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REGULATIONS FOR THE AWARDING AND MAINTENANCE OF THE CERTIFICATION IN ACCORDANCE WITH THE EXCIPACT™ CERTIFICATION SCHEME

1. DESCRIPTION OF THE INSTITUTE

CERTIQUALITY S.r.l. is a Certification Institute that operates according to the general criteria defined by the standards of the UNI CEI EN ISO/IEC 17000 series and, as an independent Body, provides requesting Organisations with services aimed at assessing and certifying the conformity of their Management Systems with the provisions of the reference standards.
Certiquality S.r.l. does not offer any consultation service, either directly or through agency relationships with sub-contractors, to support Organisations setting up a Management System or prepare the relative documentation.
The legal nature of the Institute is described in its Articles of association.
The Institute's activities are financed by the application of Certification fees.

2. PURPOSE AND SCOPE

These Regulations define the relationships between CERTIQUALITY SRL - hereinafter referred to as the Institute - and the Organisations aiming at achieving and having registered the Certification of their Management System in accordance with the document EXCiPACT™ Certification Scheme – in the text referred to as EXCiPACT™.
The enforcement of these Regulations is supervised by the Committee for Safeguarding Impartiality, appointed by the Institute's Board of Directors, which include members from all the parties involved in the Certification.
The CERTIQUALITY Certificate is the document whereby the Institute certifies that the requesting Organisation employs a Management System compliant with EXCiPACT™.

3. DEFINITIONS

The definitions provided in UNI EN ISO and UNI CEI EN standards and the definitions for the following terms used in the text, shall apply.

As far as the specific terms concerning Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP) of excipients are concerned, the definitions mentioned in the document Certification Standards for Pharmaceutical Excipient Suppliers: Good Manufacturing Practices – Good Distribution Practices – Requirements for Auditor Competency and 3rd Party Audit Organizations Providing Certification of the Management System shall apply.

Organisation
Term used to indicate the Subject filling an application for Certification.

Operative Unit
Corporate facility where the activities, for which the Management System is being certified, are carried out.

Production site
The whole area where the activities controlled by an Organisation are carried out, along with neighbouring and connected worksites or warehouses for raw materials, by-products, intermediate goods, finished goods and waste materials, and any facility and plant, fixed or otherwise, used to carry out the abovementioned activities.

Team in charge of the evaluation of the Management System
Personnel appointed by the Institute to evaluate the Organisation's Management System.

Assessment, evaluation and audit are used as synonyms

GVI:
Audit team appointed to carry out the audit

EXCiPACT absl: Non-profit, independent organisation that has developed and owns the property of the Certification Scheme document.

Classification of findings (original English definition based on the EXCiPACT™ "Conformity Assessment Requirements for Certification Bodies" document:
Life Threatening: A nonconformity or other situation which has produced a product that is harmful to the human or veterinary patient, or one which poses a very high risk of producing product that is harmful to the human or veterinary patient.
Critical: The excipient poses an significant risk to patient safety. Remediation before further excipient is produced would be indicated and/or a recall should be considered.
Major: Evidence indicates that the Quality Management System is not effectively developed or implemented. For instance, the system is poorly designed or not followed; or multiple or repetitive minor nonconformities in the same aspect of the quality management system, and or evidence that the product consistently fails to meet the requirements for use as an excipient.
Minor: A departure from the standard that is neither a critical nor major. Action to rectify the finding is indicated.

4. GENERAL CONDITIONS

4.1 Certification is available to all Organisations that produce or distribute excipients intended to the pharmaceutical sector.

