

# OTABU GLOBAL SERVICES PVT. LTD.

FLAT NO. 954, BLK-D, PKT 3, BINDAPUR, DWARKA, WEST DELHI, DELHI - 110059, INDIA

## GENERAL CONDITION FOR SYSTEM CERTIFICATION

### STEP: 1 CLIENT INFORMATION

Client will fill information in an application form which is provided in website and ask to OTABU.

### STEP: 2 QUOTATION & ASSESSMENT APPLICATION

Based upon the information provided, the marketing manager reviews the scopes available with OTABU and prepares the quotation with the letter for registration service agreement, which will be sent along with the application for registration.

### STEP: 3 CERTIFICATION AUDIT CONTRACT

Once the Application for registration received & reviewed, which confirms the exact way client company name and site address will appear along with the description of scope (products or services) for which registration is sought. The certification audit contract will be made and sent to the client.

### STEP: 4 SUBJECT MATTER OF THE AGREEMENT

The subject matter of the agreement between both parties applies to the provision of conditions for granting the certification which confirms that the management system (system in following) conforms to the specified standard or other normative documents for the system. The client is aware of the fact that the system certification is performed on the basis of a dynamic system audit at the given moment. The client is bound to assure that the relevant provisions of this agreement will be met by the organisation whose management system will be certified (organisation in following). OTABU will perform the certification according to the application of the client and the price offer accepted by the client.

### STEP: 5 START OF AGREEMENT VALIDITY

This agreement is applicable after it is signed by both parties, and the OTABU price offer is signed by both parties and the filled in OTABU form APPLICATION FOR MANAGEMENT SYSTEM AUDIT is signed and submitted by the client, all included without any exclusions

### STEP-6 AUDIT

#### 6.1 AUDIT PLANNING

Once the certification audit contract received, the technical manager plans the audit on the basis on audit time allocation and audit assignment, which is defined as below and raise the audit plan in duplicate, which should narrate the requirements of the relevant management system standard; size and complexity, name, address and scope of the client, date of audit and the constitution of the audit team and send it to the auditors before fifteen working days. After getting the consent from auditor, audit assignment register will be filled and the statement of confidentiality and no conflict of interest

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will be obtained. The Audit plan shall be sent to the client there after. The operational manager will confirm the date then about the auditor & technical expert detail with the client.

## 6.2 AUDIT INTIMATION

Audit plan shall reach the client before ten working days of audit. The receptionist shall confirm the dates of audit and the constitution of the auditors and mark the same on the office copy of audit plan

## 6.3 STAGE-1 AUDITS

The stage one audit is performed by lead auditor at client's premises, to audit the client's management system documentation. To evaluate the client's location and site-specific conditions and to undertake discussions with the client's personnel to determine the preparedness for the stage 2 audit. To evaluate if the internal audits and management review are being planned and performed, and that the level of implementation of the quality management system substantiates that the client is ready for the stage 2 audit.

## 6.4 STAGE-1 AUDIT REPORT

After the stage one audit the auditor shall submit his finding & advise by written report.

## 6.5 STAGE-2 AUDITS

Stage two audits is an assessment audit, which is carried out after phase one audit's inadequacies have been removed and the organization is all set to demonstrate the compliance to the selected international standard. Auditors will plan and conduct the assessment audit.

## 6.6 SURVEILLANCE AUDITS

Surveillance audits are carried out bi-annually/annually to ensure that the certified management system is in compliance and demonstrates continual improvement in terms of Systems, products and resource management.

## STEP: 7 CERTIFICATION

Based on the audit report, the list of nonconformities and the action plan of the client taking corrective actions OTABU will decide autonomously about granting, postponing or the rejection of the certification. This decision is made in writing to the client.

## STEP: 8 GRANTING CERTIFICATIONS

- If the certification is granted, the certificate is issued in the language and for the activities according to the application, and is sent to the client and recorded into the OTABU list of certificated organisations & details will be updated on web pages also.

