

Testing and Certification Regulations of TÜV Rheinland Japan Ltd.



1. Scope of Application

- (1) The Testing and Certification Regulations govern all testing and certification services of TÜV Rheinland Japan Ltd. ("TRJ"), renders for manufacturers or other parties for product testing, product certification, and related services for manufacturing sites and quality management systems.

2. Contractual Basis

- (1) The ordering party, hereinafter referred to as "Client", places an order directly with TRJ, or with a subsidiary of TÜV Rheinland AG, hereinafter referred to as "subsidiary"
- (2) When the order includes a certification (see Clause 3. Types of Certificates), "General Agreement" must be concluded between TRJ and the client.
- (3) Tests are generally carried out in the laboratories of TRJ, in a subsidiary or in laboratories bound by contract with TRJ.
- (4) TRJ adheres to ISO/IEC 17065 ("Conformity assessment - Requirements for bodies certifying products, processes and services") and ISO/IEC 17025 ("General requirements for the competence of testing and calibration laboratories"). Also TRJ adheres as a "Third Party Certification Body" based on the PMD Act, to ISO/IEC 17021-1 ("Conformity assessment-Requirements for bodies providing audit and certification of management systems").
- (5) Only the Client as the license holder (licensee) has the right to use the mark of conformity. The transfer of this right to any other party is not permitted.

3. Types of Certificates

- (1) On the basis of the favorable assessment and evaluation of test and audit reports the certification body of TRJ issues the following certificates:
 - (a) Product certificates according to the international IECEE Agreement (CB Scheme) in its capacity as a „National Certification Body“ (NCB).
 - (b) Certification of Specially Controlled Medical Devices etc. according to the Pharmaceuticals and Medical Devices Act (PMD Act), Article 23-2-23 (Certification to Market Designated Specially Controlled Medical Devices etc.) and "Kijyun-Tekigo" Certification according to the Pharmaceuticals and Medical Devices Act (PMD Act), Article 23-2-24 (Issuance of "Kijyun-Tekigo" Certification etc.), in its capacity as a "Third Party Certification Body".
 - (c) Certificate of Conformity according to the DENAN law in its capacity as a "Registered Conformity Assessment Body" (RCAB).
 - (d) Certificate of design for terminal equipment according to the Telecommunications Business law, Article 56, and Type approvals to the technical regulations to the telecommunications Business law, Article 53, as a "Registered Accreditation Body" of Telecommunication Business Act.
 - (e) Certificate of technical regulations conformity for the special radio equipment according to the Radio Act, Article 38-6-1, and Certificate of production design for special radio equipment according to the Radio Act, Article 38-24-1, as a "Registered Certification Body" of Radio Act.
 - (f) Japanese S-Mark licenses.
 - (g) Telecom-Mark licenses.
 - (h) Photovoltaic Modules and PV Power Plant licenses.
 - (i) Other Licenses and Certificates of Conformity to certify that a product is in conformity with specified requirements.

4. Rights and Obligations

- (1) The Client affirms the obligations:
 - (a) That the certified products specified in the license is and will be in compliance with applicable requirements stated in the standards and the general and specific rules specified in the license. To always fulfil the certification requirements, including implementing appropriate changes when they are communicated by TRJ.
 - (b) The certified product continues to fulfil the product requirements if the certification applies to ongoing production.
 - (c) To make all necessary arrangements for:
 - 1) the conduct of the evaluation and surveillance (if required), including provision for examining documentation and records, and, without prior notification, access to the relevant equipment, location(s), area(s), personnel, and Client's subcontractors.

