Testing, Certification, Validation/Verification Regulations – TÜV SÜD Group

Glossary
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The terms and definitions given in ISO/IEC 17000; in addition and especially the following apply.

Fundamentals	
conformity assessment	demonstration that specified requirements are fulfilled Note: Conformity assessment follows a specified process (functional approach), which always includes a decision on conformity of the assessed object as conclusion based on the assessment results. The decision can be negative, i.e. the outcome of conformity assessment can be a statement that the specified requirements are not fulfilled. Results of individual activities, that are conducted in context of conformity assessment (e.g. testing, inspection, auditing) but do not contain a decision on conformity, can be issued (e.g. as analysis, audit report, test report, inspection report) without a statement of conformity.
object of conformity assessment	entity to which specified requirements apply Note: Examples for objects of conformity assessment are products, processes, services, systems, management systems, installations, facilities, projects, data, designs, materials, claims, persons, organisations, or any combination thereof.
normative documents	statement of specified requirements that apply to a specific object of conformity assessment Note: Normative documents can be, e.g., EU harmonisation legislation, laws, directives, standards, technical specifications, which contain specifications of detailed or general requirements. Certificates and attestations of conformity refer to the respective version of the normative documents taken as basis. This version can differ from the actual edition of the normative documents.
scheme, programme	set of rules and procedures that (i) describes the object of conformity assessment, (ii) identifies the specified requirements, and (iii) provides the methodology for performing conformity assessment Note: A person or organisation is responsible as scheme owner for development and maintenance of certification schemes or validation/verification programmes. A conformity assessment scheme can be managed within a conformity assessment system, which sets rules and procedures for the management of similar or related schemes.

	Schemes and systems can be operated at international, regional, national, sub-national, or industry sector level. The EU Legislative Framework (s. Regulation No 765/2008, Decision No 768/2008/EG, Blue Guide) provides various conformity assessment procedures, which are implemented in Directives and Regulations. These “modules” are based on the standards series ISO/IEC 17000 and vary from internal control of production, for simple products or products not necessarily presenting serious risks, to the most comprehensive module (full quality assurance with EU-design examination), where the risks are more severe, or the products and technologies are more complex.
conformity assessment activity	activity to demonstrate that specified requirements are fulfilled by the object of conformity assessment Note: Examples for conformity assessment activities are sampling, laboratory testing, document review, inspection, audit, evaluation, validation, verification, production control, site visits.

Conformity assessment bodies	
conformity assessment body, CAB	legal entity, or part of a legal entity, that performs conformity assessment activities (i.e. testing laboratory, inspection body, certification body, validation or verification body) and, if applicable, issues a statement of conformity
accreditation	third-party attestation related to a conformity assessment body, conveying formal demonstration of its competence, impartiality, and consistent operation in performing specific conformity assessment activities
accreditation body	authoritative body that performs accreditation Note: Within the EU, the authority of the national accreditation body is derived from government.
notified body	conformity assessment body designated by public authority to conduct specified conformity assessment activities Note: Designation is considered as an act of the designating authority, which can be the same body as the notifying authority. Only the act of notifying the EU Commission and the other Member States allows a “designated body” to become a “notified body”. A notifying authority is the governmental or public body that is tasked with designating and notifying conformity assessment bodies under Union harmonisation legislation.
entrusted body	legal entity, on which the authority to independently assume public responsibilities outside governmental administration has been transferred
testing laboratory	body that performs testing activities Note: Sampling, associated with subsequent testing, can be included in the performed activities.

certification body	conformity assessment body that issues statements of conformity independently from the provider of the object of certification and with no user interest in the object (third party) Note: Objects of certification can be products, processes, systems, services, persons, or management systems.
validation body	conformity assessment body that confirms claims (information, data, reports, declarations etc.) as plausible for a specific intended future use or application and issues a validation statement whether all specified requirements have been fulfilled
verification body	conformity assessment body that confirms claims (information, data, reports, declarations etc.) regarding their truthfulness and issues a verification statement whether all specified requirements have been fulfilled

Results of conformity assessment	
statement of conformity	statement, based on a decision on the conformity of an object of conformity assessment, that fulfilment of specified requirements has been demonstrated Note: The statement can be issued as certificate or as attestation of conformity.
attestation of conformity	issue of a statement of conformity, which is not outcome of a certification Note: Examples for attestations of conformity are test reports with the statement “test passed” or “test failed”, inspection reports or verification statements.
test report	accurate, clear, unambiguous, and objective provision of test results in a report, which includes agreed with the client and necessary for the interpretation of the results and all information required by the method used Note: Test reports can include a statement of conformity and thereby be an attestation of conformity.
product certification process certification service certification	third-party attestation related to products, processes, and services as objects of conformity assessment Note: A product is the result of a process (e.g. hardware, software, processed materials). A process is a set of interrelated or interacting activities that transforms inputs into outputs (e.g. welding engineering processes, manufacturing processes, food production processes). A service is the result of at least one activity necessarily performed at the interface between the supplier and the customer, which is generally intangible (e.g. repair, income statement for tax declaration, knowledge transmission).