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- Certification is valid only for the certificated organisation, i.e. for the system recorded in the certificate applicable for the products / services recorded in the certificate. Any transfer of the certification and the certificate is explicitly forbidden.
- Certification is valid for one year however total validity is 3 years subject to surveillance audits are performed and the certification is not suspended or withdrawn by OTABU.
- The surveillance audit represents a visit of an auditor, nominated by OTABU to ensure the maintaining of the system level. Surveillance audits will be performed every 12 months. However, this number could be changed if it is imposed by any official regulation or based on the recommendation of the auditor.
- OTABU can perform follow-up audits out of the regular cycle, if the system amendment is considered by OTABU to be the principal or if the scope of the application is changed.

## STEP: 9 POSTPONMENT OF GRANTING CERTIFICATION

OTABU can decide autonomously to postpone its decision on certification while the required corrective actions are implemented by the organisation. After these actions are executed, the auditor will perform a new audit. Based on this, OTABU will decide autonomously about granting the certification. The extent of this new audit depends on the extent of the nonconformities and relevant corrective actions.

## STEP: 10 REJECTION OF CERTIFICATION

In case the certification is rejected, the validity of this agreement automatically comes to an end three months after the rejection is announced to the client, if the client does not submit an appeal or will not submit a new application for audit. The costs will be charged by OTABU to the client in accordance with the beforehand agreed prices regardless to any appeal.

## STEP: 11 RENEWING CERTIFICATION

The certification must be renewed before its expiry. Renewal of the certification requires a total audit. This agreement is the order for certification renewal. Also, a new OTABU price offer must be agreed by the client.

## STEP: 12 RESTRICTING, SUSPENDING, WITHDRAWING AND EXPIRY OF CERTIFICATION

Provisions 12.1 to 12.5 are valid for the entire scope of certification or for its part.

### 12.1 - RESTRICTING CERTIFICATION

Restricting certification is a temporary arrangement, not exceeding a 3 months period and will be applied if the critical nonconformities of the system are identified (e.g. during surveillance audits), or if the certified organisation does not submit adequate corrective actions for identified nonconformities in time. Restricting will be announced to the client and organisation in writing and becomes valid 30 days after it is announced to the client, except if the client appeals within time, according to the procedure given in Clause appeal & claim procedure.

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## 12.2 - SUSPENDING CERTIFICATION

OTABU is authorised to suspend the certification in case of detecting (e.g. during the regular, follow-up, or surveillance audit) that the system is not in conformity with the standard or in case the obligations of this agreement including financial obligations are not kept to by the client / organisation. Suspension can come with or without previously restricting the certification. Suspension will be announced to the client and the organisation in writing, and becomes valid 30 days after it is announced to the client, except if the client appeals within time, according to the procedure given in clause 7.

## 12.3 - WITHDRAWING CERTIFICATION

The certification will be withdrawn:

- when the activities subjected to the certification cease to exist e.g. suspension of the activity, bankruptcy etc. (in case of bankruptcy the certification loses its validity on the day the bankruptcy is announced)
- In case the agreement is cancelled.

## 12.4 RESTORATION OF CERTIFICATION:

Restoration of a suspended certificate can only take place after all issues have been resolved and verification of such resolution (audit/documentary evidences/other as per suspension requirements) has been undertaken not more than 6 months from the original suspension. Where scope of certification has been reduced instead of complete suspension of a certificate, this too can be restored following issue resolution and, where appropriate, an audit or documentary evidences/other method of evaluation has taken place to confirm and verify resolution. In all cases a certification decision will be recorded and act accordingly by Certification Technical Committee

## 12.5 - EXPANDING

Upon the request of the client at any point of certification cycle, the scope of certification can be extended after the verifications conducted as per the OTABU certification process.

## 12.6 - REDUCTION

Upon the request of the client or during the surveillance audit as identified/verified by the audit team, the scope of certification can be reduced after the verifications conducted as per the OTABU certification process.

## 12.7 EXPIRY OF CERTIFICATION

The certification automatically and legally loses its validity after expiry, unless it is renewed.

## 12.8 CONSEQUENCES

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In case of restricting the certification, neither the client nor the organisation may either lay claim to the certification or refer to the certification in external contacts (e.g. offer, negotiations about a contract, publication, advertisement) during the time of restriction. In case of suspending, withdrawing or expiry, the client / organisation is obliged to immediately send the certificate to OTABU and to stop any use of the certification or any reference to it. Any misuse or misleading of this, will lead to penalties. Besides this, OTABU can publicise the suspension and the withdrawal. In case of suspension, withdrawal or expiry, obligations to OTABU will legally cease to be.