4.2 For the Certification procedure to be initiated by the Institute, the requesting Organisation must:
- have a Quality Management System certificated under accreditation in accordance with the ISO 9001 Standard for the production and/or distribution of excipients. As an alternative, the Organisation shall demonstrate to be regularly audited according to the requirements of the NSF/IPEC/ANSI-363-2014 US National Standard document;

- should the ISO 9001 certificate not be certificated by Certiquality, the Organisation undertakes, upon signature of these Regulations, to send a copy of the valid certificate and to provide annual evidence of the maintenance of the existing certificate;

- have a Good Manufacturing Practices and/or Good Distribution Practices system, compliant with the EXCiPACT™ Certification Scheme document;
- describe the abovementioned System in appropriate documents (Management Manual, Procedures, etc.);

- accept the rules set forth by these Regulations and the conditions communicated by the Institute.

4.3 Acceptance of the application, issue of the Certification and maintenance of the Registration thereof are subject to the payment of the prescribed fees; failure to fulfil such obligations by the established deadline shall lead to the suspension or revocation of the Certificate, pursuant to the provisions set forth in Sections 8 and 9.

4.4 The Organisation undertakes to conform and keep its products and/or services to all applicable legal and compulsory requirements (such as directives, laws and regulations). It is the Institute's responsibility to verify on the basis of a sampling that is congruent with the audit time, that the Organisation is aware of, and capable of managing for all the compulsory aspects connected to the management system involved in the certification.

4.5 Certification requirements may change as a result of:
- amendments to the reference standards.
- amendments to the Certification issuance conditions.
In the former case, notification is provided by the standard-setting and/or accrediting Bodies; in the latter case, the Institute shall promptly notify the Organisations entered in the Register of certified Organisations and/or waiting to be certified.
The Institute shall define the date on which the new changes come into force, along with a reasonable interval of time to allow Organisations to comply with the new provisions.
Organisations that do not wish to upgrade their Management System to ensure compliance with the changes to reference standards or Certification issuance conditions, may cancel their Certification by giving notice thereof to the Institute in accordance with the procedures set forth in Section 10 of these Regulations.
In the event of amendments to reference standards, the Institute reserves the right to verify the compliance of the Organisation's

Management System with the new provisions of the standards.
All audit expenses are at the certified Organisation's expense.

4.6 The Institute keeps a list of certified Organisations that is published on the Website: www.certiquality.it. The Institute makes data public even in the case of suspension, revocation and waiver of certification.
The references of the certified Organisation, including the contact e-mail, are published in the section of certificated companies on the EXCiPACT™ website.

5. MANAGEMENT SYSTEM CERTIFICATION PROCEDURE

Before starting the actual certification procedure, an Organisation may request a preliminary inspection in order to evaluate its readiness for assessment, in relation to the requirements of the reference standard. This visit is supported by adequate documentation but is not considered for Certification audit purposes.

5.1 Request of Certification Offer / Certification Application and Acceptance of Certification Offer
Organisations that intend to obtain certification must request a Certification Offer of the Institute by filling an application and enclosing the required documentation.
The Institute proceeds with a formal examination of the documentation presented in order to verify the completeness and accuracy of the general information and to prepare and send the certification offer.

The signature and acceptance of the offer finalizes the contract between the parties.
The Organisation undertakes to respect and accept the provisions in these Regulations, and subsequent amendments, that is part of the offer and it declares to know its content.
Certiquality's regulations are available on website: www.certiquality.it.

All the conditions governing the issue of Certification to national Organisations shall apply also to foreign Organisations, unless other specific provisions are defined by the Institute in international agreements.
In the case of bids, in accordance with the specific regulations set forth in the terms and conditions of the call for bids, procedures or documentation different from those referred to in these Regulations may be followed.

5.2 Certification Issue

5.2.1
Following the acceptance of the offer, the Institute agrees with the Organisation the period for conducting the audit. Acceptance of the contract does not constitute either a direct or an indirect obligation to certify.
The Institute appoints the Audit Group and duly notifies the Organisation. The Organisation may, however, request in writing the replacement of one or more of the suggested members whenever there exist plausible reasons that are not directly related to the professionalism of the inspectors. Said reasons must be provided.
One member of the Group serves as Team Leader.
The Audit Group may also be constituted by one member only for small and medium-sized Organisations.

