

Code of Practice for Certification

1. INTRODUCTION

This Code of Practice has been structured in accordance with the applicable requirements of the accreditation bodies whose accreditation is currently held by SGS Belgium NV (hereinafter referred to as the "Certification Body").

This Code also applies to certification outside accredited schemes.

2. SCOPE

The Certification Body provides services to persons, firms or companies (each a "Client"). The Certification Body may provide its services directly or, in its absolute discretion, through (1) its own employees, (2) any SGS affiliated company or (3) any other person or organization, as may be entrusted by the Certification Body. Where part of the work is subcontracted to others, the Certification Body retains full responsibility for granting, maintaining, extending, reducing, suspending or withdrawing certification and for ensuring that properly documented agreements are in place.

The Certification Body will notify its Clients of any changes to the requirements for certification within a reasonable timeframe.

3. ORGANIZATIONAL STRUCTURE

A copy of the organization chart of the Certification Body, showing the responsibility and reporting structure of the organization, and documentation identifying the legal status of the Certification Body are available on request.

4. APPLICATION FOR CERTIFICATION

On receipt of the Certification Body's Questionnaire duly completed by the Client, a Proposal is sent to the Client outlining the scope and costs of services. Once the Proposal is accepted by the Client, the project will be allocated to an auditor who will be responsible for ensuring that the services are carried out in accordance with the procedures of the Certification Body.

5. CLIENT'S OBLIGATIONS

In order to obtain, continue, reinstate, renew and retain certification, the Certification Body shall perform one or more assessment activities such as but not limited to conformity assessments, technical assessments, audits or inspections, assessment of technical

documentation, assessment of clinical evaluations, samplings, and/or short notice-audits (the "Assessment") and the Client shall comply with the following procedures and rules:

a) The Client shall make available to the Certification Body all documents, samples of products, drawings, specifications and other information required by the Certification Body to complete the Assessment program and shall appoint a designated person who is authorized to maintain contact with the Certification Body.

b) The Certification Body, if not satisfied that all certification requirements are met, shall inform the Client of those aspects in which the application has failed.

c) When the Client can show that remedial action has been taken by it, within the time limit specified by the Certification Body, to meet all the requirements, the Certification Body will arrange, at additional cost to the Client, to repeat only the necessary parts of the Assessment.

d) If the Client fails to take acceptable remedial action within the specified time limit it may be necessary for the Certification Body, at additional cost, to repeat the Assessment in full.

e) Identification of conformity shall refer only to the sites or products assessed as specified in the Certificate and Assessment schedule (if any) or other attachments which may accompany the Certificate.

f) The Client shall when requested accommodate the presence of observers during the Assessment, e.g. accreditation auditors or trainee auditors.

g) Refusal to grant, continue, reinstate, renew or retain the Certificate: On refusal by the Certification Body to grant, continue, reinstate, renew or retain the Certificate, the assignment and the certification procedure automatically come to an end without notice. The costs for the services rendered and/or ordered are invoiced to the Client in accordance with the agreed prices irrespective of whether certification is ultimately deferred or refused and irrespective of whether an appeal is lodged; services rendered must always be paid for.

6. ISSUANCE OF CERTIFICATE

When the Certification Body is satisfied that the Client meets all the certification requirements, it will inform the Client and issue a Certificate. The Certificate shall remain the property of

the Certification Body and may only be copied or reproduced for the benefit of a third party if the word "copy" is marked thereon.

The Certificate will remain valid, until its expiry or earlier cancellation or withdrawal should surveillance reveal that the management system and/or products of the Client no longer meet the standards, norms or regulations. Expiry takes place upon the expiry mentioned in the Certificate, or earlier on the date of cancellation or withdrawal and/or if the Client enters bankruptcy proceedings, ceases to exist or transfers the relevant site(s) to a third party.

The Certification Body reserves the right to decide, on a case by case basis, at its sole discretion and after taking into account various local requirements, that the issuance of the Certificate will be conditioned to the full payment of all fees invoiced by the Certification Body in relation to the concerned Certificate and or any other previous services.

7. CERTIFICATION MARKS

Upon issuance of a Certificate, the Certification Body may also authorize the Client to use a designated certification mark. A Client's right to use any such mark is contingent on maintaining a valid Certificate in respect of the certified management system or products and compliance with the Regulations governing the Use of SGS System Certification Marks issued by the Certification Body. A Client who has been authorized to use the mark of an accrediting body must also comply with the rules governing the mark of such body. Improper use of such a mark is non-conformity with certification requirements and shall permit the Certification Body to suspend and/or withdraw the certification.