**NOTE: In the case of QMS Medical Device (ISO 13485:2016), Where it is required by law or by relevant Regulatory Authority, the OGS will provide the information about certifications granted, suspended or withdrawn to the Regulatory Authority without asking with certified client.**

## STEP: 13 APPEAL AND CLAIM PROCEDURE

The appeal can be received by e-mail, fax, written, verbal. On receipt of an appeal, committee evaluates gathers and verifies all necessary information to validate the appeal. The appeal is recorded, acknowledged and communicated to the appellant by Certification committee.

Certification committee carries out investigation of the appeal taking into account results of previous similar appeals. Certification committee submits a report indicating the results of investigation and the actions to be taken as well as the reply to be sent to the client.

The final decision is made by Certification committee on the basis of the review of report received from AC committee/Nominee. In case Certification committee was previously involved in the certification decision related to appeal, the decision is taken by another nominated person who was not previously involved in the specific certification audit / decision process.

Certification committee tracks and records the actions taken and the appellant is kept informed by Certification committee on the progress till the appeal is resolved. At the end of appeal handling process, formal notice is given to the appellant by Certification committee.

Certification committee would ensure that appropriate correction and corrective actions are identified and implemented where required.

Certification committee ensures that submission, investigation and decision on appeals shall not result in any discriminatory actions against the appellants.

Certification committee submits his report to director technical and the decision will be communicated to the appellant.

The progress report shall be send to appellant and request him for the feedback within fifteen days. if the complainant does not come back it means the appeal is solved.

This shall be shown and discuss with impartiality committee.

Confidentiality shall be maintained throughout.

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## 13.1 RESOLVING OF DISPUTES AND COMPLAINTS

OTABU shall constructively and quickly resolve all Appeals and complaints from the client. In case it is not possible to come to an acceptable solution, or a suggested procedure is not acceptable, the client can appeal according to the following provisions.

## 13.2 INTERNAL APPEAL

In case of dissatisfaction with resolving a complaint or appeal, also the rejection, restriction or suspension the certification, the client can appeal. This appeal has to be presented within 30 days after OTABU announces its decision. OTABU is bound by the agreement to examine this appeal with the necessary attention and independence, and announce its decision with explanation in writing within 30 days. If OTABU agrees to the appeal, it shall accept the new decision. If OTABU decides to reject the appeal, it will be of the same effect as the original decision, with the notification that the procedure of another internal appeal is not possible. Each party bears its own costs connected with this procedure of an internal appeal.

## 13.3 EXTERNAL PROCEDURE

After the procedure of an internal appeal is completed, or if it was not acted in accordance with the procedure for an internal appeal, each party can submit a disagreement related to this agreement for arbitration through the accreditation body or an independent third party, or legal interpretation if necessary. This procedure has no suppressive effect to the OTABU decision.

## STEP: 14 SPECIAL OBLIGATIONS OF THE CLIENT / ORGANISATION

### 14.1 ACCESS

The client / organisation is bound by the agreement to perform all necessary arrangements to meet the purpose of this agreement, to permit OTABU representatives access to buildings and establishments of the organisation with an accompaniment of the organisation during regular working hours, and instruct them about keeping provisions on work safety, fire safety and protection of the environment. It also guarantees the right to review all the documentation, data, records and activities considered by OTABU as important, to interview its personnel and to gain their full co-operation.

### 14.2 OBLIGATION TO REPORT

The client / organisation is bound by the agreement to inform OTABU immediately in all cases and especially during periodical and follow-up audits, or during the renewal of certification about all planned and executed amendments of the system legal, commercial status of ownership, organisation & management, significant events concerning health and safety and any related findings from any third parties, contact address & sites and its scope compared to the certificate. Neglecting this obligation to inform about the forthcoming changes can lead to the suspension of the certification.

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## 14.3 LIST OF COMPLAINTS

The organisation is bound by the agreement to maintain the list of all complaints and corrective actions (internal and/or external) obtained in the certified system which shall be submitted to OTABU representatives during each audit. Maintenance of the list is an imperative part of the system and it is the condition for maintaining or renewing the certification.