- 2) investigation of complaints.
 - 3) the participation of observers, if applicable.;
 - (d) To make claims regarding certification consistent with the scope of certification. Not to make or permit any misleading statement regarding its certification To amend all advertising matter when the scope of certification has been reduced. Not to allow reference to its management system certification to be used in such a way as to imply that TRJ certifies a product (including service) or process that are outside the scope of certification. Not to imply that the certification applies to activities and sites that are outside the scope of certification;
 - (e) Not to use its product certification in such a manner as to bring TRJ into disrepute or losing public trust and not to use or permit the use of a certification document or any part thereof in a misleading manner.
 - (f) Upon suspension, withdrawal, or termination of certification, to discontinue its use of all advertising matter that contains any reference thereto and takes action as required by the certification scheme (e.g. the return of certification documents) and takes any other required measure.
 - (g) If providing copies of the certification documents to others, the documents shall be reproduced in their entirety or as specified in the certification scheme.
 - (h) To comply with the requirements as specified in the certification scheme when making reference to its product certification in communication media such as Internet, documents, brochures or advertising.
 - (i) To comply with any requirements that may be prescribed in the certification scheme relating to the use of marks of conformity, and on information related to the product.
 - (j) To keep a record of all complaints made known to it relating to compliance with certification requirements and make these records available to TRJ when requested, and
 - 1) take appropriate action with respect to such complaints and any deficiencies found in products that affect compliance with the requirements for certification.
 - 2) document the actions taken.
 - (k) To notify TRJ, without delay, of changes that may affect its ability to conform with the certification requirements. This includes changes in;
 - the legal, commercial, organizational status or ownership,
 - organization and management,
 - modifications to the product or the production method,
 - contact address and production sites,
 - major changes to the quality management system.Any intended relocations of inspected manufacturing premises or the intended transfer of its firm to another firm or another firm owner shall be notified promptly. If changes are made to the company name, address or legal form, a new General Agreement must be signed and certificates shall be drawn up again at the Client's expense.
 - (l) To pay fees for participation in the certification system and the issue of certificates. License fees, graded in units, shall also be paid annually for maintaining and filing of the certificates and for the use of test marks.
 - (m) For certificates based on the PMD Act, the scope of clause (e) and (h) apply also on certification of management systems.
- (2) The Client has the right:
 - (a) To publish the fact that he has been authorized to label the products or quality management systems to which the license applies.
 - (b) To complain to or raise an objection with the management of TRJ, if he is not satisfied with decisions of the certification body made during the test, audit or certification procedure. TRJ will give the Client its decision and justification. If these reasons are not acceptable to the Client and no final decision can be reached with the management of TRJ, the Client is free to call on the Governing Board, the accreditation body or take legal actions.
 - (3) If the requirements applying to the products covered under this agreement are modified, TRJ should inform the applicable licensees among its Clients, stating at what date the modified requirements will become effective and a transition time will end, and advising the Client of any need for a supplementary examination of the products. Within a given time after receipt of the advice, the Client shall inform TRJ whether he is prepared to accept the modifications and decide on option a) or b):
 - (a) The Client confirms acceptance of the modified requirements. If the result of any supplementary examination is favorable, the certification body will issue a supplementary license or make other modifications of the certification body's records.

- (b) If the Client advises TRJ that he is not prepared to accept the modification or if the Client allows the term for acceptance to lapse, or if the result of any supplementary examination is not favorable, the license covering the particular product shall cease to be valid on the end date of the transition time to the modified specifications, unless otherwise decided by the certification body.
- (4) TRJ or the subsidiary reserves the right to publish the corporate names of Clients who hold certification. A special consent of the Client to this is not required.

5. Test Samples and Documentation

- (1) After placing the order, the client shall supply TRJ or the commissioned subsidiary with the amount of test samples needed, free of charge.
- (2) The client shall cover any additional expenses incurred by submitting incomplete test documentation, or by re-testing and delayed testing due to delayed, incorrect or incomplete information or improper assistance by the client.
- (3) TRJ or the subsidiary shall only be liable for damages to or the loss of test samples that are the result of burglary, theft, water, fire or transport if they act with gross negligence.
- (4) TRJ or the subsidiary shall not be liable for the damage or destruction of test samples or outer packaging as a result of testing.
- (5) The costs of the handover and dispatch of the test samples for storage on the client's premises are borne by the client.
- (6) TRJ or the subsidiary will be liable for the loss of test samples or reference samples from the laboratories or warehouses of TRJ or the subsidiary only in case of gross negligence.
- (7) The retention period for the documentation shall be 10 (ten) years after the expiry of the test mark certificates or shall meet the applicable legal requirements.

6. Surveillance

- (1) TRJ carries out continuing surveillance of the Client's conformity with the accepted requirements and obligations. While an annual inspection is assumed as a minimum, the actual inspection interval depends on the type of certificate. At least one of the products covered by the certification must be presented during the factory inspection. If none of the products covered by the certification can be presented, TRJ decides, whether a different or an additional surveillance method must be applied.
- (2) This surveillance is carried out by TRJ employees or by employees of the subsidiary.
- (3) If nonconformities come to the knowledge of TRJ, this may lead to reduction of the inspection intervals, to suspension or to withdrawal of the license.

