Certification Process

ISO 13485:2016 Certification Steps (Region of Accreditation: Egypt, Saudi Arabia, Jordan)

1. CONTRACT CONCLUSION AND PRICE

In the initial phase, we verify the necessary documents - a request for certification, we check whether our CB is able to carry out the certification of management system according to the requirements of the potential client and in accordance with its own procedures and accreditation rules. Then we process and send a specific offer, sign a system certification contract with the customer, agreeing on a certification audit.

2. AUDIT PREPARATION

The Head of the **IETQAN** certification body appoints the lead auditor and other members of the audit team and sends the above to the customer for approval.

The lead auditor will request the documentation of the customer's management system necessary to prepare for the audit and, based on the known information, prepare an audit plan that will be sent to the customer for approval.

3. INITIAL CERTIFICATION AUDIT

The objective of the initial two-stage certification audit is a detailed verification of the compliance of the established management system with the requirements of the ISO 13485 standard.

The first stage of the initial certification audit is aimed at auditing the documentation of the customer's management system, examining the conditions of the customer's location, his understanding of the requirements of the standard. It is assessed whether internal audits are planned and carried out, management review and whether the level of implementation of the management system creates assumptions that the customer is ready for the second stage of the audit. Based on the documented findings, the plan of the second stage of the audit will be confirmed/adjusted. Where higher risk medical devices are concerned, the stage 1 should be performed on-site.

The purpose of the second stage of the initial certification audit is to evaluate the implementation of the client's management system, including its effectiveness in the overall scope and in accordance with the relevant standard on site at the assessed customer.

4. CERTIFICATION DECISION

Based on the results of the audit, so called certification decision maker will check the conclusions of the Lead auditor stated in audit report. On the basis of the above, he decides on the granting or non-granting of a certification.

The same certification decision process is used for maintaining, renewing, suspending, restoring or withdrawing of certification or for expanding or reducing the scope of certification.

5. SURVEILLANCE OF THE CERTIFIED CLIENT

As part of the surveillance audit, selected parts of the client's management system are checked, while the emphasis is mainly on the review of the actions taken in relation to the non-conformities found in the previous audit, the handling of complaints, the review of any changes, the use of marks and/or any appeals for certification, the overall evaluation of the effectiveness of the management system and its maintenance (internal audits and management review). The surveillance audit is carried out on site at the client.

In total, two surveillance audits are conducted within the 3-year cycle

6. RECERTIFICATION

Three years after the initial certification is performed the recertification audit, the purpose of which is to verify the overall effectiveness of the management system with regard to internal and external changes, its continued relevance and applicability to the subject of certification, a proven commitment to maintaining the effectiveness and improvement of the management system throughout the scope of the standard.

Certification Process

ISO 9001:2015 Certification Steps (Region of Accreditation: Egypt, Saudi Arabia, Jordan)

1. CONTRACT CONCLUSION AND PRICE

In the initial phase, we verify the necessary documents - a request for certification, we check whether our CB is able to carry out the certification of management system according to the requirements of the potential client and in accordance with its own procedures and accreditation rules. Then we process and send a specific offer, sign a system certification contract with the customer, agreeing on a certification audit.

2. AUDIT PREPARATION

The Head of the **IETQAN** certification body appoints the lead auditor and other members of the audit team and sends the above to the customer for approval.

The lead auditor will request the documentation of the customer's management system necessary to prepare for the audit and, based on the known information, prepare an audit plan that will be sent to the customer for approval.

3. INITIAL CERTIFICATION AUDIT

The objective of the initial two-stage certification audit is a detailed verification of the compliance of the established management system with the requirements of the ISO 9001 standard.

The first stage of the initial certification audit is aimed at auditing the documentation of the customer's management system, examining the conditions of the customer's location, his understanding of the requirements of the standard. It is assessed whether internal audits are planned and carried out, management review and whether the level of implementation of the management system creates assumptions that the customer is ready for the second stage of the audit. Based on the documented findings, the plan of the second stage of the audit will be confirmed/adjusted. Where higher risk medical devices are concerned, the stage 1 should be performed on-site.

The purpose of the second stage of the initial certification audit is to evaluate the implementation of the client's management system, including its effectiveness in the overall scope and in accordance with the relevant standard on site at the assessed customer.

4. CERTIFICATION DECISION

Based on the results of the audit, so called certification decision maker will check the conclusions of the Lead auditor stated in audit report. On the basis of the above, he decides on the granting or non-granting of a certification.

The same certification decision process is used for maintaining, renewing, suspending, restoring or withdrawing of certification or for expanding or reducing the scope of certification.

5. SURVEILLANCE OF THE CERTIFIED CLIENT

As part of the surveillance audit, selected parts of the client's management system are checked, while the emphasis is mainly on the review of the actions taken in relation to the non-conformities found in the previous audit, the handling of complaints, the review of any changes, the use of marks and/or any appeals for certification, the overall evaluation of the effectiveness of the management system and its maintenance (internal audits and management review). The surveillance audit is carried out on site at the client.