8. SURVEILLANCE

Periodic surveillances shall be carried out and shall cover aspects of the management system, documentation, manufacturing and distributing processes and products, depending on the type of certification services provided, at the discretion of the nominated auditor. The Client shall give access to all sites or products for surveillance purposes whenever deemed necessary and the Certification Body shall reserve the right to make additional announced or unannounced audits as required either under the requirements of a certification scheme or as a result of a reported incident or complaint, or a breach of regulation

necessitating the involvement of the competent regulatory authority.

The Client shall maintain a register recording all customer complaints and safety related incidents related to the scope of certification, reported by an enforcing authority or users and make this available to the Certification Body on request. In addition, the Client shall without delay inform the Certification Body of any serious incident or breach of regulation relevant to the scope of certification necessitating the involvement of the competent regulatory authority.

Additional inspections: If during an audit major non-conformities are found, the Certification Body can, after the Client has reported that it has implemented corrections and actions, proceed to carry out an additional inspection on-site (insofar as it is not sufficient to provide evidence in writing) for the verification of the actual implementation and appropriateness of the corrections and corrective actions reported.

a) If the Client is not able, within the specified time, to introduce appropriate solutions to the reported non-conformities, the Certification Body can proceed to repeat a full Assessment.

b) If changes to the management system, which must be reported to the Certification Body in writing and immediately, as further described under Clause 11, are considered by the Certification Body to be substantial and, in any case, if the scope is changed, the Certification Body can proceed to one or more additional inspections or to a full audit.

c) None of the additional inspections and any subsequent new audits are included in the initially agreed audit frequency. They must be paid for separately.

9. RENEWAL OF CERTIFICATION

Clients are generally informed of the certification renewal requirements during the pre-renewal visit, which is typically the last surveillance visit of each certification cycle.

Notwithstanding the above, the Client remains solely responsible for ensuring that all certification renewal requirements are fulfilled in a timely and complete manner. Certification may only be renewed where a valid contract for certification services is in place.

For the avoidance of doubt, a new contract for certification services is not required where the existing contract for certification services remains in full force and effect.

10. EXTENSION OF CERTIFICATION

In order to extend the scope of a Certificate to cover additional sites or products, Client shall complete a new Questionnaire. The application procedure outlined in Clause 4 will be followed and an Assessment will be carried out on those areas/products not previously covered. The cost of extending the scope of certification will be based on the nature and program of work.

Following a successful Assessment an amended Certificate will be issued covering those aspects covered by the extended Certificate.

11. SYSTEM/PRODUCT MODIFICATION

The Client shall inform the Certification Body, in writing, of any intended and/or incurred modification to the management system, products or manufacturing process which may affect compliance with the standards, norms or regulations. The Certification Body will determine whether the notified changes require additional Assessment. Failure to notify the Certification Body of any intended modification may result in suspension of the Certificate.

12. PUBLICITY BY CLIENT

In compliance with the applicable Regulations governing the Use of SGS System Certification Marks, a Client may render public that its relevant management system or products have been certified and may print the relevant Certification Mark on stationery and publicity materials relating to the scope of certification.

In any case, the Client shall abide by all Regulations governing the Use of SGS System Certification Marks being part of the contract between the Client and the Certification Body and ensure that its announcements and advertising material do not create confusion or could otherwise mislead third parties about certified and non-certified systems, products or sites.

13. MISUSE OF CERTIFICATE AND CERTIFICATION MARK

The Certification Body shall take suitable action, at the expense of the Client, to deal with incorrect or misleading references to certification or use of Certificates and certification marks.

These include suspension or withdrawal of the Certificate, legal action and/or publication of the transgression.

14. SUSPENSION OF CERTIFICATE

A Certificate may be suspended by the Certification Body for a limited period in cases such as the following:

a) if a Corrective Action Request has not been satisfactorily complied with within the designated time limit; or

b) if a case of misuse as described in Clause 13 is not corrected by suitable retractions or other appropriate remedial measures by the Client; or

c) if there has been any contravention of the Proposal, application for registration, General Conditions for Certification Services, this Code of Practice or the Regulations governing the Use of SGS System Certification Marks; or

d) if products are being placed on the market in an unsafe or non-conforming condition; or

e) if audits are not carried out within the prescribed timeframe.

The Client shall not identify himself as certified and shall not use any certification mark on any products that have been offered under a suspended Certificate.