The initial certification audit is conducted in two stages:
- stage 1 is aimed at assessing the documentation and the Organisation's degree of preparation for the execution of stage 2.
At the end of stage 1, the GVI sets the dates for stage 2.
No more than a year may pass between stage 1 and stage 2; if it happens, stage 1 must be repeated.
- stage 2, aimed at assessing that the implementation and effectiveness of the Good Manufacturing Practices and/or Good Distribution Practices System complies with the EXCiPACT™ Certification Scheme document of the Organisation.

An appropriate amount of time must pass between the stage 1 and stage 2 audits to ensure that any failures reported during stage 1 have been corrected.

5.2.2 The audit can be carried out only if the Organisation has a fully operative Management System compliant with the requirements of the EXCiPACT™ Certification Scheme document and in particular the Organisation shall have performed one full cycle of internal audits and that the Management has performed at least one review.
The Organisation shall ensure that:
a) All documents relating to the Management System to be certified, including all the records relating to the enforcement of the Management System are made available to Auditors.
b) Auditors receive assistance during the audit
c) Access is granted to the Information System, in line with the audit requirements.

5.2.3 The purpose of the audit inspection is to verify the compliance with the requirements of the reference standard and all the processes and activities forming the object of certification.
The Audit Group starts the evaluation activities of both stages by conducting an opening meeting with the Organisation's top management aimed at illustrating the audit plan.

5.2.4 Upon completion of the audit, the Audit Team meets to discuss the findings and process collected data.
During the audit closing meeting and in the presence of the Organisation's top Management, the Audit Team reports on the audit results and the detected findings compared with EXCiPACT™ requirements.
The Audit Team issues a summary report that includes findings.
The final report is provided by the Institute to the Organisation within 4 weeks from the audit closure.

5.2.5 Should non-conformities be detected, the Organisation shall submit to the Institute an implementation schedule detailing the corrective actions that will be taken for the purposes of the Certification issue.
Presence of non-conformities classified as"Life-Threatening", "Critical" or "Major" prevents the certification issue.
In all cases of non-conformities, "Minor" NC included, the Organisation shall demonstrate that corrective actions have all been implemented by sending documentation confirming their management to the Institute, which reserves to conduct a supplementary audit to complete its evaluations.
The effectiveness of the plan of corrective actions implemented by the Organisation shall be assessed by the Institute during the subsequent audit.

5.2.6 The documentation relating to the evaluation steps of the Management System shall be submitted to the resolution of the Technical Commission of the Institute for the purpose of Certification issue.
Surveillance inspections take place annually, at 12-month intervals, unless specifically prescribed otherwise by the reference standard.
On the basis of the audit outcome, the Technical Commission may request an additional audit to annual audit aimed at the prompt verification of the critical points recorded.

5.2.7 Multi-site Organisations are periodically obliged to provide the Institute, and the Team Leader prior to each audit inspection, a list of the currently active operative units specifying the type of excipient produced or distributed by each of them.
Issue of Certification by the Institute implies the Organisation's commitment to adopt the EXCiPACT™ requirements in all operative units covered by the certification.
For Certification purposes, the audit is extended to all involved operative units of the Organisation.

5.2.8 The Institute informs EXCiPACT asbl about:
a) the decision to grant the certification to the Organisation;
b) administration information that will be used by EXCiPACT asbl to issue the certification fee to the Organisation.

After having paid all the due amount by the Organisation, the Institute issues the certificate and sends it to Organisation, then registers the Organisation in the Registry of CERTIQUALITY certified Organisations, and transmits all the information regarding the certificate status (certification, suspension, revocation or waiver) to EXCiPACT asbl and to all parties requesting the same information. Moreover CERTIQUALITY publishes the status of the Certification on its website.

