Regulation

"Regulations governing TÜV Rheinland Nederland agreements for Product Certification"

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1 General

1.1 Definition of Terms

Advisory Board	The independent body set up by TÜV Rheinland Nederland to assess and control the accredited .
Applicant	Formal representative of the Organization, authorized to submit applications for certification.
Assessment Guideline	The list of requirements that the product or system must meet, established by the Advisory Board after proper consultation with all interested parties and that, following acceptance by TÜV Rheinland Nederland, serves as the criterion for the issue of Certificates.
CE marking	Mark used by the Organization or its attorney, indicating that its product is in accordance with European guideline(s) applying to the product.
Certificate	A document issued in accordance with the rules of a certifying system to express legitimate confidence that a clearly described object of certification is in agreement with a given standard or with another standard-setting document.
Certification Agreement	An agreement defining the mutual rights and obligations of an Applicant or Certificate Holder and of TÜV Rheinland Nederland.
Certification System	General system of rules and procedures for monitoring and implementing certification.
Committee of Experts	An independent committee of interested parties that may be set up by the Advisory Board when taking decisions on Assessment Guidelines.
Conformity Certification	Activities on the basis of which an independent body expresses legitimate confidence that a clearly described object of certification is in agreement with a given standard or with another standard-setting document.
Inspection Module	Description of an inspection procedure established by the Commission of the European Union.
Organization	The party marketing the product to be certified and therefor responsible for this product with respect to the Assessment Guideline used for certification.
Quality	The total of properties and characteristics of a product or service playing a part in satisfying specifications required or self-evident requirements.
Quality Requirements	Technical and functional requirements of a product. These may include: (a) Guidelines of the Commission of the European Union, and specifically the fundamental demands included therein; (b) Harmonized European standards; (c) Technical and functional requirements and research methods drawn up and recorded in joint consultation with all interested parties.

Quality System	The Organizational structure, responsibilities, procedures, processes and facilities for quality assurance.
TÜV Rheinland Nederland	The independent legal person engaged in conformity certification and issuing Conformity Certificates, among other responsibilities.
TÜV	TÜV Rheinland Nederland B.V.

1.2 General

1.2.1 These regulations comprise the conditions applying to the product Certification Agreements entered into by TÜV Rheinland Nederland for assessing products, and to the subsequent issue of certificates or statements (hereinafter to be referred to as Certificate) within the framework of European directives for CE marking.

1.2.2 TÜV Rheinland Nederland may conclude contracts with Organizations for performing certification investigations. Such assignments are subject to strict terms and conditions, including confidentiality. Observance thereof shall be checked at least once annually. TÜV Rheinland Nederland reserves all rights of investigation, assessment and decision on whether a Certificate is to be granted.

1.2.3 In principle, TÜV Rheinland Nederland is prepared to grant a Certificate to Organizations whose product and, if applicable, quality system or parts thereof, comply with the EU directive concerned. The conditions governing this right are laid down in the relevant European directives, in the present regulations and in the Certificate at issue, and in all that may have been further agreed upon in writing and explicitly by parties, without prejudice to what may have been further stipulated by law, by order in council or by Government decree concerning CE marking.
If the Organization is represented by an attorney, all aforementioned stipulations and rules shall likewise apply to such attorney.

1.3 Confidentiality

1.3.1 TÜV Rheinland Nederland shall ensure, by any and all means available to it, that all staff members involved in certification shall agree to confidentiality towards third parties about all information which may come to their knowledge in the course of implementing the Certification Agreement.

1.3.2 When consulting external experts, these parties shall sign a pledge of confidentiality as laid down in article 1.3.1.

1.3.3 The Organization shall not be permitted, under any name or title whatsoever, to induce or attempt to induce TÜV Rheinland Nederland staff and other staff employed by TÜV Rheinland Nederland who, in the course of their duties, may have become acquainted with information as a result of implementing the Certification Agreement in the product sector concerned, to act as consultants, nor shall it appoint such staff as its consultants within two years after termination of their employment with TÜV Rheinland Nederland.

1.3.4 TÜV Rheinland Nederland shall provide information to the competent authority, insofar as prescribed by law.

2 Assessment Guidelines

2.1 The Assessment Guideline for products whose conformity to the European safety requirements must be demonstrated, is included in the directives of the Commission of the European Union which are incorporated in the national legislation.
This guideline comprises:
– the demands made upon the product;

– the Inspection Modules to be used for granting Conformity Certificates.

