

TÜV NORD Nederland B.V.

Regulation for product certification

and the use of the conformity mark

Document no. 401-01-01-004e
Version 1.1 | 2025-02-20

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1 Introduction

1.1 General

This regulation is published by TÜV NORD Nederland B.V. (trading as: TÜV NORD Nederland).

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This document serves to inform any organization that wishes to have its product(s) certified, or already has its product(s) certified by TÜV NORD Nederland B.V. (hereafter “TÜV NORD Nederland”), about the used methods and the applicable mutual agreements.

This regulation applies to all activities carried out by TÜV NORD Nederland within the framework of certification of products conforming ISO 17065. TÜV NORD Nederland is accredited to assess products (ISO/IEC 17020, ISO/IEC 17065) and management systems (ISO/IEC 17021) by the Dutch Accreditation Council (Raad voor Accreditatie, RvA). TÜV NORD Nederland has also earned the trust of the Dutch government and European Union through various designations for assessment based on national and European legislation.

Chapter 6 contains the most important terms and their definitions. Every first time that one of these terms is used, it is printed in *italics*.

1.2 Status of this regulation

A certification agreement has been concluded between TÜV NORD Nederland and the (to be certified) *client/certificate owner*. When this certification agreement refers to this regulation, this regulation is an integral part of the certification agreement between both parties. Both parties are therefore responsible for complying with the requirements of this regulation.

It may be that a (*Central*) *Board of Experts* ((C)BoE) has laid down additional provisions. If these provisions are additional to or conflict with the provisions in these certification regulations, those of the (C)BoE shall prevail.

Within the framework of its *accreditations* and *designations*, TÜV NORD Nederland must comply with several directives. TÜV NORD Nederland is responsible for complying to these directives. These directives do not apply directly to the clients of TÜV NORD Nederland, but may be translated through the certification agreement, the *certification scheme* and/or this certification regulation into requirements for the organisation to be certified.

1.3 Structure of this regulation

Chapter 1 of the regulations describes the general issues relating to the regulations. Chapter 2 explains the certification process. Chapter 3 deals with the certificate and the responsibilities that apply after the certificate is granted. Chapter 4 contains the conditions attached to the use of the conformity mark. Chapter 5 describes the activities required to verify the continuous validity of the certificate.

1.4 General responsibilities TÜV NORD Nederland

1.4.1 Confidentiality and conflict of interest

TÜV NORD Nederland is responsible for ensuring confidentiality by every person working for or on behalf of TÜV NORD Nederland, who is involved in the certification process and has become aware of confidential company information as a

result of its work. Every internal and external employee of TÜV NORD Nederland has signed a declaration of confidentiality. TÜV NORD Nederland does not carry out consultancy work in areas overlapping or adjacent to certification activities, in order to avoid conflicts of interest.

1.4.2 Non-disclosure

By signing the Certification Agreement, TÜV NORD Netherlands is bound by a duty of confidentiality. This duty of confidentiality focuses on all information / data that TÜV NORD Netherlands receives from the organisations during its investigations and assessments. A number of exceptions apply to this duty of confidentiality, namely:

1. The data on the certificate and the status of certification may be published and provided to third parties.
2. If TÜV NORD Nederland is contractually obliged to supply data to a scheme administrator, this is permitted.
3. Accreditation bodies and other regulators may inspect files of individual organisations as part of their investigations.
4. If there is an obligation from a designation order to supply information to a government agency, TÜV NORD Nederland may do so.
5. Conclusions (unless confidential) from investigations (e.g. complaints) may be disclosed to those involved.

1.4.3 Introduction of amendments to this regulation

In the event of amendments to this regulation affecting the certification cycle of customers and certificate holders, TÜV NORD Nederland will:

- give these organisations the opportunity to comment on these intended change(s);
- set a date on which the change(s) will take effect, in order to give these organisations sufficient time to adapt the management system and/or process;
- notify these organisations of the effective date of the change and of the measures required of the organisations concerned.

2 Certification process or -cycle

2.1 General

This chapter explains how a complete certification process is structured. In principle, a certification route starts with the application for certification by an organisation. After the certification agreement is signed between the organisation and TÜV NORD Nederland, the implementation of the assessment by TÜV NORD Nederland is planned in consultation with the organisation.