5.3 Certified Organisation Surveillance
The resolutions of the Technical Commissions are promptly communicated to the Organisation by the Institute.
The surveillance audits to the Certified Organisation are carried out at an annual frequency within a time interval of +/- 6 weeks, calculated having as a reference the last day of the certification audit or the certification renewal audit.
The Institute monitors the certified Management System to verify its ongoing compliance with EXCiPACT™ requirements.
The Team leader contacts the Organisation in order to agree upon an audit date and plan.
Surveillance audits are carried out in a single stage.

During surveillance audits, the Institute auditors must be allowed to verify that the conditions that have led to the issue of the EXCiPACT™ Certification have not changed.
At the end of the surveillance audit the Audit team issues a draft of the audit final report.

The final report is transmitted by the Institute to the Organisation within 4 weeks from the audit closure.
Should non-conformities be detected, the Organisation shall submit to the Institute an implementation schedule detailing the corrective actions necessary to meet the requirements for maintaining the Certification.
Presence of non-conformities classified as"Life-Threatening", "Critical" or "Major" prevents the maintenance of the certification.
In all cases of non-conformities, "Minor" NC included, the Organisation shall demonstrate that corrective actions have all been implemented by sending documentation confirming their management to the Institute, which reserves to conduct a supplementary audit to complete its evaluations.
The effectiveness of the plan of corrective actions implemented by the Organisation shall be assessed by the Institute during the subsequent audit.
Failure to take the required corrective actions may lead to the start of the suspension and/or revocation process of the certificate, pursuant to art. 8 and 9 of these Regulations.

5.4 If necessary, the Institute may decide to perform extraordinary unscheduled surveillance audits, with a minimum of two day's notice, for example: to assess the accurate management of complaints received by the Institute; to assess the impact of organisational changes; in the event of requests made by Accreditation bodies (in this case, said bodies may take part in the audit).
In these cases, the Organisation cannot ask to replace the Institute auditors.
The costs of unscheduled, extraordinary audits shall have to be paid by the Organisation.

6. MANAGEMENT SYSTEM CERTIFICATION VALIDITY

The validity of the Certification issued by the Institute is submitted to a periodical monitoring, with a frequency of at least once a year, and to a full review of the Management System every three years. The certificate issued indicates the three-year date of expiry.

Every three years, the Institute shall perform a renewal audit, which consists in:
- review of the documentation and
- an in-depth inspection entailing an assessment of all the requirements of EXCiPACT™ for all the processes and products pertaining to the object of certification.

The renewal audits are generally carried out in a single stage. In the event of significant changes to the Organisation or its management system, the Institute reserves the right to plan for the execution of the renewal in two stages.
The renewal audit must be carried out within 36 months from the last day of the certification audit.
At the end of the renewal audit the Audit team issues a draft of the audit final report.
The final report is transmitted by the Institute to the Organisation within 4 weeks from the audit closure.
Should non-conformities be detected, the Organisation shall submit to the Institute an implementation schedule detailing the corrective actions necessary to meet the requirements for the renewal of the Certification.
Presence of non-conformities classified as"Life-Threatening", "Critical" or "Major" prevents the renewal of the certification.
In all cases of non-conformities, "Minor" NC included, the Organisation shall demonstrate that corrective actions have all been implemented by sending documentation confirming their management to the Institute, which reserves to conduct a supplementary audit to complete its evaluations.
The effectiveness of the plan of corrective actions implemented by the Organisation shall be assessed by the Institute during the subsequent audit.
Certification maintenance is subordinate to the application of the provisions set forth in art. 12 of these Regulations.

6.2 The Institute informs EXCiPACT asbl about:
a) the decision to grant the renewal of the certification to the Organisation;
b) administration information that will be used by EXCiPACT asbl to issue the certification fee to the Organisation.
After having paid all the due amount by the Organisation, the Institute issues the renewed certificate and sends it to Organisation

7. RIGHTS AND DUTIES OF THE CERTIFIED ORGANISATION

7.1 After receiving the Certification, the Organisation can advertise the attainment of the same in the ways it deems most appropriate, provided that proper reference is always made to the scope and limitations of the Certification obtained according to the provisions set forth in art. 17 of these Regulations. Having ascertained the improper use of the Certification, the Institute shall take all measures to prevent its continuation and

safeguard its interests and the interests of EXCiPACT asbl.