2.2 Harmonized standards may be used in implementing the guidelines.

2.3 During a period that harmonized standards are not available for certain products, the directive of the Commission of the European Commission may serve as a basis. TÜV Rheinland Nederland shall discuss, with similar notified bodies in the same sector, the need for further concentration on the directives of the Commission of the European Union for certain products or product groups.

3 Application and audit conformity certification

3.1 Submitting the Application

3.1.1 If the Organization applies for a Certificate by submitting the application form for Conformity Certification, TÜV Rheinland Nederland will submit a quotation for performing the certification audit, the incurred costs, and any expenses of auditing, produced as a draft contract proposal.

3.1.2 In the application the product to be certified shall be identified by industrial or trade mark and product type number. In the case of the directive of the Commission of the European Union allowing selection from different Inspection Modules, the Organization shall furthermore specify which Inspection Module it has selected.

3.2 Procedure for the Application

3.2.1 After TÜV Rheinland Nederland has received the proposed Certification Agreement, without alteration, duly completed and signed, and including the technical information stipulated in the relevant EU directive, the application will be considered within one month, unless otherwise agreed. The application will only be dealt with after the Organization has paid the advance bill for fifty per cent of the amount of the quotation.

3.2.2 TÜV Rheinland Nederland reserves the right to decline instructions received more than thirty days after the quotation was submitted to the Organization.

3.2.3 If TÜV Rheinland Nederland finds the information provided inadequate, it may visit the Organization for a preliminary investigation, or may inform the Organization that extra information is required. In such case, the application will be considered at a time to be agreed upon.

3.2.4 Subject to any statutory obligations, TÜV Rheinland Nederland shall not inform third parties not involved in the certification procedure about the application and the procedure, unless the Organization has consented thereto in writing.

3.2.5 TÜV Rheinland Nederland, having consulted the Organization, shall establish the procedure for the further treatment of the application, within the framework of the present regulations. After payment of the advance bill, TÜV Rheinland Nederland shall proceed with the application.

3.2.6 During the application and certifcation procedure it is not permitted to applicant or his representatives to suggest to third parties possession of the declaration of conformity issued by TÜV Rheinland Nederland as Notified Body, preliminary to the formal issue of same certificate.

3.3 Certification Investigation

3.3.1 The certification investigation shall be performed in conformity with requirements stated in the EU directive.
The certification investigation, with the objective of demonstrating compliance with requirements of the European legislation, depends on the procedure selected by the Organization. In the case of Inspection Modules being used for product inspection, the

investigation shall be performed as indicated in the sections below. Furthermore, if use is also made of Inspection Modules based on system certification, such part of the investigation shall be performed according to the Certification System for system certification. Any agreement shall explicitly include the system certification.

3.3.2 Sampling will take place on the Organization's premises by or on behalf of TÜV Rheinland Nederland under conditions to be agreed upon.

3.3.3 The Organization shall provide all samples and relevant documentation to TÜV Rheinland Nederland free of charge, as stated in the Product Assessment Plan. These shall remain the property of TÜV Rheinland Nederland, unless the Applicant has requested their return beforehand.

3.3.4 Testing of the samples will be performed by or on behalf of TÜV Rheinland Nederland.

3.3.5 Any business assessment shall be carried out by TÜV Rheinland Nederland and conducted during the regular production of the product.

3.3.6 The business assessment shall contain the items listed in the Quality Requirements.

3.3.7 The company assessment shall not be carried out if the quality system of the production system of the products for which an application for certification has been made, has been granted a system certificate issued by a certifying authority recognized by the Dutch Council for Accreditation or any equivalent organization, unless special inspections require verification.

3.3.8 If the time schedule of the certification procedure at risk of being exceeded, TÜV Rheinland Nederland shall consult the Applicant in good time.

3.3.9 TÜV Rheinland Nederland shall make an interim report for the Organization if the Certification investigation requires it. If the conclusions of the interim report indicate that a positive final result cannot reasonably be expected, the application procedure may be discontinued by mutual consent.

3.3.10 In case of serious stagnation of the certification investigation caused by the Organization failing to meet the time schedule, the Organization shall be informed and TÜV Rheinland Nederland may discontinue the application.