The Certification Body will confirm in writing to the Client the suspension of a Certificate. Suspension has immediate effect. At the same time, the Certification Body shall indicate under which conditions the suspension may be removed. At the end of the suspension period, an investigation will be carried out to determine whether the indicated conditions for reinstating the Certificate have been fulfilled. On fulfilment of these conditions, the suspension shall be lifted and the Client shall be notified of the Certificate reinstatement. If the conditions are not fulfilled the Certificate shall be withdrawn.

In cases of suspension, no reimbursement of Assessment fees shall take place and suspension of the Certificate shall be published by the Certification Body and notified to the appropriate accreditation body, standard owner and/or governmental body, if any.

All costs incurred by the Certification Body in suspending and reinstating a Certificate will be charged to the Client.

15. WITHDRAWAL OF CERTIFICATE

A Certificate may be withdrawn (1) if the Client does not meet all the conditions for reinstatement of the Certificate in case of suspension and this within the agreed timeframe; (2) if in the case of product certification, the

products do not conform to the standards, norms or regulations or are no longer offered; (3) if the Certification Body terminates its contract with the Client, (4) at the request of a relevant accreditation body, a governmental body or the standard owner or (5) in case of Client's bankruptcy. In any of these cases, the Certification Body has the right to withdraw the Certificate by informing the Client in writing. The withdrawal has immediate effect.

The Client may give notice of appeal (see Clause 18).

In cases of withdrawal, no reimbursement of Assessment fees shall take place and withdrawal of the Certificate shall be published by the Certification Body and notified to the appropriate accreditation body, standard owner and/or governmental body, if any.

16. CANCELLATION OF CERTIFICATE

A Certificate will be cancelled if (1) the Client advises the Certification Body in writing that he does not wish to renew the Certificate or goes out of business, (2) the Client no longer offers the products or (3) the Client does not timely commence application for renewal.

In cases of cancellation no reimbursement of Assessment fees shall take place and the cancellation shall be notified to the appropriate accreditation body, the standard owner and/or the governmental body, if any.

17. RECOGNITION OF ACCREDITED ORGANIZATIONS

The Certification Body, in its absolute discretion, generally recognizes the certificates issued by other accredited organizations where this does not compromise the integrity of a system or product certification scheme.

18. APPEALS

The Client has the right to appeal any of the decisions made by the Certification Body.

Notification of the intention to appeal must be made in writing and received by the Certification Body within seven days of receipt by the Client of the notification of the non-issuance, suspension or withdrawal of the Certificate.

An Appeals Form will be sent to the Client for completion and must be returned to the Certification Body within 14 days of receipt by the Client, supported by relevant facts and data for

consideration during the Appeals Procedure.

All appeals are forwarded to the Certification Body and are put before the appeal's committee. The Certification Body shall be required to submit evidence to support its decision. Any decision of the Certification Body shall remain in force until the outcome of the appeal.

The decision of the appeal's committee shall be final and binding on both the Client and the Certification Body. Once the decision regarding an appeal has been made, no counter claim by either party in dispute can be made to amend or change this decision.

In instances where the appeal has been successful and the Certificate issued or reinstated, no claim can be made against the Certification Body for reimbursement of costs or any other losses incurred.

19. COMPLAINTS

If anybody has cause to complain to the Certification Body, the complaint shall be made in writing, without delay, and addressed to the Certification Manager of the Certification Body. If the complaint is made against the Certification Manager, the letter of complaint shall be addressed to the Business Manager of the Certification Body.

The complaint shall be acknowledged in writing following receipt. The complaint will then be independently investigated by the Certification Body and closed on satisfactory conclusion of the investigation. Following closure, the complainant will be informed that the investigation has reached its conclusion.

20. TERMINATION FOR CONDUCT AFFECTING REPUTATION OF THE CERTIFICATION BODY

The Certification Body shall be entitled to either (i) suspend the certification granted to the Client; and/ or (ii) suspend or terminate the Agreement with the Client if the Client has caused or has become involved in any situation or activity which:

a) tends in the reasonable opinion of the Certification Body to have a negative effect on its reputation or any aspect of its business; or

b) would expose the Certification Body or any aspect of its business to disrepute, scandal or offend the public in any territory in which the Certification Body operations or services are marketed; or

c) reflects unfavorably on the reputation of the Certification Body, its brands or services; or

d) might affect the supply, successful sales and exploitation of the services of the Certification Body.

THE CERTIFICATION BODY RESERVES THE RIGHT TO ADD TO, DELETE OR CHANGE THIS CODE OF PRACTICE WITHOUT PRIOR NOTIFICATION WHERE SUCH CHANGE IS REQUIRED BY OPERATION OF LAW, A GOVERNMENTAL AUTHORITY AND/OR THE STANDARD OWNER.