7.2 Certification is issued to the Organisation on the basis of the Standard, and only for the activities certified and the operative units mentioned in the Certificate. It cannot be transferred to other units.
Organisations wishing to extend the scope shall submit a request to the Institute, that sets up a suitable extension procedure.
The Institute must be notified of any changes related to identification and Organisational data or ownership, changes in corporate structure or slight changes in the description and editorial aspects of the subject of Certification, and this may allow the maintenance of Certification, with issue of a new certificate, where needed. According to the extent of such changes, the Institute reserves the faculty to request further documentation or perform further audits on site, in order to verify that the changes do not affect the conformity of the Management System.

7.3 Certified Organisations shall agree:
- to keep their structure in conformity with the EXCiPACT™ requirements;
- to keep the certification of their Quality Management System in accordance with the ISO 9001 standard or, as an alternative, to undergo periodical audits in accordance with the document NSF/IPEC/ANSI-363-2014 US National Standard. In the latter case, the Organisations shall make available the audit report to the Institute;
- to accept, at their own expenses, the evaluation audits necessary to maintain the validity of the Certification;
- not to use their certification, including audit reports and marks, in such a way as to damage the reputation of the Institute and/or of EXCiPACT asbl and/or of the certification system, thus compromising the public's trust in same;
- to allow the Institute's auditors and Observers or Experts, if any, as well as auditors send by EXCiPACT asbl to access its facilities and information system to verify the Institute's work, assisting them during the audits. Should the Organisation refuse to admit Institute Observers or control and accreditation Bodies accompanying the Certiquality Auditors, the Institute may refuse certification issue, or suspend or revoke Certification,
- to implement the corrective actions required to correct the reported deviations to the EXCiPACT™ requirements;
- to record all the customers' complaints concerning EXCiPACT™ and the related corrective and preventive actions undertaken, making them available to the Institute and its auditors during surveillance audits;
- to cease exhibiting or making any other use of the Certification documents and, if applicable, of the CERTIQUALITY or EXCiPACT asbl symbols and logos immediately after the expiry, suspension, revocation, waiver and consequent withdrawal of the Certification;
- to authorize the Institute to notify the audit results and transmit the relating reports to EXCiPACT asbl;
- to inform the Competent Authorities of the countries where the excipient is put on the market, in case the Institute detects non-conformities categorized as "Life Threatening". The Institute informs EXCiPACT asbl about such non-conformities

7.4 Obligation to provide information regarding any legal and/or administrative proceedings in progress.
Certified Organisations undertake to:
- promptly inform the Institute, by fax/e-mail and subsequently by registered letter with return receipt, of any non-conform situation recorded by monitoring Authorities, any suspension or revocation of authorisation, concessions, etc. relating to the production /distribution of products and/or services connected to the certification.
- notify the Institute immediately of any legal and/or administrative proceedings in progress, regarding the subject of certification, within the limits posed by law;
- give immediate notification of any serious events or accidents or environmental damage;
- keep the Institute informed of the developments of the aforesaid proceedings.

As regards the above, the Institute reserves the faculty to conduct appropriate and timely extraordinary audits and suspends or revokes certification when necessary, in the event of actual non-conformity of the Organisation's Management System.

8. CERTIFICATION SUSPENSION

In case of problematic situations or persistence of deviations after the term agreed for their correction, the Institute can suspend the Certification.
Examples of such severe deficiencies include the following:
- when monitoring reports a non conformity with relevant requisites, but a revocation is not deemed necessary;
- if the Organisation does not submit the evidence relating to the management of major