3.3.11 The Applicant may withdraw its application at any time, without prejudice to its obligation to pay the expenses already incurred by TÜV Rheinland Nederland.

3.3.12 TÜV Rheinland Nederland shall report to the Organization within four (4) weeks after completion of the certification investigation. The report shall contain the results of the laboratory study, the business assessment, advice from the product expert regarding the product assessment, and any other relevant facts.

3.3.13 TÜV Rheinland Nederland shall provide the assessment report to the Applicant, who shall be enabled to respond within four (4) weeks after the date of issue.

3.4 Decision regarding the Application

3.4.1 On the basis of the investigation reports, the product expert's recommendations and any comments by the applicant, TÜV Rheinland Nederland shall decide whether the Organization is qualified to receive a Conformity Certificate. TÜV Rheinland Nederland shall communicate its decision to the Organization within four weeks after completion of the certification investigation.

3.4.2 If the results of the certification investigation are negative, TÜV Rheinland Nederland shall decline the application while providing written reasons for such decision.

3.4.3 The provisions of General Administrative Law [de Algemene wet bestuursrecht] shall govern the lodging of objections to the decision referred to in Section 3.3.2. This requires a notice of objection to be submitted to TÜV Rheinland Nederland within six weeks after the date of mailing the decision. The notice of objection shall indicate why the decision was found incorrect. Copies of the decision and of any other documents referring to the case shall be enclosed. In accordance with the provisions of General Administrative Law [de Algemene wet bestuursrecht], TÜV Rheinland Nederland shall decide on the objection.

3.4.4 The provisions of General Administrative Law [de Algemene wet bestuursrecht] shall govern the lodging of appeals against the decision on the objection referred to in Section 3.3.3. This requires an appeal to be submitted to the District Court of the place of residence of the party lodging the objection, within six weeks after the date of mailing the decision on the notice of objection. The appeal shall indicate why the decision was found incorrect. A Court registry fee will be levied for handling the appeal.

3.4.5 If an application has been rejected or if the certification procedure has been prematurely discontinued after mutual consultation, TÜV Rheinland Nederland will accept no new application for the same or a similar product until the Organization has demonstrated that it has taken sufficient measures to improve the product aspects causing discontinuation of the previous application.

3.4.6 Any rejection or suspension of a Conformity Certificate shall, where applicable, be reported to the competent authorities, according to the guideline and the Dutch legislation for implementation.

3.5 Certification Costs

3.5.1 TÜV Rheinland Nederland shall charge the Organization the costs of the certification investigation on the basis of the quotation submitted while deducting the originally invoiced advance. The final invoices shall be paid within thirty (30) days after receipt.

3.5.2 If the Organization fails to settle the (advance) invoices on time, TÜV Rheinland Nederland may suspend or cancel the Certification Agreement. A Certificate shall only be issued after all outstanding invoices have been paid in full.

3.5.3 Unless stated otherwise, all amounts stated in TÜV Rheinland Nederland's tender exclude sales tax.

4 Provisions governing certificates

4.1 Certificate

4.1.1 The granting of a Certificate shall be based on the positive outcome of the certification investigation. The Certificate shall be valid from the date of issue and expire on the date as indicated in the Certificate, except for modifications of the product or the process that affect the investigation requirements for the product or the Assessment Guideline, and subject to termination of the Certification Agreement.

4.2 Obligations of the Organization

4.2.1 The Organization shall ensure that all products supplied by it, produced or assembled by the plants listed in the Certificate, shall meet, upon delivery, the specifications and any other requirements of the directives of the Commission of the European Union.

4.2.2. Upon request the Organization shall provide each client with a copy of the Conformity Certificate at issue.

4.2.3 The Organization shall inform TÜV Rheinland Nederland of any intention to alter conditions (e.g., production or system changes affecting issues stated in the standard or Assessment Guideline) related to the granting of the Conformity Certificate. TÜV Rheinland Nederland shall then decide on the need for an additional certification investigation. If this need arises, TÜV Rheinland Nederland may withhold its authorization to use the Certification Mark on products manufactured under the altered conditions and use the Conformity Certificate for the duration of the follow-up investigation. This ban shall be lifted upon TÜV Rheinland Nederland having informed the Organization of the positive outcome of the follow-up investigation.

4.2.4 Upon request, the Organization shall make available to TÜV Rheinland Nederland the records of all complaints entered by purchasers of the certified product and the resulting corrections.