2.2 Examination

The implementation consists of conducting investigations in order to obtain evidence with which the correct application of a normative document can be assessed. This investigation consists, among other things, of assessment of documented technical information and/or physical inspection or testing, depending on the nature of the product and the normative document and/or certification scheme being assessed.

When all activities pertaining to the investigation have been satisfactorily completed and it can be demonstrated on the basis of the evidence that all requirements from the normative document are met, the assessment team issues a positive opinion. The assessment team's report is then reviewed by a qualified colleague who is not involved in conducting the study. Once the report is approved, it is up to a qualified certification decision-maker to determine whether all certification requirements have been met. If the decision is positive, the organisation receives the certificate.

2.3 Investigation team

TÜV NORD Nederland puts together an investigation team with all the necessary qualifications to carry out a full certification cycle. An investigation team¹ consists of one or more inspectors/auditors. Although the investigation team is appointed for a full certification cycle, circumstances may lead to changes being made.

¹ For readability, if only one person is deployed, this regulation still refers to a team.

One inspector from the investigation team acts as the investigation team leader. This inspector is the primary point of contact for the organisation regarding the course of the certification, is responsible for planning the investigation and audit activities and preparing the final report.

An industry (or technical) expert may support the team. This person does not act as an inspector or auditor, but provides the investigation team with advice for preparing, planning or carrying out the activities.

The composition of the investigation team is announced to the organisation at the start of the certification process. Interim changes in the composition will be communicated in a timely manner.

2.3.1 Objecting to members of the investigation team

The client may object to members of the appointed investigation team if a conflict of interest may arise. The organisation must notify the objection in writing to the management of TÜV NORD Nederland within five (5) working days of the announcement of the composition.

2.4 Observers on behalf of TÜV NORD Nederland

The investigation team may be accompanied by an observer. This may be an assessor from the Accreditation Council or a designating body assessing the team's compliance with the rules and procedures applicable to them, within the framework of an accreditation assessment or designation.

The client is contractually obliged to grant access to these observers to carry out their assessment.

The investigation team may also be accompanied by a witness auditor or a trainee, respectively. A witness-auditor is a (fellow) inspector/auditor who observes his or her colleague in the context of assessing qualification to perform inspections/audits. A trainee is an inspector/auditor in training, who, as part of his or her qualification, has to follow a number of inspections/audits with an experienced colleague.

2.5 Surveillance activities

Where the certification concerns a product, which is then produced on an ongoing basis under certification, surveillance activities will periodically assess the certificate holder's compliance with all applicable conditions during the period of validity of the certificate. The scope and frequency are determined on the basis of the nature of the product and the volume of production. At the end of the certificate's validity period, the certificate holder submits a request for recertification to extend the certification.

If the certification concerns a single product, this cycle does not apply.

3 The certificate

On positive completion of the certification process, a certificate is issued.

3.1 Information on the certificate

TÜV NORD Nederland states the following information on the certificate:

1. the name, including legal designation of the organisation;
2. the product to which the certificate relates;
3. the normative document against which the product has been assessed;
4. the scope of the certificate;
5. the certificate number or registration number;
6. the effective date of the current certificate, the end date of the current certificate, the date of issue of the first certificate (if any);
7. the logo of the scheme administrator and/or RVA, and conformity mark of TÜV NORD Nederland.

3.2 Rules for certificate owner

3.2.1 Monitor conformity with the normative document

After receiving the certificate, the certificate owner ensures that continued conformity with the *normative document* is guaranteed. This includes any interim changes communicated by TÜV NORD Nederland, in case the normative document is revised or amended.

TÜV NORD Nederland will perform surveillance on the continued production of the certified product(s). The certificate owner makes all necessary arrangements for

- the conduct of the evaluation and surveillance, including provision for examining documentation and records, and access to the relevant equipment, location(s), area(s), personnel, and client's subcontractors;
- investigation of complaints;
- the participation of observers, if applicable.

3.2.2 Changes in the organisation's registration

The certificate owner may request a change in registration and certification. TÜV NORD Nederland decides whether an additional assessment should be carried out and whether a new application is required.