non-conformities issued during audit within the prescribed timeframes;
- when the Organisation refuses to undergo periodical audits in accordance with the provisions set forth in Art. 5.3;
- when the Organisation refuses to undergo additional or supplementary audits;
- if the Organisation fails to notify the Institute of significant amendments to its Management System and/or organisation;
- when the improper use of the Certification persists, symbols or logos owned by CERTIQUALITY or EXCiPACT™ included.
- in the event of any other failure to comply with the provisions of EXCiPACT™ certification scheme, these Regulations or the procedures of the Institute;
- when Public Authority orders prejudice the implementation of the Company Management System;
- if inspections by Competent Authorities have detected significant deviations from the requirements of Good Manufacturing and/or Distribution Practices that seem to be critical non-conformities;
- if problems exist regarding the compulsory requirements of the product/service distributed or the Management System in question;
- when the Organisation fails to notify the Institute pursuant to par. 7.4;
- if payment of services already completed has not been made, with respect to any type of service performed by Certiquality, whether or not related to the certification; when the Organisation is in default more than once in the same three-year programme, certification shall be immediately revoked
- if the Organisation has not paid the certification fee issued by EXCiPACT asbl pursuant to art. 12 of these Regulations.

Following the resolution of the Technical Commission, the revocation is notified by registered letter with return receipt, indicating the start date of validity, the duration, the prohibition to promote any activity related to the use of certification, including its utilization for taking part to calls for tenders, and the conditions for revoking the suspension.
The certified Organisation shall be responsible for undertaking prompt and adequate actions to correct any failure to comply with the Institute's provisions and for providing the Institute with formal notification of the proposed or implemented corrective actions.
The Institute informs EXCiPACT asbl about the suspension of certification with the related reasons for suspension.
Suspension shall only be repealed when the Institute has ascertained that satisfactory actions have been taken to ensure compliance with the certified requisites. The Institute reserves the faculty to perform an audit on site.
If the causes that have led to the suspension are not removed within the deadline defined by the Institute, then the Institute shall submit the revocation proposal to the resolution of the Technical Commission.
In exceptional cases, and only once during the same three-year certification period, the Organisation may request for certification to be suspended for a maximum period of six months; such decision is submitted to the resolution of the Technical Commission.

9. CERTIFICATION REVOCATION

9.1 The revocation and consequently the cancellation and withdrawal of the Management System Certification is approved by the Institute's Technical Commission as a result of:
- failure to remove the causes that have led to the suspension of the Certification within the deadline defined by the Institute,
- when the cases indicated in par. 8 are of such a severe nature as to warrant immediate revocation,
- persistence of default beyond 1 month from receipt of the Administrative suspension sent by the Institute by registered mail with return receipt;
- breach of laws or legally binding regulations regarding the products or processes object of certification.

The decision to revoke the Management System Certification shall be notified to the Organisation by registered mail with return receipt.

9.2 Following revocation, the Organisation undertakes to:
- return or destroy the original CERTIQUALITY certificate.
- not to use any copies or reproductions thereof.
- remove from the letterhead, technical documents and advertising materials any and all references to or symbols of the CERTIQUALITY Certification, including any logos owned by EXCiPACT asbl.
- notify customers, particularly with reference to call for tenders, by the same means used to inform them of the attainment of the Certification.

9.3 Moreover, the Institute shall delete the Organisation from the Registry of certified Organisations.

In the case of revocation due to administrative reasons, the Organisation, which pays for her arrears within one month, may request reinstatement of the Certification.
The withdrawal of the Certification shall not entitle the Organisation to reimbursement of the amounts already paid of any kind and entails payment of a penalty, as set forth in Section 12.1.