4.3 Alteration of Assessment Guideline

4.3.1 Following changes in the Assessment Guideline, including the essential demands stated in the directive of the Commission of the European Union, TÜV Rheinland Nederland shall report as soon as possible in writing to the Organization about the nature, the scope and the cost of any supplementary investigation that may be necessary.

4.3.2 In case of the Organization not agreeing with the alterations or the proposed supplementary investigation, it shall report this in writing to TÜV Rheinland Nederland within the period specified. This causes the Certification Agreement to become null and void as from the date on which the altered Assessment Guideline becomes binding upon TÜV Rheinland Nederland.

4.3.3 In the case of the Organization accepting the nature, the scope and the cost of any supplementary investigation, and if the outcome of any supplementary investigation is positive, the Certification Agreement shall be adapted to the alterations where required. If the outcome of any supplementary investigation is negative, the Certification Agreement shall become null and void as from the date the directive of the Commission of the European Union becomes binding.

4.4 CE Marking

The Organization shall provide products with CE marking in accordance with the directive of the Commission of the European Union. Only in case TÜV Rheinland Nederland plays a part in the stage of production monitoring, as referred to in the Decree of the Council of the European Union of 22 July 1993 (EEC/93/465), is the CE marking to be followed by the identification number of TÜV Rheinland Nederland, which is 0336.

4.5 Fees

4.5.1 The Organization shall pay TÜV Rheinland Nederland a fee for the right to use the Certificate as well as the costs of setting up and maintaining the certification procedure for the product or product group at issue and the investigation. Payment of such fee shall be due on TÜV Rheinland Nederland's invoice.

4.5.2 The amount of the fee shall be determined by TÜV Rheinland Nederland

4.6 Audits

4.6.1 If required by the Assessment Guideline or the Inspection Module selected, TÜV Rheinland Nederland shall ensure through periodic audits that the Organization continues to comply with the requirements. The audits shall be carried out by or on behalf of TÜV Rheinland Nederland.

4.6.2 The Organization shall fully cooperate with any audits. It shall provide TÜV Rheinland Nederland with the required samples, equipment, and information, free of charge, and shall grant inspection of the records of complaints about the certified product.

4.6.3 The severity of any deviations revealed by an audit shall determine whether or not TÜV Rheinland Nederland will impose disciplinary measures.

4.6.4 In case of deviations, as referred to in Section 4.6.2, the Organization shall indicate and specify any corrective measures taken and the procedures followed for any deviating goods or products.

4.7 Complaints

4.7.1 The Organization shall record and immediately inform TÜV Rheinland Nederland of serious or structural purchasers' complaints about the certified products, acting in accordance with legal rules. The Organization shall record any and all complaints and the corrective measures taken with respect to the product for which a Certificate has been granted.

4.7.2 Any complaints found to be justified may result in a further discussion between TÜV Rheinland Nederland and the Certificate Holder about modifications of the product and revision of the internal quality control system or the quality system, and, if necessary, in disciplinary measures.

4.8 Disciplinary action

4.8.1 TÜV Rheinland Nederland, upon finding reason therefor, may institute disciplinary action against the Certificate Holder. Such action shall be communicated to the Organization in writing and may comprise:
– a written notice, with or without:
– follow-up audits with appertaining financial consequences.

4.8.2 The Certificate Holder may submit an appeal to the Board of Appeal against the decisions of TÜV Rheinland Nederland within thirty (30) days after receipt of the notice according to Section 4.8.1, in accordance with the provisions of the General Administrative Law Act [de Algemene wet bestuursrecht].

4.9 Termination and Suspension

4.9.1 Except for the provisions of Section 4.9.2, termination of the Certification Agreement may only take place on the final day of any month, subject to three-month notice.

4.9.2 If either party has seriously failed in the performance of one or more obligations of the Certification Agreement and the conditions laid down therein, the other party shall be entitled to terminate with immediate effect the Certification Agreement because of this mere fact.

4.9.3 In case of one party wishing to terminate the Certification Agreement, this party shall notify the opposite party in writing, stating reasons, while mentioning the date on which termination is to be effective, thus canceling the Certificate.

4.9.4 Canceling shall leave unimpaired the Organization's financial obligations toward TÜV Rheinland Nederland. Also, after termination, TÜV Rheinland Nederland's confidentiality shall remain in force.

