

All conditions regarding the recertification process will be stipulated in the Additional Act concluded at the initial Certification Contract or a new recertification contract.

5.8 SPECIAL AUDITS- Short-notice audits

Short-notice audits are unannounced audits determined by:

- complaints received by SYSTEMA in relation to the respective organization;

- significant modifications of the management system – technological modification in the process, reference standard modification, modification in the management of the organization etc;
- restoration of suspended organizations.

A short-notice audit shall be conducted as follows:

- it may focus the said complaint and modification only – and it may be a limited audit supplemented by documents and evidence;
- it may be a complete additional audit – when the complaints or modifications may impact the whole management system;
  or
- in case of suspended organizations – it may be conducted as an initial audit (stage 1 and stage 2).

The IAS can perform unannounced audits when it has justified concerns regarding the compliance with standard requirements and/or regulations, as well as to ensure compliance from the perspective of accreditation standards, and the BENEFICIARY will allow its access to the address stated in the certificate, as well as to the relevant system documentation.

5.9 APPEALS AND COMPLAINTS

Applicants may complain against/appeal the activities conducted by the personnel of SYSTEMA, as well as their decisions at the email address published on the website Systema- office@systema.ro. SYSTEMA shall handle the appeals and complaints according to its own procedures.

6. TERMINATION OF CERTIFICATION PROCESS

When an organization undergoing the certification process no longer wants to continue it, the certification process may be terminated amicably.

SYSTEMA shall notify the organization on the termination of the certification process when:

- the organization renounces the certification, when it is unable to implement the corrective actions required for the identified nonconformities;
- the organization considers that the effort to implement the corrective actions it too big;
- nonfulfilment of contractual terms or of the requirments of the certification procedure leading to the termination of the agreement (e.g. failure to implement corrective actions, need of more than two folllow-up audits and the refusal of such audits by the organization etc.).

When the organization renounces the certification, due to the lack of financial means for the implementation of corrective actions or for solving the nonconformitites identified by SYSTEMA based on conducted review it may termorarily suspend the certification process. The supension may not last more than 12 months (taking into consideration the downtime specifically in the field of constructions), the certification process being resumed with an assessment corresponding to an initial certification process.

7. RIGHTS AND OBLIGATIONS OF CERTIFIED ORGANIZATIONS

1. Rights of certified organizations

The organizations certified by SYSTEMA shall have the following rights:

- to use the SYSTEMA Certification Mark on advertising publicity documents boards placed on its sites, under the provisions of Systema's "Rules for the use of Certificate and Certification mark for management systems".
- to be published by SYSTEMA on the certified organizations list;
- to have SYSTEMA ensure the confidentiality of its provided information;
- to have access to all the updated information necessary to the certification process;
- to be informed of any modifications to the requoirements/certification process conducted by SYSTEMA;
- to challenge the members of SYSTEMA's audit teams for well-grounded reasons;
- to formulate documented observations to the audit reports and annexes thereto;
- to formulated a documented opinion on the nonconformities identified by
- SYSTEMA;
- to agree with SYSTEMA on documents of mutual interest (e.g. audit plan);
- to be informed of the decisions made by SYSTEMA before they are enforced;
- to have the possibility to be heared before a decision of suspension or withdrawal and cancelation of the Certificate is made;
- to challenge and/or appleal the decisions relating to it and which were made by SYSTEMA.

2. Obligations of certified organization

In order for an organization to get the certification of its management system it shall:

- have a management system documented and put in place according to the provisions of the reference standards based on which it applies for certification;
- request the certification by submitting the Application of the initiation of the certification process;
- pay in advance the fees of every stage of certification;
- state in its Application of the initiation of the certification process that it has the necessary resources, organization, endowment and competence to undergo the certification process;
- state in the name of the management, its agreement with the specific requirements for the certification and its availability for the certification;
- provide the certification body with the relevant documentation for the management system put in place;
- implement corrective actions for the nonconformities identified by the audit teams;
- after obtaining the Certificate, the applicant shall only use the SYSTEMA Certification mark and shall refer to it under the provisions of the "Rules of use of the Certificate and Certification Mark for management systems";
- keep record of all complaints received and of the corrective actions implemented;
- allow the access of audit teams to all areas requsted for the assessment;
- refer to the certification granted by SYSTEMA, for the scope set out in the granted certificate only;
- allow the representatives of the Certification body with which SYSTEMA is accredited to participate, as observers, in the audit teams of the certification body;

- to notify SYSTEMA within maximum 30 days of any modifications occurred during the certification period which may affect the functioning of the existing management system. Such modifications may refer to: the scope, legal status, organizational and administrative structure, changes within the management team, production sites and premises of the organization, production equipment used, other changes that may have a major influence in the functioning of the certified management system;
- provide the certification body with all the data necessary for the activity of certification, surveillance or settlement of disputes, complaints, appeals or modifications of the initial conditions;
- facilitate the unfolding of the audit actions and to ensure the working, security, training conditions as required by the law as well as the necessary equipment, if any;
- ensure the access of the audit team to the aras and sites to be evaluated;
- establish corrective measures and corresponding time limits for the application thereof and to present them to the lead auditor;
- guarantee that it shall not claim any of the amounts paid, for the stages completed, in case of suspension or termination of the certification agreement;
- cease the use of the certificate and of any other documents referring to certification in case it is suspensed or if the certification was cancelled;
- notify SYSTEMA in writing in case it renounces the certification;
- return, upon SYSTEMA's demand, the certification documents when its right to use them ceased;
- not to affect SYSTEMA's image through its activities and statements made, including for advertising purposes.