3.2.3 Communicating changes in the product or process

The certificate owner notifies TÜV NORD Nederland, without undue delay, of any significant changes to the product or manufacturing process.

Following the changes, TÜV NORD Nederland will decide whether further investigation will be carried out or whether the verification cycle needs to be adjusted.

This may involve additional costs. These costs are borne by the certificate owner.

3.2.4 Reporting

One month before the end of the year, the certificate owner shall report on its use of the conformity mark, more specifically:

- advertisements;
- brochures of the entire product portfolio;
- points of sale of the product range.

The certificate owner keeps a record of all complaints made known to it relating to compliance with certification requirements and makes these records available to the certification body when requested, and

- takes appropriate action with respect to such complaints and any deficiencies found in products that affect compliance with the requirements for certification;
- documents the actions taken.

3.2.5 Cooperation with (additional) control activities

The certificate holder shall, without undue delay, fully cooperate with planned inspection activities (see chapter 2) and unplanned inspection activities, such as in response to (persistent) negative publicity or complaints about the certificate holder (see section 3.5).

3.3 Publicity

TÜV NORD Nederland maintains records of certificate holders and may distribute or publish information from these, or provide this information to a scheme manager, the Accreditation Council or the government (in the context of designations).

If the certificate of a certificate holder is temporarily suspended or withdrawn by TÜV NORD Nederland, this decision may be published by TÜV NORD Nederland or passed on to a scheme administrator. TÜV NORD Nederland will grant third parties access to this register upon request.

The certificate holder is allowed to:

- inform relations such as potential customers, clients or authorities of the full and exact details of the registration;
- display the certificate.

The certificate holder is not allowed to:

- imply that the certification covers activities outside the scope of certification;
- use the certification in such a way as to reduce public confidence in TÜV NORD Nederland or the certification scheme or to damage the image of TÜV NORD Nederland.

3.4 Misuse of registration

The certificate holder shall refrain from displaying, applying and using the certificate, the conformity mark of TÜV NORD Nederland and any logos of scheme administrators in the event that:

- The certificate expires, is suspended or withdrawn;
- a major change is made to the product and/or production process which affects the suitability for registration to such an extent that it cannot be accepted by TÜV NORD Nederland in these regulations;
- the certificate holder fails to implement an amendment to these certification regulations issued by TÜV NORD Nederland;
- other circumstances adversely affecting the certificate holder's product and/or process.

3.5 Complaints about a certified product

Interested parties can submit a complaint regarding the certificate owner's product to TÜV NORD Nederland. TÜV NORD Nederland investigates the nature and cause of the complaint submitted. The certificate owner will be informed of this by letter.

If TÜV NORD Nederland considers the complaint to be justified, one or more of the following actions will be undertaken:

- an additional investigation regarding the complaint at/with the certificate owner;
- a verification audit of the certificate owner's management system and/or process;
- suspending or revoking the certificate.

The costs involved are borne by the certificate owner.

TÜV NORD Nederland does not participate in considerations regarding compensation for the financial consequences of proven defects in delivered products that have been certified by TÜV NORD Nederland.

3.6 Suspension or withdrawal of a certificate

3.6.1 Introduction

The Business Unit Manager (or his designated delegate) has the decision-making authority to *suspend* and *withdraw* a certificate.

If prescribed in the certification scheme or other normative document, TÜV NORD Nederland also informs other bodies such as Certification Bodies, Notified Bodies (accredited or designated for the relevant work area), supervisors or the relevant scheme owner with regard to this negative decision.

3.6.2 Suspension of a certificate

3.6.2.1 Reasons for suspension

TÜV NORD Nederland can suspend a certificate for a limited period of time, for example when:

- The certificate owner is unable to demonstrate that adequate corrective measures have been adopted upon reported nonconformities;
- TÜV NORD Nederland takes a negative certification decision;
- incorrect use of the registration, certificate and/or mark of conformity of TÜV NORD Nederland, of the logo of the relevant scheme or the accreditation logo;
- the certificate owner does not fulfil its financial obligations to TÜV NORD Nederland;

- TÜV NORD Nederland is unable to carry out the required assessment activities within the specified period.