7. Expiration, Suspension or Withdrawal

- (1) Certificates and Licenses which carry an expiration date shall automatically become invalid if not duly extended before.
- (2) Suspension may apply for a limited time in the following cases:
 - (a) If surveillance shows nonconformity with the requirements of such nature that immediate withdrawal is not necessary.
 - (b) If a case of improper use of the certificate or the mark (e.g. misleading publications or advertisement) is not solved by appropriate corrective actions by the Client in due time.
 - (c) After the Client obtained agreement from TRJ for a limited period of non-production or for other reasons.
 - (d) If there has been contravention of the requirements of the certification scheme or actions bringing the certification scheme or the certification body into disrepute.
- (3) A certificate or license shall be withdrawn in the following cases:
 - (a) If the surveillance shows serious nonconformity (e.g. the certified product is hazardous).
 - (b) In case of suspension, if the actions taken by the Client are inadequate.
 - (c) If it has been confirmed that Pharmaceuticals and Medical Devices Act (PMD Act), Article 23-4 "Cancellation etc. of Certification" is applicable for the Specially Controlled medical device etc. certified under the PMD Act, Article 23-2-23 (Certification to Market Designated Specially Controlled Medical Devices etc.).
 - (d) If the Client fails to settle financial obligations in due time.
 - (e) If there is any other contravention of the licensing agreement.
- (4) Advice of suspension or withdrawal shall be sent by TRJ by registered letter (or equivalent means) to the Client, stating the reason and date of the termination of the license. Before declaring a certificate, suspended, withdrawn, restricted or invalid, TRJ gives the Client the opportunity to

state his views, unless such a hearing is impossible owing to urgency of the actions to be taken.

- (5) The holder of the certificate automatically forfeits the right to continue to label the products listed in the certificate with test marks of TRJ for products which are affected by the restriction or suspension or which have expired by notice of termination on a particular date or have been declared invalid at short notice.
- (6) Amendments or cancellations which are to be taken into account in the calculation of the license fees for the following calendar year must be received by TRJ by 15 November of the current year.

8. Payment

- (1) The Client shall pay to TRJ all expenses quoted in relation to the surveillance, including sampling, test, assessment and administration cost as outlined in the Guideline on Fees and Dues of TRJ.
- (2) If a certificate is terminated or cancelled in the course of the year, no proportional reimbursement of the license fees shall be made.

9. Confidentiality

- (1) TRJ ensures that confidentiality is maintained by its employees concerning all confidential information with which they become acquainted as a result of their contacts with the Clients.
- (2) The Client accepts that TRJ is entitled, by virtue of reporting obligations imposed by law or by authorities, to pass on information about the certification which has come to its knowledge. At the request of an authority, such as an Accreditation Body, information, documentation etc. concerning both the contract with the Client and the subject of the contract may be passed on to the Accreditation Body. This includes, in particular, information about the performance of audits, the granting and withdrawal of licenses, attestations, certificates, etc. and incidents which occur and risks indirectly or directly connected with the tested products and/or management systems. TRJ reserves the right to debit to the Client's account the cost incurred for identifying and clarifying such incidents.

10. Liability

- (1) The liability of TRJ for all damage in connection with a contract for personal injury and damage to property, unless the damage was caused by premeditation, intent or gross negligence shall be limited to:
 - (a) in the case of contract with a fixed overall fee, ten times the overall fee for the entire contract;
 - (b) in the case of framework agreements that provide for the possibility of placing individual orders, to an amount equal to three times the fee for the individual order under which the damage occurred. The maximum liability of TRJ is limited in any event of damage or loss to 2.5 Mio Euro (or the equivalent in Japanese Yen).
- This limitation on liability shall not apply to the absence of guaranteed qualities.
- (2) The limitation on the liability of TRJ shall be similarly applicable to its employees, agents, managerial staff, and constituent bodies.
 - (3) The limitation period for compensation claims shall be in accordance with the statutory provisions.
 - (4) TRJ is not liable for any damage the Client may suffer as a result of the non-granting, suspension or withdrawal of a certificate.

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