Terms and Conditions of Certification (TÜV Rheinland Singapore Pte Ltd)

I. General Terms and Conditions of Certification

1. Scope

1.1 These General Terms and Conditions of Certification apply to the agreed certification services plus any ancillary services provided within the scope of contract performance established under the MS-0050357 Contract on SAC ISO 13485 Certification Scheme entered into between the parties ("**Agreement**").

1.2 These General 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 (or any other documents of a similar nature in a comparable context) ("**client's T&C documents**"), if any, shall not apply and shall hereby be expressly excluded. The client's T&C documents will not become part of these General Terms and Conditions of Certification even if not expressly excluded by us.

1.4 For the purpose of these General Terms and Conditions of Certification, 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.

1.5 For the purpose of these General Terms and Conditions of Certification, the terms "**Certification Body**" and **"Certification Bodies"** are defined as an organization(s) which has been accredited for a sector that performs conformity assessment services and provides compliance certificates.

2. Scope of services

2.1 We assess and certify systems and products of manufacturers and service providers as per national and international standards for which we hold accreditations, approvals or recognitions ("**accredited certifications**") or as per national and international standards for which we do not hold accreditation ("**standard certifications**") and also provide own third-party certification services ("**in-house certifications**").

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 certifications as per the certification standards agreed in the Agreement and/ or the rules and regulations referred to therein, including the generally applicable accreditation standards pertaining to the specific certification standards, 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 (compared to the applicable accreditation standards or regulations) will be necessary to comply with the accreditation requirements, the client shall bear any additional costs and expenses incurred thereby, with the exception being instances where we are directly accountable for such additional costs and expenses.
Standard certifications are carried out in line with the respective national and international standards.
Certification procedures to issue in-house certifications are carried out in line with the rules and regulations established by us.

2.4 If certification is completed with a positive result/ decision, 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 (including the external auditors, as defined herein) 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 us/ TÜV Rheinland Group ("**external auditors**") are appointed to and used in the audit team (that consists of, without limitation, lead auditor, the external auditors, product assessor/ product specialist, observer and translator). The client's approval shall be deemed granted if the client has not objected to the use of external auditors within one (1) week of being notified in writing of the external auditors' appointment to the audit team.

2.7 For accredited certifications 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 activity.

2.8 In cases of complaints and appeals against progress or the content of our auditing or certification process, our advisory committee or board of directors may be called in.

2.9 The client has the right to appeal against the certification result/ decision, and such appeal will be handled by impartial and independent third-party entity (save for the external auditors appointed for the initial certification) in accordance with established protocols. All associated costs and expenses incurred in the appeal process shall be solely borne by the client without exception.

3. Scope of right of use of certificates

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 Agreement or, if not defined there, in our Special Terms and Conditions of Certification.

3.2 The permit to use the certificate 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 for areas not quoted in the scope of application shall be prohibited.

3.3 The client undertakes to use the certificate 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.

3.4 The client shall not be authorized to change the certificate in any way.

3.5 The client undertakes to demonstrate in its advertising and similar materials that certification is voluntary and carried out on the basis of a contract.

3.6 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.

3.7 The client's right to use the certificate shall expire with immediate effect, without requiring termination, if the client uses the certificate in violation of the provisions set forth in Articles 3.1 to 3.6 above or contrary to other relevant provisions of these General Terms and Conditions of Certification, the Agreement, the Special Terms and Conditions of Certification and any other agreed documents intended to be utilised in respect of the provision of certification services plus any ancillary services based on the scope of contract performance established under the Agreement.

3.8 The client's right to use the certificate will end upon termination of the Agreement.

3.9 The right of use shall also expire automatically if maintenance of the certificate is prohibited by administrative regulations or court.

3.10 In cases involving expiry of the right of use, the client shall be obligated to return the certificate to us without delay.

3.11 In cases involving violation of contractual terms and conditions we reserve the right to claim damages.

3.12 The certification must not have the effect of bringing us into disrepute.

3.13 The client shall not be entitled to make statements about certification which we may consider unauthorized and misleading.

3.14 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".

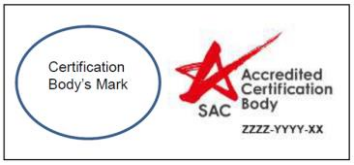
3.15 If the reasons for suspension are not remedied within the agreed period of time, the certificate will be withdrawn.

3.16 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 accreditation standards to monitor proper use by way of random sampling. Information from third parties will be checked by us.

3.17 The client shall inform us immediately if it discovers that a third party is improperly using the certificate.

3.18 The client shall provide certification documents to any third parties only in their entirety or as specified in the certification scheme.

3.19 The specimen of the accreditation mark issued by the Singapore Accreditation Council ("**SAC**") designated for use by certified organizations:



Notes:

i) The Certification Body's mark should precede the SAC accreditation mark.

ii) The Certification Body's mark and SAC accreditation mark should preferably be enclosed within the same box.

iii) The Certification Body's mark should maintain proportions similar to the SAC accreditation mark, with a maximum height difference of 5%.

iv) The abbreviation (ZZZZ) may vary depending on the accreditation scheme/ programme - for e.g. QS for Quality Management System, PD for Product.

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 us in in a timely manner and without 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; and
- Other documents mentioned in the quotation.

4.3 The client shall disclose all records associated with the scope of application to the audit team and shall grant them access to the organizational units concerned.

4.4 The client shall appoint one (1) or several audit representative(s) who shall support the audit team in performing the contractually agreed services and act as the client's contact persons.

