Terms and Conditions of Certification (TÜV Rheinland Malaysia Sdn. Bhd.)

I. General Terms and Conditions of Certification

1. Scope

1.1 These Terms and Conditions of Certification apply to the agreed certification services plus any ancillary services provided within the scope of contract performance and any other ancillary duties.
1.2 These Terms and Conditions of Certification prevail over our General Terms and Conditions of Business.
1.3 The client's General Terms and Conditions of Business, including the client's terms and conditions of purchasing, if any, shall not apply and shall hereby be expressly excluded. Terms and conditions by the client will not become part of this contract even if not expressly excluded by us.
1.4 For the purpose of these Terms and Conditions of Business, the term "Accreditation Body" will also include approval and recognition bodies and the terms "Accreditation Rules", "Accreditation Requirements" and "Accreditation Procedures" will apply mutatis mutandis also to the procedures of these bodies.

2. Scope of services

2.1 We assess and certify systems and products of manufacturers and service providers as per national or international standards for which we hold accreditations, approvals or recognitions ("accredited certification") or as per national or international standards for which we do not hold accreditation ("standard certification") and also provide own third-party certification services ("in-house standards").
2.2 The agreed services shall be provided in line with the generally accepted rules of technology and in compliance with the regulations applicable at the time of contract conclusion. Unless otherwise agreed in writing or unless a certain approach is compulsory on the basis of mandatory regulations, we shall also be authorized, at our reasonable discretion, to make our own decision concerning the method and type of assessment.
2.3 We carry out accredited certification as per the standard agreed in the contract and/or the rules and regulations referred to therein, including the generally applicable accreditation standards pertaining to the specific certification standard, the certification standards plus all relevant application guidelines and the accreditation requirements defined by the competent accreditation body. Should the audit reveal that a higher number of auditor days will be necessary to comply with the accreditation requirements, the client shall bear any additional costs incurred thereby, unless we are to blame for these additional costs.
Standard certifications are carried out in line with the respective national or international standards.
Certification procedures to issue in-house certificates are carried out in line with the rules and regulations established by us.
2.4 If certification is completed with a positive result, the appropriate certificate will be issued as set forth in Article 3 of these General Terms and Conditions of Certification. 2.5 The client shall be entitled to object to the appointment of certain auditors or technical experts, provided the client has and submits good reasons for objection.
2.6 The client's approval shall be obtained before auditors who are not permanently employed with TÜV Rheinland Group (external auditors) are appointed to and used in the audit team. Approval shall be deemed granted if the client has not objected to the use of external auditors within one week of being notified of the external auditor's appointment to the audit team.
2.7 For accredited certification processes, the client agrees that the accreditation body's or standard owner's assessors may verify the client's documentation and may participate in monitoring of the audit.
2.8 In cases of complaints and appeals against progress or the content of our auditing or certification process, the Governing Board or an arbitration committee may be called in with the client's approval.