3.6.2.2 Procedure for suspension

TÜV NORD Nederland will inform the certificate owner of the suspension of the certificate in a registered letter. This letter states the conditions that the certificate owner must meet in order to have the suspension of the certificate reversed.

The period during which the certificate is suspended is a maximum of six (6) weeks and depends on the stated and described reasons. The letter announcing the suspension will indicate the period applicable in the specific situation.

Once the conditions regarding the stated reasons have been met within the established period, TÜV NORD Nederland will undo the suspension of the certificate and inform the certificate owner accordingly.

3.6.2.3 Reversion of the suspension

To undo a suspension, the certificate owner will take appropriate (corrective and/or remedial) measures without undue delay to enable TÜV NORD Nederland to lift the suspension. The certificate owner approaches TÜV NORD Nederland in writing (on paper or digitally) regarding the proposed measure(s).

TÜV NORD Nederland verifies the measures by means of an audit or inspection on the location of the certificate owner.

3.6.3 Withdrawal of a certificate

3.6.3.1 Reasons for withdrawal

The Business Unit Manager is authorized to withdraw the certificate, and the use of the TÜV NORD Nederland mark of conformity, in the following cases:

- the measures, mentioned in subsections 3.6.2.3 and 3.6.3.2 are not deemed adequate by TÜV NORD Nederland;
- the normative document and/or processes have been changed and the organization cannot demonstrably meet the new requirements;
- the certificate owner does not enable TÜV NORD Nederland to carry out the necessary assessments/inspections within the specified period;
- the certificate owner stops manufacturing the product(s) for more than six (6) months;
- the client/certificate owner does not fulfil its financial obligations to TÜV NORD Nederland;
- on the basis of other reasons, provided that this reason is specifically included in this certification regulation or this reason has been formally agreed between TÜV NORD Nederland and the certificate owner;
- after the evaluation of complaints as specified in section 3.5 of this regulation.

3.6.3.2 Procedure of withdrawal

TÜV NORD Nederland will inform the certificate owner of the withdrawal of the certificate by registered letter. This initially concerns a provisional withdrawal and after one (1) week this withdrawal becomes final.

TÜV NORD Nederland may publish the certificate withdrawal notice. If requested, TÜV NORD Nederland always informs third parties of the current status of a certificate (valid/suspended/withdrawn/restricted).

3.6.3.3 Reversion of withdrawal

The withdrawal of a certificate cannot be undone. If an organization still wishes to demonstrate that it meets all the requirements of the normative document, a completely new certification process must be completed.

4 Use of the Mark of Conformity

After positive completion of the certification process by TÜV NORD Nederland, the opportunity is offered to use the TÜV NORD Nederland *mark of conformity*.

By confirming this agreement, TÜV NORD Nederland grants the certificate owner the right to use the mark of conformity of TÜV NORD Nederland and any other logos after certification and only for the duration of the validity of the certificate. During all audits/inspections following the initial inspection, the correct application of the mark of conformity and of any other logos is verified.

4.1 The TÜV NORD Nederland mark of conformity

The certificate owner may use the mark of conformity of TÜV NORD Nederland in accordance with the provisions of the General Terms and Conditions of TÜV NORD Nederland B.V.

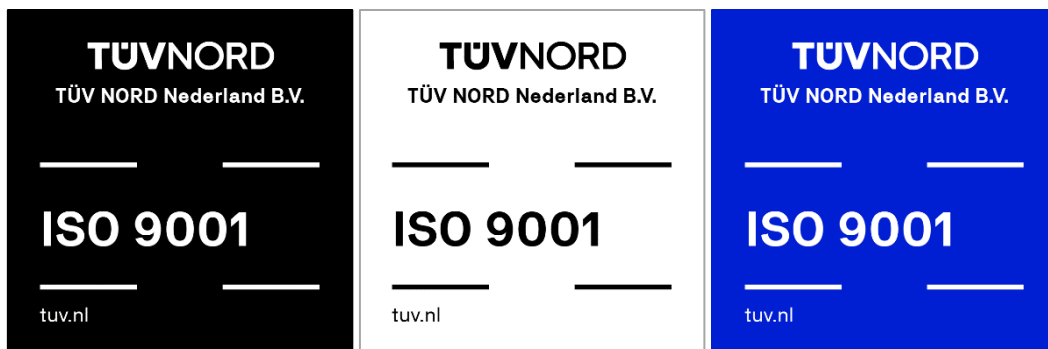
In addition, the following conditions apply:

- Colouring: The conformity mark is produced in colour as standard but may additionally be used in white on black (PMS process black) black on white (always depending on substrate to be printed on) and white on blue (PMS 293 C) by organisations on printed material. The certification mark may not be printed smaller than 2,4 x 2,4 cm on printed material (this is to maintain legibility).
- The conformity mark of TÜV NORD Nederland may only be used in unaltered form. Changes to the mark of conformity and/or the caption on the mark of conformity are not permitted.
- The conformity mark of TÜV NORD Nederland (for products) may not be used in any form in which it could be interpreted as process or management system certification. Examples are: applying the mark of conformity to a website, on a calibration certificate, inspection report, laboratory results, business cards and other document that could suggest that anything but the product was certified.
- The conformity mark may not be used in any form in which it may be interpreted as applying to non-certified (parts of) companies, sites, products, or processes.

If the user is unsure about the correct use, he shall contact TÜV NORD Nederland for further instructions.



Example of the TÜV NORD Nederland mark of conformity



Alternative colour schemes of the TÜV NORD Nederland mark of conformity

4.2 Use of other logos

The certificate owner has to comply with the relevant regulations and rules of the *scheme owners* when using logos of scheme owners.

For schemes without their own regulations or rules, the use of the logo mark is not permitted, other than when displaying the certificate.

The use of the logo of the Dutch Accreditation Council (RvA) is not permitted, other than when displaying the certificate.

The certificate owner is also not allowed to use the (commercial) company logo of TÜV NORD Nederland.

4.3 Termination or revocation of the right of use

TÜV NORD Nederland shall terminate or revoke the right to use the conformity mark if:

- The certificate owner does not notify TÜV NORD Nederland without undue delay of changes or other developments in respect to the assessed product;
- The rules on the use of the conformity mark, regardless in what capacity, are not observed; or
- Conflicts arise, regardless of what kind, with respect to the use of the TÜV NORD Nederland mark of conformity in connection with competition or industrial property laws.

4.4 Termination of the contract

Upon termination of the contract, or upon suspension, withdrawal, or termination of certification, the certificate owner loses the right to link the TÜV NORD Nederland mark of conformity to the assessed product or to use it in any other way for advertising purposes. For each violation the certificate owner forfeits a contractual penalty of € 2,500, whereby the certificate owner shall be obliged to demonstrate that no loss has occurred.

5 Verification activities

Following (re)certification, TÜV NORD Netherlands carries out, in principle, annual inspection activities to check whether the certificate holder effectively maintains compliance with the normative document. Depending on the certification scheme or at the request of the certificate holder, the frequency of inspections should or may be different.

5.1 Planned surveillance audits

5.1.1 Scheduling of surveillance audits

TÜV NORD Nederland will approach the certificate holder's representative approximately three (3) months before the date that the audit activity is to be carried out. The certificate holder shall ensure that the audit can be carried out within the deadlines set for this purpose at the latest. If the certificate holder is unable to do so, TÜV NORD Nederland reserves the right to revoke the certificate, after notifying the certificate holder. A delay in the date of execution of an audit does not affect the date of the next audit to be carried out or the end date of the certificate.

5.1.2 Execution of surveillance audits

The surveillance audit is a random check with the aim of verifying whether the certificate holder's product and/or process is still operational and still meets the requirements in the applicable normative document. This should take into account changes in the organisation.

TÜV NORD Nederland carries out the audit activity remotely or at the certificate holder's site. These are not always audits on the entire product(ion process) and can be scheduled together with other control activities, so that TÜV NORD Nederland maintains confidence that the certificate holder continues to meet the requirements.

5.2 Unanticipated control activities

5.2.1 General

TÜV NORD Nederland may proceed with unplanned inspection activities for the following reasons:

- persistent negative publicity (related to the scope of the certificate) about the certificate holder;
- a notification about a change within the organisation of a certificate holder (see section 3.2);
- complaints about a certificate holder (see section 3.5);
- notices or notifications of investigations / stoppages of certificate holder's activities by the competent authority;
- suspension of certificates (see section 3.6).