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4.5 Following certificate issue, the client shall be obliged, throughout the term of the Agreement, 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; and
- changes in the organizational structure and the organization itself. This also applies to implementation or modification of shift work.

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 audit team during the audit activity.

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 standards to the audit team during the audit activity.

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 The client commits to fulfilling the certification requirements at all times, including the implementation of corresponding changes without delay.

4.11 Parties 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 client's premises, during which the client proves that it applies its documented procedures in practice. Standards or standard elements that are not complied with and for which the client 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 of the audit team. 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 result/ decision on certificate maintenance, is completed by our Certification Body, the certificate shall become invalid. In this case, all copies of the certificate must be returned to our 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, complaints related to the management system, products or processes 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 be determined by us and shall depend on the scope of extension or upgrade which shall be clearly defined by the client prior to the audit activity.

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 Agreement, either party shall immediately inform the other party to discuss and agree on the consequences of such changes for the auditing process in terms of duration for the completion of the audit activity and any associated costs and expenses incurred derived from the 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.

4.21 If the Certification Body's certified client declines SAC's audit witnessing, the client's certification may be withdrawn. SAC will notify all its accredited Certification Bodies of the withdrawal. If the client opts for certification from another Certification Body ("**New Certification Body**"), SAC will inform the New Certification Body that it wishes to witness the audit. This would only be applicable for SAC accredited certification that is mandatory.

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 and the disclosing party shall thereafter put such oral information into writing.

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 purpose of certification, 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; and
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 or subcontractors ("**Authorised Representatives**") who need this information to perform services required for the subject matter of the Agreement. The receiving party undertakes to place the Authorised Representatives under the obligation to observe the same level of secrecy as that set forth in this non-disclosure article.

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 these General Terms and Conditions of Certification.

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 the 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 the Agreement. 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 those reports and certificates and of any underlying confidential information to furnish proof that our result/ decision is correct and to fulfil general documentation purposes.

5.7 From the start of the Agreement and for a period of five (5) years after termination or expiry of the Agreement, the receiving party shall maintain strict secrecy of all confidential information and shall not disclose the confidential information to any third parties or use it itself.

6. Termination

6.1 Both contracting parties shall be entitled to terminate the Agreement observing a period of six (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(s).

6.3 For the purpose of the Agreement "**important reason**" shall be defined as follows:

a) The client fails to notify us without delay of any changes or indications of changes in the organization, products or processes which are relevant for certification;
b) The client misuses a certificate or uses them contrary to the Agreement; and/ or
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 Agreement with immediate effect, 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).

6.5 In case of termination, client shall no longer be entitled to use the certificate.

7. List of certified organizations

7.1 TUV Rheinland (Singapore) Pte Ltd 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 3.14 and withdrawn certificates according to Articles 3.7 and 3.15 are included in the directory.

7.3 TUV Rheinland (Singapore) Pte Ltd is entitled to provide the directory specified in Article 7.1 to the public on request.

8. Certificate replacement

8.1 Observing a period of notice of one (1) month, we are entitled to replace issued certificates with new certificates ("**certificate replacement**") at any time in the event of a change of our name.

8.2 In the event of certificate replacement, the client will be obligated to return to us the issued certificate to be replaced with the new certificate without delay.

9. Complaints

9.1 Complaints must be presented in writing to us.

9.2 Should the complaint be justified, we shall the initiate appropriate measures.

9.3 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 thirty (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.

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II. Special terms and conditions of certification governing accredited certifications schemes of (TÜV Rheinland Singapore Pte Ltd)

The regulations set forth herein apply in addition to the General Terms and Conditions of Certification and are restricted to accredited certifications schemes (as defined herein), i.e. schemes based on a national and international standard or code with accreditation, approval or recognition ("**accredited certifications schemes**"). For the purpose of these Special Terms and Conditions of Certification, the term "**Accreditation Body**" will also include approval and recognition bodies and the terms "**Accreditation Rules**", "**Accreditation Requirements**", "**Accreditation Standards**" and "**Accreditation Procedures**" will apply mutatis mutandis also to the procedures of these bodies. The accredited certifications schemes follow global standards and guidelines set by the respective accreditation body. The standards encompass adherence to:

- Generally accepted international accreditation standards such as ISO/IEC 17021-1:2015 and ISO 19011:2018;
- Certification standards such as ISO 13485; and
- Accreditation rules established by the relevant accreditation body.

For the purpose of these Special Terms and Conditions of Certification, the terms "**Certification Body**" and **"Certification Bodies"** are defined as an organization(s) that has been accredited for a sector that performs conformity assessment services and provides compliance certificates.

1 General Terms and Conditions for Accredited Certifications Schemes

1.1 Certification audit

1.1.1 Certification audits consist of two (2) stages. **Stage 1** audit 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 reveals, 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 solely borne by the client.

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

1.1.4 When determining the interval between the **Stage 1** audit and the **Stage 2** audit, we will consider the client's needs and ensure there is enough time to address any weaknesses. Generally, the **Stage 2** audit consumes the majority of the auditing time.

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 twelve-month intervals. The due date is defined on the anniversary of the certification decision date. Audits may be performed in a time window +/- 3 months around the defined due date.

1.2.2 To ensure compliance with established deadlines, even in the event of short-notice postponements, it is recommended to schedule surveillance audits at the beginning of the designated 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 the **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 three (3) years, starting from the expiration date of the previous certificate. The re-certification audit and the positive certification result/ decision must have been issued/ done by the expiration date of the previous certificate.

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 applicable standards.
- 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 (as defined in ISO 13485 QMS Standard) 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; and
- 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 have the discretion to select the sites to be audited.