4.9.5 In the event of the Organization failing to meet its obligations, TÜV Rheinland Nederland may decide, without prejudice to the provisions of Section 4.9.2, to suspend the Certificate Holder's right to use TÜV Rheinland Nederland's product Certificate or Certification Mark. TÜV Rheinland Nederland's decision to suspend shall become effective upon TÜV Rheinland Nederland's notice to the Certificate Holder, by registered or certified mail, while stating its

reasons.

4.9.6 On satisfactory evidence being provided that the previously observed failure of compliance with obligations has been permanently removed by the Organization, TÜV Rheinland Nederland shall lift the suspension.

4.9.7 TÜV Rheinland Nederland shall be entitled to publish its decision to terminate the Certification Agreement and to suspend the Organization's right to use the TÜV Rheinland Nederland Certificate in any media it considers appropriate.

4.9.8 On termination of the Certification Agreement as well as on suspension of the Organization's right to use the Conformity Certificate granted by TÜV Rheinland Nederland, the Organization shall refrain from any use thereof as from the date that the termination or suspension became effective and shall not in any way convey the impression that it is still entitled to such use, all this subject to an immediate penalty of € 12,500 (twelve thousand five hundred euros) in the event of a violation of this stipulation, plus € 2,500 (two thousand five hundred euros) per day for each day of such violation.

4.9.9 Within thirty (30) days after receipt of the notification referred to in Sections 4.9.2 and 4.9.5, the Organization may appeal to the Board of Appeal against TÜV Rheinland Nederland's decision of termination or suspension, in accordance with the provisions of the General Administrative Law Act [de Algemene wet Bestuursrecht].

4.10 Publicity

4.10.1 The Organization shall be permitted to publicize its right to use the Conformity Certificate for the products referred to in the Certification Agreement concluded with it. For publications that connect TÜV Rheinland Nederland in any other way with these products, the Organization shall require TÜV Rheinland Nederland's permission.

4.10.2 The content of reports and other documents shall only be made available to third parties unabridged and in the original language. Prior written permission of TÜV Rheinland Nederland shall be required in all cases, with the exception of cases in which statutory obligations must be complied with.

4.11 Liability

4.11.1 TÜV Rheinland Nederland shall not be liable for any loss incurred by the Organization resulting from the use of a Certification Agreement or its termination, or in the event of TÜV Rheinland Nederland showing culpable negligence in implementing its obligations for direct losses to the client up to a maximum of the amount owed by the client for the certification procedure.

4.11.2 The Certificate Holder shall hold TÜV Rheinland Nederland harmless against any claims by third parties regarding defects in products supplied by the Organization under the TÜV Rheinland Nederland Conformity Certificate.

4.12 Objections and Appeal

4.12.1 TÜV Rheinland Nederland performs Conformity Certification under its appointment by the Dutch Government as a Notified Body. The implementation of this delegated government task is governed by the General Administrative Law [de Algemene wet Bestuursrecht]. Objections and appeal may be lodged according to the provisions stated in Chapters 6 and 7 of the General Administrative Law [de Algemene wet Bestuursrecht].

4.12.2 The Board of Appeal, as part of the Organization of TÜV Rheinland Nederland, pursuant to Section 4.12.1, does not have any competence in matters of Conformity Certification.

5 FURTHER TERMS AND CONDITIONS

5.1 Any dispute arising between parties in connection with the Certification Agreement, or as a result of other agreements arising therefrom, that cannot be settled by mutual consent or not governed by the General Administrative Law Act [de Algemene wet Bestuursrecht], shall be settled by the competent judge in The Hague.

This does not affect in any way the powers of the Organization to appeal to administrative justice in regard to TÜV Rheinland Nederland's decisions on certification.

5.2 Any disputes shall be governed by the law of the Netherlands.

5.3 These conditions may be referred to as TÜV Rheinland Nederland's Regulations governing Conformity Certification.

5.4 TÜV Rheinland Nederland reserves the right to alter these conditions. Organizations having concluded a Certification Agreement shall be kept informed of any alterations in the regulations if these alter the conditions of their Certification Agreement. Organizations not agreeing with the alterations shall be deemed to have terminated their Certification Agreement, whereupon TÜV Rheinland Nederland will cancel the Certificate.

5.5 The present regulations shall be effective as from 29 May 2002, thereby causing all earlier versions to become null and void.