10. WAIVER TO THE CERTIFICATION

The Organisation may waive its Management System Certification:
a) at the end of the three-year period, by providing formal notice of its intention at least 3 months in advance;
b) in the event of amendment of the reference standards, as set forth in Section 4.5 of these Regulations;
c) in the event it disagrees with the reviews of these Regulations;
d) in the event it disagrees with the amendments of the financial terms defined by the Institute;
e) in the event of: cessation of activity or transfer of the Company branch, to which the Certification of the Management System refers, to a different juridical subject, legal provisions, bankruptcy or winding up of the Organisation.
If the waiver originates from the transfer to a different juridical subject, the Contract shall continue to be valid until the end of the three-year period, subject to verification by the Institute of the maintenance of all the conditions that led to certification.
In cases b), c) and d), notification shall be sent by the Organisation no later than 1 month from the date in which the Institute has notified the amendments.
In cases b), c), d) and e), the waiver shall become effective from the date on which the Institute gives notification of its acknowledgement of the waiver, with contextual termination of certification validity.
In the event of waiver, the Organisation shall comply with the obligations set forth in Section 9.2.
In the event of waiver for reasons other than those listed above, the Organisation shall pay a penalty, as set forth in Section 12.1.

11. CONFIDENTIALITY

All records (documentation, letters and communications) relating to the activities connected with the Certification of the applicant Organisation's Management System shall be regarded confidential and made available only in accordance with the provisions of the agreed internal procedure.
All collaborators of the Institute who come into possession, while performing their work, with the aforementioned documents shall be obliged not to divulge them.
Access to and consultation of certification-related documents is reserved to those Institute functions involved in the certification course, the certified Organisation and the personnel of EXCiPACT asbl. In the case of information relating to the Organisation must be disclosed under legal obligations, the Institute shall give notification thereof to the Organisation.
Except in these cases, Certiquality will not disclose information on certified Organisations without the authorisation of same.
The Institute in any case operates in full respect of the provisions set forth in Legislative Decree 30 June 2003, no. 196 (processing of personal data).

12. CONTRACTUAL FINANCIAL CONDITIONS

12.1 Fees

The offers prepared by the Institute are based on the financial principles and criteria defined by the Board of Directors.
Contracts have three-year validity and renewal rules are defined in the specific contract signed by the parties.
As provided in Sections 9 and 10 of these Regulations, should the certificate be waived or withdrawn, the Organisation shall pay to the Institute a penalty of an amount equal to 20% of the total contract price for the three-year term, provided, however, that such penalty shall be no less than 500 € and no greater than 5000 €.
All requests relating to the amendment of the audit schedule, made by the Organisation, may entail the payment of a supplementary fee, which shall be defined in accordance with the higher expenses incurred.
If the request is made in the 5 working days prior to the agreed date, the Institute reserves the right to charge a sum equal to 50% that envisaged for the audit.
Payment for any services performed by CERTIQUALITY shall be owed by the Organisation notwithstanding failure of the certification for reasons not attributable to CERTIQUALITY itself.

12.2 Payment Terms

Fees for the activities carried out in connection with the Certification and Certification maintenance shall be paid to the Institute according to the instructions provided time after time on the invoices issued.
Failure to comply with the aforementioned obligations shall entitle the Institute to apply

the provisions set forth in art. 8 and 9 of these Regulations.

12.3 Certification Fee
The Organisation shall pay the certification fee due to EXCiPACT asbl, owner of the EXCiPACT™ Certification Scheme document.
The certification fee is due by the Organisation upon certification and upon every 3-year renewal. The amount is defined by EXCiPACT asbl and it may periodically change. Changes are immediately notified to certificated Organisations.
The issue of the certificate is bound to the execution of the payment of the certification fee.