management system certification	third-party attestation related to management systems as objects of conformity assessment Note: A management system is a set of interrelated or interacting elements of an organization to establish policies and objectives, and processes to achieve those objectives.
certification of persons	third-party attestation related to persons as objects of conformity assessment
certificate	issue of a statement based on a decision by a certification body, that fulfilment of specified requirements has been demonstrated for an object of certification Note: Objects of certification can be products, processes, systems, services, management systems, or persons.
termination of certificate	ending of the validity of the certificate, either after a specified period (expiry) or before expiry of a specified period (withdrawal or revocation)
expiry of certificate	ending of the validity of the certificate after a period specified with issue of the certificate Note: In previous versions, this termination of a certificate is also called
withdrawal of certificate	ending of the validity of a certificate through cancellation of the certificate by the certification body that issued the certificate (e.g. if certification requirements are no longer fulfilled or upon request of the client)
revocation of certificate	ending of the validity of a certificate through cancellation of the certificate with retroactive effect by the certification body that issued the certificate
reduction of certificate	temporal limitation of the period of validity or technical limitation (e.g. on conditions) of the scope of a certificate
suspension of certificate	temporary restriction of the certificate as interim measure of protection until either final withdrawal or restoration of the certificate for all or part of the specified scope of attestation
mark of conformity	legally against unauthorized use protected mark issued by a conformity assessment body, indicating that an object of conformity assessment fulfils the applicable specified requirements Note: Marks of conformity that are issued by certification bodies, indicating that an object of certification fulfils the applicable specified requirements, are called “certification marks”. Other marks related to attestations of conformity can be, e.g., “inspection marks” or “verification marks”.
CE marking (fr: Conformité Européenne)	marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in EU harmonisation legislation Note: Depending on the conformity assessment procedure or the respective harmonisation legislation, the CE marking can be used in connection with the number of

	the notified body (e.g. „CE 0123“ for TÜV SÜD Product Service GmbH).

Conformity assessment activities	
testing	determination of one or more characteristics of an object of conformity assessment, according to a procedure Note: The output of testing can include comments (e.g. opinions and interpretations) about the test results and fulfilment of specified requirements. There can be overlap between the use of the terms “testing”, “test”, and “inspection”. The differentiation, however, is crucial for determining the standard applicable to the body performing the activity (e.g. ISO/IEC 17025, 17020 or 17065).
inspection	examination of an object of conformity assessment and determination of its conformity with detailed requirements or, on the basis of professsional judgement, with general requirements Note: There can be overlap between the use of the terms “testing”, “test”, and “inspection”. The differentiation, however, is crucial for determining the standard applicable to the body performing the activity (e.g. ISO/IEC 17025, 17020 or 17065).
audit	process for obtaining relevant information about an object of conformity assessment (e.g. management system, process, service) and evaluating it objectively to determine the extent to which specified requirements are fulfilled Note: Audits can be conducted on site or remotely (i.e. irrespective of the distance at any site except the site of the audited object). A combination of conducting an audit on site and remotely is possible. Audits can be conducted announced or unannounced.
unannounced audit	audit that is conducted without announcement, either planned or event driven
certification audit	audit carried out by a certification body for the purpose of certifying the client’s management system Note: Certification audits include initial, surveillance, re-certification audits, and can also include special audits.
audit programme	arrangements for a set of one or more audits planned for a specific time frame and directed towards a specific purpose Note: The latest possible dates of planned audits, announced and unannounced, are the due dates.
audit plan	description of the activities and arrangements for an audit
validation	confirmation of a claim (information declared by the client), through the provision of objective evidence, that the

	requirements for a specific intended future use or application have been fulfilled Note: Validation is applied to claims regarding an intended future use based on projected information (confirmation of plausibility).
verification	confirmation of a claim (information declared by the client), through the provision of objective evidence, that specified requirements have been fulfilled Note: Verification is applied to claims regarding events that have already occurred or results that have already been obtained (confirmation of truthfulness).

Client relation	
client	legal entity or individual as contractual partner of TSG who is, among other things, responsible for ensuring that the relevant requirements for conformity assessment are fulfilled, including the requirements applicable to the object of conformity assessment Note: Clients can be several persons together as joint debtors. The term “client” includes “applicant” as well as “certificate holder”. In management system certification, the client is the organisation whose management system is audited. In validation/verification, the client is the organisation or person requesting validation. In product certification, the client can be the manufacturer or the importer. In person certification, the client can be the person him- or herself.
critical supplier	supplier of crucial material, components, or services who significantly influence the conformity, safety, or performance of finished products by their activities (e.g. software provider) Note: In the context of the audit of medical device manufacturers, a critical supplier is a supplier of a product or service, the failure of which to meet specified requirements could cause unreasonable risk to the patient, clinician or others, or could cause significant degradation in performance. This can include suppliers of services, which are needed for compliance with quality management system or regulatory requirements, e.g. documentation service providers, internal audit contractors or Authorized Representatives.
appeal	request by the person or organization that provides, or that is, the object of conformity assessment to a conformity assessment body for reconsideration by that body of a decision it has made relating to that object
complaint	expression of dissatisfaction, other than appeal, by any person or organization to a conformity assessment body or an accreditation body, relating to the activities of that body, where a response is expected

text form	readable statement on a permanent data medium that identifies the person making the statement Note: A permanent data medium is any medium that allows for the recipient to store or safe a statement, which is addressed to him or her personally, such that it is accessible for an appropriate period, and that is suitable to reproduce the statement without any changes.