Other control activities may include:

- questions from TÜV NORD Netherlands to the certificate holder in connection with elements of certification;
- reviewing the certificate holder's statements in relation to its activities (e.g. promotional material, website);
- requests to the certificate holder to make documented information (paper or digital) available;
- any other means of monitoring the certificate holder's performance;
- conducting a verification audit or inspection.

5.2.2 Execution of verification audits

The management of TÜV NORD Nederland determines in appropriate cases whether a verification audit or inspection is necessary. A verification audit is always announced in writing to the certificate holder. If the certificate holder does not cooperate in the performance of a verification audit, the management of TÜV NORD Nederland reserves the right to suspend and/or withdraw the certificate in question.

6 Terms and definitions

The definitions of ISO 17020 'Conformity assessment - Requirements for the operation of various types of bodies performing inspection' and ISO 17065 'Conformity assessment - Requirements for bodies certifying products, processes and services' apply. Additionally the following definitions and/or notes apply.

6.1.1 Accreditation

An independent confirmation of the expertise, impartiality and independence of a conformity assessment organization, based on (international) harmonized standards.

Note: Part of accreditation is that the Accreditation Council conducts regular audits to determine whether TÜV NORD Nederland complies with the requirements that apply to certification.

6.1.2 (Central) Board of Experts

An independent advisory body that advises on everything relating to the certification of a system and/or process, the requirements to be applied (where applicable), the methods of examination and the regulations for the use of the certificate.

Members of a Board are appointed on the basis of their industry expertise or their specific independent expertise.

6.1.3 Certificate

A declaration of conformity with a normative document, which is provided to the organization, and on which the applicable product specification and normative document are stated.

6.1.4 Certificate holder

The organisation that is responsible for the manufacturing of the certified product.

6.1.5 Certification scheme

A conformity assessment system related to specified products, to which the same specified requirements, specific rules and procedures apply.

Note: Where this regulation refers to scheme or certification scheme, one should also read 'Normative document' (6.1.11).

6.1.6 Designation

A regulation that a lower-ranking person or organization must follow in response to a (political) decision, of a hierarchically high-ranking person, for example a minister, or an important one institution.

Note: TÜV NORD Nederland is designated by the ministry for various subjects to carry out specific (safety) checks against laws and regulations on behalf of the government. Part of these designations is that government agencies such as the NVWA regularly carry out audits to determine whether TÜV NORD Nederland complies with the regulations.

6.1.7 Nonconformity

Non-fulfilment of a requirement

Note 1: In practice, TÜV NORD Nederland has the view that a nonconformity is reported if an investigation does not provide sufficient evidence of compliance. In other words, a nonconformity is a situation where insufficient evidence of conformity is available.

Note 2: An observation of such a nature that it is considered to have a direct negative impact on the integrity, quality or safety of the product(s).
The resolution of a nonconformity by taking effective corrective measures is a condition for certification or retention of the issued certificate.

Note 3: For definitions of nonconformities, the scheme owner (6.1.12) can use an alternative definition. The wording in the certification scheme is leading.

6.1.8 Mark of conformity

The logo with which a certificate owner may communicate that its product has been positively assessed by TÜV NORD Nederland.

Note: The mark of conformity should not be confused with the TÜV NORD company logo. Certificate holders (6.1.4) are not entitled to use the TÜV NORD company logo in any form whatsoever.

6.1.9 Revocation

Certification that has been stopped voluntarily (by the certificate owner) or imposed (by TÜV NORD Nederland).

6.1.10 Client

Party on whose behalf a product assessment for certification is carried out.

6.1.11 Normative document

A document that contains the requirements for a system, process or product and/or service.

Note: A normative document is also called a norm, standard, guideline or assessment guideline.

6.1.12 Scheme owner

Person or organization responsible for developing and maintaining a specific certification scheme. In these schemes they describe the subject of assessment and which requirements apply. Laboratories, inspection bodies and certification bodies use these schemes in the execution of their assessment tasks.

6.1.13 Suspension

The temporary withdrawal of (part of) a certification.