8. USE OF THE SYSTEMA CONFORMITY CERTIFICATE AND CERTIFICATION MARK

The organizations certified by SYSTEMA may only use the Conformity Certificate for the certified activities and the Certification Mark only on letters, working documents and/or advertising documents, under the terms below and in the "Rules for the use of the Certificate and of the Certification Mark for management systems":

- The certified organization owning a trademark for a product or multiple certifications, may use the SYSTEMA certification mark together with its own marks;
- In the above case, the organization shall take the necessary measures to ensure that the reference to the certification is not extended to the uncertified activities and/or products manufactured by the organization;
- The SYSTEMA certification mark shall be accompanied by the number of the Conformity Certificate and the reference standard for the management system certified by SYSTEMA;
- The SYSTEMA certification mark shall only be used by the organizations in the form transmitted by SYSTEMA without any modifications to the text or graphical elements;
- The SYSTEMA certification mark may be enlarged or diminished provided the proportions are observed.
- The SYSTEAM Conformity Certificate/Certification Mark shall only be used by the certified body on documents concerning the certified scope(s).
- In case of certification withdrawal, the organization shall return the Conformity Certificate to SYSTEMA and shall cease immediately and kind of use of the Certification Mark;

- In case of certification withdrawal for certain areas of activity only, the organization shall cease immediately any use of the SYSTEMA Conformity Certificate/Certification Mark for the respective areas of activity.
- The SYSTEMA Certification Mark, on electronic format, together with a copy of the "Rules for the use of the Certificate and of the Certification Mark for management systems" shall be handed over to the certified organization together with the Conformity Certificate.

9. FEES FOR MANAGEMENT SYSTEM CERTIFICATION

The fees applied by SYSTEMA for management system certification are presented in the Certification Offer, made available to any applicant organization (under the SYSTEMA certification procedure: "T-SCS-01 - FEES FOR SYSTEM CERTIFICATION").

The methodology of establishing the fees shall take into consideration the audit time and shall consider the fulfilment of the provisions of international standards (IAF MD 5 IAF Mandatoy Document for Duration of QMS, EMS and OH&SMS Audits; IAF MD 11 IAF Mandatory Document for the Application of ISO/IEC 17021-1 for Audits of Integrated Management Systems, IAF MD 22- IAF Mandatory Document for the Application of ISO/IEC 17021-1 for the Certification of Occupational Health, ISO/TS 22003 Food safety management systems. Requirements for the bodies that perform the audit and certification of food safety management systems, ISO/IEC 27006:2015- Information technology- Security techniques- Requirements for bodies providing audit and certification of information security management systems and IAF MD 9:2017- Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems).

The fees shall be paid in advance for every stage of certification. Any additional stages, which are not included in the contractual value shall be paid for based on addenda to the initial Certification Agreement.

10. PUBLICATIONS

SYSTEMA publishes:

- information on the undertaken activity/its own certification system;
- the list of certified organizations and relevant data about them, certified scopes/activities; information on the Conformity Certificates withdrawn and /or cancelled;
- articles on the certification activity, considered to be important for the applicants/beneficiaries of the certification.

This information shall be published on the webpage: www.systemaglobal.ro or in various publications.

11. MODIFICATIONS OF THE CERTIFICATION SYSTEM

SYSTEMA may change its own rules of undertaking the desired certification procedure:

- modifications of reference standards;
- modification of the legislation and/or technical regulations; of the requirements set by the accreditation body.

In case SYSTEMA intends to make modifications, which may be completed dyring the unfolding of the certification process to which the organization is submitted, SYSTEMA shall inform the organization and they shall establish together the exact kind and date of the modifications.

Should such modifications occur during the process of certification, the organization shall only be informed of those modification that are incumbent upon it.

In case of modifications occurred after the granting of the certificate, the certificate holders shall be informed of the number of the edition in force and the deadline for the performance of modifications.

SYSTEMA shall provide the client with all the information required for the proper performance of the certification process in the 'Folder of informative documents' and on the webpage.

In all cases when modifications are made, SYSTEMA shall keep records of the information and the schedule for the implementation of such modifications.

SYSTEMA establishes together with the client/certification holder a program, in stages, which shall ensure the implementation of the modifications (as necessary). The implementation of actions resulting from the modifications shall be assessed in the planned audits.

For already certified clients, the implementation of the modifications to the procedures shall be verified at the mutually agreed deadline, through additional audits.

When establishing the deadlines for the adaptations required by the procedures, SYSTEMA envisages to allow the organizations to set a deadline deemed as reasonable and likely to be observed by them.