## 14.4 MAINTAINING SYSTEM

The client / organisation are bound by the agreement to do everything necessary to ensure the functionality of the system and its conformity with the standard.

## 14.5 UTILISING CERTIFICATION

An organisation can utilise its certification and OTABU certification mark in commercial relations and in the media (e.g. in documents, brochures, advertisements etc.) in accordance with OTABU conditions. The organisation can utilise its certification only to express that the system meets the specified standards or other normative documents, still for the activities certified. The organisation can neither use its certification nor the certification mark to mark its services, products and coverings, nor any other way indicate that the product or the service are conforming or approved by OTABU. The organisation must not use its certification in a way that could endanger OTABU reputation and must not make statements which could be considered by OTABU as misleading or unauthorised. The client / organisation shall ensure that no certification document, mark, report or any of their parts be used in a misleading way. Any use or reference which could lead to a mistake will cause immediate suspension of the certification. In such a case, OTABU will be entitled to require correction in the pertinent publication on the client's expenses without the possibility of presenting a claim to recompense possible losses. The client / organisation must not in any circumstance allow a third party to use the Certification and the certification mark neither free nor for a charge. OTABU is entitled to claim compensation of any damage caused by incor.

## STEP: 15 VALIDITY AND VOIDING OF THE AGREEMENT

This agreement was concluded for an unlimited period. Both parties are entitled to terminate this agreement unilaterally with a 6-months notice period upon written notice communicated to the other party by a recommended letter. The notice period begins on the day of the postal stamp of the registered letter. OTABU is entitled to give notice of this agreement at any time without the notice period. If the client / organisation does not comply with this agreement, including financial obligations. OTABU is entitled to present a claim for compensation of losses resulting from it. Notice of this agreement has the same results as withdrawal of the certification according to clauses 5.3 and 5.5.

## STEP: 16 CONFIDENTIALITY

Both parties are bound by the agreement to keep confidentiality towards third parties. The obligation of confidentiality remains valid for both parties, also after this agreement is finished. Information can not be disclosed to a third party without the written consent of the both parties. Where the certification

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body is required by law to release confidential information to a third party, the client or individual concerned shall, unless regulated by law, be notified in advance of the information provided.

## STEP: 17 PUBLICITY

Both parties and the organisation are entitled to make public the fact that the certification of the organisation is going on or has finished. If a previous agreement is not contrary.

## STEP: 18 PROHIBITION OF TRANSFER

The client / organisation must not transfer its rights and obligations unless OTABU gives written permission.

## STEP: 19 PRICES, PRICE ADJUSTMENT AND MATURITY PERIOD

Financial conditions are agreed between the client and OTABU or, an OTABU representative in the residential country of the client.

## STEP: 20 RESPONSIBILITY AND LEGAL CLAIM

This agreement is an agreement on work, not on the result. OTABU shall be responsible only for the direct losses caused to the organisation resulting from material negligence or a serious mistake by OTABU, its bodies, appointed persons, subordinates, representatives or suppliers. This responsibility is limited to the amount equal to 10 multiple of the amount accepted by OTABU or its nominated representative based on the survey of results of the material negligence or serious mistake. All claims to compensation lose their validity six months after the event that the claim is based on.

## STEP: 21 RECRUITMENT OF PERSONAL

The client is bound by the agreement not to recruit OTABU personnel and representatives or use their services except from previous written approval by OTABU. Breach of this agreement gives OTABU the reason to terminate this agreement immediately, and legally entitles OTABU to claim financial compensation for the losses in the amount of the gross annual income of the person whose services were lost for OTABU, minimum in the amount of seventy multiple of the minimal monthly salary in the client's country in the time the OTABU person has left. To prevent misunderstanding, the client / organisation has to always consider all the persons taking part in the performing of this agreement are the employees of OTABU.

## STEP: 22 IMPARTIALITY AND INDEPENDENCE DECLARATION OF OTABU

- The top management of OTABU understands the importance of impartiality when performing QMS, EMS, OH&S, FSMS, ISMS & QMSMD activities; manages potential conflict of interests and ensures the objectivity of its QMS, EMS, OH&S, FSMS, ISMS & QMSMD activities. OTABU has developed and implemented procedures in compliance with the requirements of ISO/IEC 17021-1:2015.