3. Scope of right of use of certificates and certification marks

3.1 If the agreed certification procedure is completed successfully, we will issue the corresponding certificate to the client. The certificate shall be valid for the period defined in the contract or, if not defined there, in our Special Terms and Conditions of Certification.
3.2 Upon being issued with the certificate as outlined in Article 3.1 above, the client shall be granted the simple, non-transferable and non-exclusive right to use the certification mark throughout the defined certificate validity as outlined in Articles 3.3 to 3.15 below. This also applies to certification references in communication media, such as documents, brochures or advertising materials.
3.3 The permit to use the certificate and a certification mark issued by us shall apply exclusively to the areas of the client's organization quoted in the certificate's scope of application. Use of the certificate and/or the certification mark for areas not quoted in the scope of application shall be prohibited.
3.4 Certification marks relating to management system certification may only be used by the client in direct connection with the name or logo of the client's organization. They may not be attached or used in reference to the client's products. This also applies to product packaging, laboratory test reports, calibration notes or inspection reports.
3.5 The client undertakes to use the certificate and/or the certification mark only to make a statement about the client's organization or the certified area of the client's organization which is in line with certification. The client shall further avoid creating the impression that certification is an official inspection and/or that system certification is a form of product testing.
3.6 The client shall not be authorized to change the certificate or the certification mark.
3.7 The client undertakes to demonstrate in its advertising and similar materials that certification is voluntary and carried out on the basis of a civil law contract.
3.8 The right of use shall expire if the client no longer holds a valid certificate, in particular if the certificate's period of validity has expired or the required surveillance audits have not been carried out.
3.9 The client's right to use the certificate and/or the certification mark shall expire with immediate effect, without requiring termination, if the client uses the certificate and/or the certification mark in violation of the provisions set forth in Articles 3.1 to 3.8 above or contrary to other terms of this contract.
3.10 The client's right to use the certificate and/or the certification mark will end in the period agreed in the event of an effective ordinary termination, or with immediate effect in the event of a justified extraordinary termination for good cause.
3.11 The right of use shall also expire automatically if maintenance of the certificate is prohibited by administrative regulations or court.
3.12 In cases involving expiry of the right of use, the client shall be obligated to return the certificate to us without delay.
3.13 In cases involving violation of contractual terms and conditions we reserve the right to claim damages.
3.14 The certification must not have the effect of bringing us into disrepute.
3.15 The client shall not be entitled to make statements about certification which we may consider unauthorized and misleading.
3.16 If it is foreseeable that the client is temporarily unable to fulfil the certification requirements, the certification can be suspended. During certificate suspension, the client may not use the certification in its advertising. in the list of certified organizations as outlined in Article 7, the status will be updated to "suspended".
3.17 If the reasons for suspension are not remedied within the agreed period of time, the certificate will be withdrawn.
3.18 The client is obliged to keep a record of the use of the certificate in business dealings. It should be noted that we are bound by the standards to monitor proper use by ways of random sampling. Information from third parties will be checked by us.
3.19 The client shall inform us immediately if it discovers that a third party is improperly using its certificate.
3.20 The client provides certification documents to others only in their entirety or as specified in the certification scheme.

4. Client's obligation to participate and general rules for the certification audit

4.1 The client shall submit all information required for certification as per the relevant standard. This information can be submitted by completing the "Questionnaire for offer preparation ".
4.2 The client shall submit all required documents to the Certification Body in good time prior to the audit and free of charge. Required documents include, in particular:

- Management system documentation
- Cross-reference matrix (standard elements cross-referenced to the management system documentation of the organization)
- Organizational plan/organizational chart
- Presentation of processes and their interfaces and interactions – list of controlled management documents
- List of official and legal requirements
- Other documents mentioned in the quotation

4.3 The client shall disclose all records associated with the scope of application to our audit team and/or our auditor and shall grant them access to the organizational units concerned.
4.4 The client shall appoint one or several Audit Representatives who shall support our auditor in performing the contractually agreed services and act as the client's contact persons.
4.5 Following certificate issue, the client shall be obliged, throughout the term of the contract, to communicate all changes which significantly affect the management system or the certified product, including in particular:

- changes in the certified management system.
- changes associated with the design or specification of the certified product.
- changes in the organizational structure and the organization itself.

4.6 The client shall be obliged to record all complaints from outside the company regarding the management system, for example from customers, and all complaints addressed to the client regarding the conformity of a certified product or process with the requirements of the certification standards, and to take appropriate measures, document the actions taken and demonstrate these upon request to us or to the auditor during the audit.
4.7 On request, the client shall be obliged to submit all correspondence and all measures associated with normative documents and the requirements set forth in the applicable certification standard to the auditor during the audit.