13. LIABILITY

The Organisation undertakes to guarantee the completeness and truthfulness of the documents and information made available to the Institute's appointed auditors.
Certiquality is expressly exonerated from all liability in the event of lacking or incomplete transmission of data or data that does not correspond to the company's actual situation.
CERTIQUALITY has the responsibility to verify that the Organisation's Management System is able to effectively manage its compliance with laws and compulsory regulations in relation to the products and/or services provided, despite the fact that it does not assume any direct responsibility regarding the adequacy of the technical choices adopted for such reasons by the Organisation – which remains the only liable party –or the ascertainment of compliance with legal requirements.
The CERTIQUALITY Certification of a Management System does not relieve the Organisation from the legal obligations originating from the supply of products, processes and services nor from the Organisation's contractual obligations with its customers, with the exception of any Institute responsibility or guarantee obligation.
More specifically, the parties agree that the Institute shall not be responsible for defects of products, processes and services supplied by the Organization to third parties; in the cases referred to by the Legislative Decree no.206 dated 6/09/2005 (Consumer Code) and subsequent modifications and additions and in Directive EEC 85/374, disciplining the liability for damages caused by defective products; nor for systemic or occasional behaviour of the Organisation in violation of laws and/or Regulations.
The Institute shall not be liable for inadequacies or damages of any kind originating from the Organisation's activity or by its products, processes or services.
Certiquality shall not be liable for any inaccuracy contained in the database of Accreditation and Control bodies, in particular when such data are transferred by them to other bodies.

14. APPEALS

The involved Organisation may appeal against the Institute's decisions.
Such appeal must be sent by registered letter to Certiquality within 30 days from the notification of such decision. Certiquality shall provide written confirmation of the receipt of such appeal.
Certiquality shall submit such appeal to a dedicated committee which shall render a reasoned decision within 30 days. Upon justification the appeals committee may render its decision within 60 days.
The decisions of the Committee are formally communicated to the Organization.
Upon granting of the appeal, the relevant decision is canceled or revoked.
In case of non acceptance of the appeal If not satisfiied with the outcome o f the appeal, the Organization may consult EXCiPACT asbl, whose decision is final.
Expenses shall be paid by the losing party.

15. DISPUTES

The only competent court for any disputes relating to the application or interpretation of these Regulations shall be the Court of Milan.

16. COMPLAINTS

Any person may submit communications/complaints regarding any behaviour of the Institute or the certified Organisations that may be regarded as not being in line with the document EXCiPACT™ Certification Scheme.
Said communications/complaints must be made by letter or email; telephone communications must subsequently be made in writing by the notifying party.
Certiquality informs EXCiPACT ABSL on receipt of the communications / complaints by an organization that requested or holds certification according to the document EXCiPACT ™ Certification Scheme and of the outcomes.
The Institute undertakes to keep the notifying party informed of the outcome of the

complaint. If not satisfied with the outcome of the complaint, the complainant may seek the advice to EXCiPACT ABSL, whose decision shall be final.
Depending on the received communications/ claims, EXCiPACT ABSL may require Certiquality to withdraw the certificate issued.
Anonymous communications/complaints will not be considered by the Institute.

17. USE OF THE CERTIFICATION LOGOS

Following the attainment of the Certification, the Organisation can advertise of the same in the ways it deems most appropriate, provided that proper reference is always made to the scope and limitations of the Certification obtained according to the provisions of REG 02 "Regulations for the use of certificates and logos".

Moreover, the certificated Organisation is authorized to use the logo made available by EXCiPACT asbl. The use of the logo is allowed on letter paper, business cards, leaflets, advertisements and other promotional material, vehicles included. The logo can also be used on external packages, commercial samples and flags.

The EXCiPACT™ absl logo shall be reproduced by including the number that EXCiPACT absl associates with every certificate issued by the Certification Body.

The EXCiPACT™ logo shall be reproduced in a way that it is clearly legible in printed version and that the texts, including the number, whose prefix identifies the Organisation that issued the certification, are legible with the naked eye.
The EXCiPACT™ logo shall be reproduced in full, outlines included.
The EXCiPACT™ logo shall be reproduced in any colour.
The EXCiPACT™ logo cannot be used on the product or otherwise be strictly associated with the product, so as it can be understood that the product itself is certificated.

While using the EXCiPACT™ logo, the Organisation shall also take into consideration further rules defined by The EXCiPACT absl.

The EXCiPACT™ logo can be used on Test Certificates when the same logo is integral part of the headed paper of the Organisation. The use of the logo shall not let believe that the certification includes the verification of the quality of the excipient.
If it finds that the organization uses the wrong way EXCiPACT ™ logo, Certiquality informs EXCiPACT ABSL.