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- The certification procedures are approved by the Director Technical and are to be abided when applicable and when QMS, EMS, OH&S, FSMS, ISMS, ABMS, QMSMD, ENMS, BCMS & ITSMS is conducted according to ISO/IEC 17021-1:2015
- The technical Manager is responsible for conducting certification services in compliance with OTABU, OTABU declares that it does not take part in any consultancy activities regarding development and implementation of any management systems.
- There shall be no pressure of any kind (financial, trade, administrative, moral or other) over OTABU and the personnel regarding the execution of their obligations as a QMS, EMS, OH&S, FSMS, ISMS, ABMS, QMSMD, ENMS, BCMS & ITSMS according to ISO/IEC 17021-1:2015.
- OTABU identifies, analyzes and documents all possibilities for conflict of interests that emerge from certification processes including any conflicts that emerge from its relations. Presence of relations does not necessarily position the OTABU in a situation of conflict of interests. If some relations create impartiality threats, OTABU documents and eliminates or decreases such threats. This information is presented to the Advisory Board members. It is necessary to cover all possible conflict of interests' sources that are identified regardless of their origin. OTABU requires from all employees, internal and external, to comply with impartiality rules as well as reveal any situation known to them that may present them or OTABU with a conflict of interests. OTABU shall use this information as input in identifying threats to impartiality raised by the activities of such personnel or by the organization that employ them. Such personnel, internal or external shall not be used unless they demonstrate that there is no conflict of interest. OTABU shall not undertake any action that threatens the impartiality and/or are potential conflict of interests.
- When certain relations create unacceptable impartiality threat, then the certification shall not be conducted. OTABU shall not certify another certification body for its activities related to management system certification.
- OTABU shall implement corrective actions against irrelevant claims of any consultancy organization declaring that the certification will be simpler, faster or cheaper if specific certification body is used due to the fact it is conflict of interests. Also OTABU shall not state or imply that certification would be simpler, faster or cheaper if a specified consultancy organization were used.
- When potential impartiality threat arises OTABU eliminates it or decreases it. This process is also controlled by the Advisory Board.
- OTABU shall not certify own group companies (if there are such companies) or organizations that OTABU is a part of or a member.

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- Personnel, who have provided consultancy (including internal audits) within two years to the organization seeking certification, are not allowed to take part in audit or other certification activities.
- OTABU shall not provide internal audits for its certified clients. OTABU shall not certify a management system for which it has conducted internal audits within two years following the end of the internal audits.
- OTABU shall not provide certification services to a client when relations between the Consultancy Company and OTABU could lead to impartiality threat.
- OTABU shall not outsource audits to a management system consultancy organization as this poses an unacceptable threat to the impartiality of the certification body. This does not apply to individuals contracted as auditors or technical experts.
- OTABU does not receive any financial support different from the invested in it and the fees of its services.
- OTABU does not pay any commissions to consultants therefore there can be no pressure exercised on OTABU by consultants.
- OTABU shall not allow any pressure from other certification bodies to influence the certification process in the organization. If other certification body declines to provide service for client and the client requests the same service form OTABU than OTABU shall investigate the reasons for declining before performing any other certification activities for the respective client.
- OTABU shall not allow pressure from clients and/or consultancy organizations. If there is such pressure than OTABU will apply requirements of ISO/IEC 17021-1:2015 internal procedures in order to stop such practice.
- OTABU shall not allow pressure from employees and/or related persons.
- All employees are obliged to work in compliance with requirements of ISO/IEC 17021-1:2015 and as per agreement of contract.
- Top management of OTABU is committed to full compliance with this declaration.

## STEP: 23 APPLIED LAW AND COMPETENCE

Both parties agree to apply the law of the Indian Govt. for this agreement. Any doubts considering the wording or interpretation of this agreement will be solved by mutual agreement of both parties; in a contradictory case the procedure given of this agreement will be used. Both parties agree that

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contractual relationships arising out of this agreement shall be governed in parts not provided for in this agreement by the relevant provisions of applicable legal regulations of the INDIA, in particular by the Commercial Code, without the application of the conflict of laws clauses.. The Parties proclaim they have read this Agreement, have understood its contents, and, expressing their free and serious will, in witness whereof, they have signed it by their own signatures.