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4.8 If, within the scope of product certification, we notice that the changes outlined under Article 4.5 above necessitate further assessments, the client shall not, after the changes have come into effect, release any products falling under the scope of product certification until the client has been notified by us that it is safe to do so.
4.9 In cases involving product certification, the client shall notify us if the product no longer satisfies product certification requirements.
4.10 Not applicable, included in Chapter 4.6.
4.11 The client and we may agree on the performance of a preliminary audit and jointly define the scope of such audit.
4.12 The effectiveness of the established management system shall be verified during the on-site audit carried out at the organization, during which the organization proves that it applies its documented procedures in practice. Standards or standard elements that are not complied with and for which the organization must provide corrective action shall be documented in non-conformity reports.
4.13 At the end of the audit, the audit result will be communicated to the client in a closing meeting and subsequently documented in an audit report. Non-conformities will be documented and may lead to a re-audit (i.e. a repeated on-site audit) or submission of revised documentation, if required by the results. The scope of the re-audit will be decided by the lead auditor. The re-audit focuses exclusively on those elements of the standard for which non-conformities were identified.
4.14 "Certificates" means all regulatory approvals listed below, e.g. official records, statements of validity, and certificates in the narrow sense of the word. "Certification" means all evaluation, auditing, validation and certification processes. After positive review of the certification documentation, we will issue the certificate(s). The certificate(s) will be sent to the client. The certificate(s) shall only be issued if all non-conformities have been corrected. The certificate(s) shall be issued for the defined period.
4.15 To maintain validity of the certificate, on-site surveillance audits shall be carried out depending on the standard in question. Unless the surveillance procedure, including a positive decision on certificate maintenance, is completed by the Certification Body, the certificate shall become invalid. In this case, all copies of the certificate must be returned to the Certification Body.
4.16 In the surveillance audit, the key elements of the standard shall be verified as a minimum requirement. Additionally, surveillance audits evaluate proper use of the certificate (and the certification mark, where appropriate), complaints related to the management system and the effectiveness of corrective action taken to address nonconformities. Each surveillance audit shall be documented in a report communicated to the client.
4.17 The geographical (e.g. additional branches) and technical (e.g. additional products) scope can be extended and/or certification upgraded to include further standards within the scope of surveillance or re-certification audits and/or separate extension or upgrade audits. The number of auditor days required for extension or upgrade shall depend on the scope of extension or upgrade which shall be clearly defined by the organization prior to the audit.
4.18 Should changes in the details on which the procedure is based (e.g. details of the organization, accreditation requirements) arise during the term of the contract, these changes must be appropriately considered in the procedures and the other contracting party informed without delay. The same applies to any changes in the number of auditor days for certification resulting from such changes.
4.19 Integrated management systems covering various standards and requirements may be certified by means of a combined certification procedure. Depending on the standards and requirements involved, these combined certifications will be offered individually.
4.20 The costs incurred for additional efforts caused by unscheduled audits or re-audits and the verification of corrective actions to eliminate non-conformities revealed in previous audits shall be borne by, and invoiced to, the client on a time and cost basis. The same applies to costs incurred for short-notice special audits as defined in Article 1.4 of the Special Terms and Conditions of Certification.

5. Confidentiality
5.1 For the purpose of this agreement, "confidential information" is defined to include all information, documents, images, drawings, know-how, data, samples and project documentation which one party ("disclosing party") hands over, transfers or otherwise discloses to the other party ("receiving party"). Confidential information also includes hardcopies or electronic copies of such information.
5.2 The disclosing party shall mark all confidential information disclosed in written form as confidential before passing it on to the receiving party. The same applies to confidential information transmitted by e-mail. If confidential information is disclosed orally, the receiving party shall be appropriately informed in advance.
5.3 All confidential information which the disclosing party transmits or otherwise discloses to the receiving party
a) may only be used by the receiving party for the purposes defined above, unless expressly otherwise agreed in writing with the disclosing party;
b) may not be copied, distributed, published or otherwise disclosed by the receiving party. An exemption from the above rule applies to confidential information, which must be passed on to supervisory and/or accreditation bodies within the scope of an accreditation procedure;
c) must be treated by the receiving party with the same level of confidentiality as the receiving party uses to protect its own confidential information, but never with less than the objectively required due diligence.
5.4 The receiving party shall disclose any confidential information received from the disclosing party only to those of its employees who need this information to perform services required for the subject matter of this contract. The receiving party undertakes to place these employees under the obligation to observe the same level of secrecy as that set forth in this non-disclosure clause.
5.5 Information for which the receiving party can furnish proof that
a) it was generally known at the time of disclosure or has become general knowledge without violation of this agreement, or
b) it was disclosed to the receiving party by a third party entitled to disclose this information, or
c) the receiving party already possessed this information prior to disclosure by the disclosing party, or
d) the receiving party developed it itself, irrespective of disclosure by the disclosing party;
shall not be deemed confidential information as defined in this agreement.
5.6 All confidential information shall remain the property of the disclosing party. The receiving party hereby agrees to immediately (i) return all confidential information, including all copies, to the disclosing party, and/or, on request by the disclosing party, to (ii) destroy all confidential information including all copies, and confirm the destruction of this confidential information to the disclosing party in writing, at any time if so requested by the disclosing party but at the latest and without special request after termination or expiry of this contract. Excluded from the above shall be all reports and certificates which we, in performance of our contractual obligations hereunder, prepared exclusively for, and which remain with, the client. We are entitled, however, to retain copies of these reports and certificates and of any underlying confidential information to furnish proof that our results are correct and to fulfil general documentation purposes.
5.7 From the start of this contract and for a period of five years after termination or expiry of this contract, the receiving party shall maintain strict secrecy of all confidential information and shall not disclose this information to any third parties or use it itself.

6. Termination
6.1 Both contracting parties shall be entitled to terminate this contract observing a period of 6 months to the end of the contractually agreed term.
6.2 We are also entitled to terminate the certification contract without notice for important reason.
6.3 For the purpose of this contract "important reason" for us shall be defined as follows
a) The client fails to notify us without delay of any changes or indications of changes in the organization which are relevant for certification,
b) The client misuses a certificate and/or certification mark or uses them contrary to the contract,
c) Insolvency proceedings are opened in respect of the client's assets or an application for such insolvency proceedings is rejected due to lack of assets,
6.4 In addition to the above, we shall be entitled to terminate the contract without notice, should the client be unable to comply with the time periods we scheduled for auditing/service provision as applicable to a certification procedure and should withdrawal of the certificate consequently be necessary (e.g. conducting of surveillance audits).

7. List of certified organizations
7.1 TÜV Rheinland Malaysia is obliged to hold a directory of certificate holders which includes the following information: name of certificate holder, applicable standards documents, scope of validity, geographical location (for multiple site certifications: geographical location of the head office and each location within the scope of validity).
7.2 Suspended certifications according to Article 3.16 and withdrawn certificates according to Articles 3.9 and 3.17 are included in the directory.
7.3 TÜV Rheinland Malaysia is entitled to provide the directory specified in Section 7.1 to the public on request.

8. Right of TÜV Rheinland Malaysia to enter the contract
TÜV Rheinland Malaysia Sdn. Bhd., located at
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Selangor Darul Ehsan, Malaysia
is entitled to enter the certification contract underlying these Terms and Conditions of Certification at any time.

9. Certificate replacement
9.1 Observing a period of notice of 1 month, we are entitled to replace issued certificates with new certificates (replacement certificates) at any time in the event of a change in the accredited certification body named on the certificate, provided replacement has not caused a change in the certification scope .
9.2 In the event of replacement, the client will be obligated as set forth in Article 9.1 to return to us the certificate to be replaced without delay.

10. Complaints
10.1 Complaints must be presented in writing to us.
10.2 Should the complaint be justified, we shall the initiate appropriate measures.
10.3 Should the complaint prove to be unsustainable in our view, the complainant will be informed of this and asked to comment within a period of 30 calendar days.
If no amicable solution can be reached with the complainant, the parties may mutually agree on the performance of arbitration proceedings, failing which legal action will be taken.

II. Special terms and conditions of conformity assessments conducted in accordance with the Malaysia Medical Device Act 2012 and Good Distribution Practice for Medical Devices (GDPMD)
(TÜV Rheinland Malaysia Sdn. Bhd)

The regulations set forth herein apply in addition to the General Terms and Conditions of Certification and are restricted to conformity assessments conducted in accordance with the Medical Device Act 2012, the Good Distribution Practice for Medical Devices (GDPMD) the their related regulations.

1 General Terms and Conditions for Conformity Assessments

1.1 Certification audit

1.1.1 Certification audits consist of two stages. Stage 1 aims at obtaining an overview of the management system and its maturity (status of implementation). After this information has been obtained, the stage 2 audit may be performed, which assesses the establishment of and compliance with the management system.

1.1.2 The stage 2 audit may be carried out directly after the stage 1 audit. Should the stage 1 audit reveal, however, that the organization is not yet ready for certification, the stage 2 audit may not be carried out directly after completion of the stage 1 audit. In this case, the client must first take appropriate action to make the organization ready for certification. Any additional costs arising therefrom for the client or for us, i.e. including travel costs, travel times and time lost, shall be borne by the client.

1.1.3 The interval between the stage 1 and the stage 2 audit must not exceed 6 months. Should more than 6 months elapse between the stage 1 and the stage 2 audit, the stage 1 audit shall be repeated. Any additional costs arising therefrom for the client or for us, i.e. including travel costs, travel times and time lost, shall be borne by the client.

1.1.4 When the interval is set between the stage 1 and the stage 2 audit, allowance shall be made for both the client's requirements and sufficient time for the correction of weaknesses. Generally, most of the auditing time is spent on the stage 2 audit.

1.2 Surveillance audit

1.2.1 To maintain validity of the certificate, on-site surveillance audits shall be carried out at least annually, at 12-month intervals. The due date is calculated from the last day of the certification audit. Surveillance audits may be carried out up to 3 months before, but at the latest exactly on, the due date.

1.2.2 To ensure these deadlines are observed even if dates have to be postponed at short notice, surveillance audits should be scheduled at the beginning of the above tolerance period if possible.

1.3 Re-certification audit

1.3.1 To renew certification for another three-year period, a re-certification audit shall be held at the client's organization prior to expiry of certificate validity.

1.3.2 The procedure is similar to that of a certification audit, where the necessity and scope of a stage 1 audit are determined subject to changes in the management system and previous audit findings.

1.3.3 Upon successful re-certification, the term of the certificate is extended by another 3 years, starting from the date of expiry date of the previous certificate. The re-certification audit and the positive certification decision must have been done by the expiry date.

1.4 Short-notice audits

A special audit may become necessary at short notice for the following reasons:

- Serious complaints and other circumstances of which the certification body becomes aware, which challenge the effectiveness of the client's certified management system and which cannot be eliminated in written form or within the next scheduled audit (e.g. alleged violation of law on the part of the client or its executives).
- Changes at the client which impair the management system's effectiveness in such a way that the organization no longer complies with the requirements of the standard.
- As a consequence of a suspension of the client's certification.

1.5 Multi-site certifications

1.5.1 Multi-site certifications may be applied to organizations maintaining multiple sites or branches functioning exclusively as field offices.

1.5.2 Multi-site certification is possible if the following criteria are fulfilled:

• All sites maintain a legal or contractual relationship with the organization's headquarters.

• Products/services are basically identical at all sites and are produced using identical methods and processes.

• A uniform management system has been defined for, and is established and maintained in, all branches/production facilities.

• The entire management system is monitored centrally under the direction of the Management Representative at the organization's central office, who is authorized to issue management system-related instructions to all branch offices/production sites.

• Internal audits and management reviews have been carried out at all branch offices sites.

• Certain areas carry out centralized activities on behalf of all branch offices/production sites, e.g. product and process design and development, purchasing, human resources (HR), etc.

1.5.3 In cases involving multi-site certification, the on-site auditing of sites may be spread over certification and surveillance audits. Headquarters must be audited annually in addition to the sampled sites.

1.5.4 We select the sites to be audited.

2 Standard-specific terms and conditions for accredited certification schemes

Terms and conditions applicable to certain accredited certification schemes, which must be observed in addition to the General Terms and Conditions outlined under Art. 1 above, are listed below, separately for each specific standard concerned.

2.1 Supplementary terms and conditions for conformity assessment in accordance with the Medical Device Act 2012

2.1.1 These supplementary terms and conditions apply to the conformity assessment of medical devices imported, exported or placed in the Malaysian market and medical device establishments in accordance with the Medical Device Acts 2012 and its regulations.

2.1.2 The entire auditing and certification process shall be governed by the provisions set forth in the Medical Device Acts 2012 and its regulations

3. Standard-specific terms and condition for Conformity Assessments by Way of Verification and Conformity Assessments by Full Assessment

3.1.1 Terms and conditions apply to the Conformity Assessments by Way of Verification will strictly follow the MDA Circulation Letter of Medical Device Authority No 2 Year 2014 (Ref. # (5)dlm.MDA.100-1/8/5 dated 22-May-2014)

3.1.2 Terms and conditions apply to the Conformity Assessments by Full Assessment will strictly follows the Conformity Assessment Procedure (Third Schedules) of Malaysia Medical Device Regulation 2012 (P.U. (A) 500 dated 31-Dec-2012)

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