In total, two surveillance audits are conducted within the 3-year cycle

6. RECERTIFICATION

Three years after the initial certification is performed the recertification audit, the purpose of which is to verify the overall effectiveness of the management system with regard to internal and external changes, its continued relevance and applicability to the subject of certification, a proven commitment to maintaining the effectiveness and improvement of the management system throughout the scope of the standard.

Certification Process

ISO 45001:2018 Certification Steps (Region of Accreditation: Egypt, Saudi Arabia, Jordan)

1. CONTRACT CONCLUSION AND PRICE

In the initial phase, we verify the necessary documents - a request for certification, we check whether our CB is able to carry out the certification of management system according to the requirements of the potential client and in accordance with its own procedures and accreditation rules. Then we process and send a specific offer, sign a system certification contract with the customer, agreeing on a certification audit.

2. AUDIT PREPARATION

The Head of the **IETQAN** certification body appoints the lead auditor and other members of the audit team and sends the above to the customer for approval.

The lead auditor will request the documentation of the customer's management system necessary to prepare for the audit and, based on the known information, prepare an audit plan that will be sent to the customer for approval.

3. INITIAL CERTIFICATION AUDIT

The objective of the initial two-stage certification audit is a detailed verification of the compliance of the established management system with the requirements of the ISO 45001 standard.

The first stage of the initial certification audit is aimed at auditing the documentation of the customer's management system, examining the conditions of the customer's location, his understanding of the requirements of the standard. It is assessed whether internal audits are planned and carried out, management review and whether the level of implementation of the management system creates assumptions that the customer is ready for the second stage of the audit. Based on the documented findings, the plan of the second stage of the audit will be confirmed/adjusted. Where higher risk medical devices are concerned, the stage 1 should be performed on-site.

The purpose of the second stage of the initial certification audit is to evaluate the implementation of the client's management system, including its effectiveness in the overall scope and in accordance with the relevant standard on site at the assessed customer.

4. CERTIFICATION DECISION

Based on the results of the audit, so called certification decision maker will check the conclusions of the Lead auditor stated in audit report. On the basis of the above, he decides on the granting or non-granting of a certification.

The same certification decision process is used for maintaining, renewing, suspending, restoring or withdrawing of certification or for expanding or reducing the scope of certification.

5. SURVEILLANCE OF THE CERTIFIED CLIENT

As part of the surveillance audit, selected parts of the client's management system are checked, while the emphasis is mainly on the review of the actions taken in relation to the non-conformities found in the previous audit, the handling of complaints, the review of any changes, the use of marks and/or any appeals for certification, the overall evaluation of the effectiveness of the management system and its maintenance (internal audits and management review). The surveillance audit is carried out on site at the client.

In total, two surveillance audits are conducted within the 3-year cycle

6. RECERTIFICATION

Three years after the initial certification is performed the recertification audit, the purpose of which is to verify the overall effectiveness of the management system with regard to internal and external changes, its continued relevance and applicability to the subject of certification, a proven commitment to maintaining the effectiveness and improvement of the management system throughout the scope of the standard.

Certification Process

ISO 14001:2026 Certification Steps (Region of Accreditation: Egypt, Saudi Arabia, Jordan)

1. CONTRACT CONCLUSION AND PRICE

In the initial phase, we verify the necessary documents - a request for certification, we check whether our CB is able to carry out the certification of management system according to the requirements of the potential client and in accordance with its own procedures and accreditation rules. Then we process and send a specific offer, sign a system certification contract with the customer, agreeing on a certification audit.

2. AUDIT PREPARATION

The Head of the **IETQAN** certification body appoints the lead auditor and other members of the audit team and sends the above to the customer for approval.

The lead auditor will request the documentation of the customer's management system necessary to prepare for the audit and, based on the known information, prepare an audit plan that will be sent to the customer for approval.

3. INITIAL CERTIFICATION AUDIT

The objective of the initial two-stage certification audit is a detailed verification of the compliance of the established management system with the requirements of the ISO 14001 standard.

The first stage of the initial certification audit is aimed at auditing the documentation of the customer's management system, examining the conditions of the customer's location, his understanding of the requirements of the standard. It is assessed whether internal audits are planned and carried out, management review and whether the level of implementation of the management system creates assumptions that the customer is ready for the second stage of the audit. Based on the documented findings, the plan of the second stage of the audit will be confirmed/adjusted. Where higher risk medical devices are concerned, the stage 1 should be performed on-site.

The purpose of the second stage of the initial certification audit is to evaluate the implementation of the client's management system, including its effectiveness in the overall scope and in accordance with the relevant standard on site at the assessed customer.

4. CERTIFICATION DECISION

Based on the results of the audit, so called certification decision maker will check the conclusions of the Lead auditor stated in audit report. On the basis of the above, he decides on the granting or non-granting of a certification.

The same certification decision process is used for maintaining, renewing, suspending, restoring or withdrawing of certification or for expanding or reducing the scope of certification.

5. SURVEILLANCE OF THE CERTIFIED CLIENT

As part of the surveillance audit, selected parts of the client's management system are checked, while the emphasis is mainly on the review of the actions taken in relation to the non-conformities found in the previous audit, the handling of complaints, the review of any changes, the use of marks and/or any appeals for certification, the overall evaluation of the effectiveness of the management system and its maintenance (internal audits and management review). The surveillance audit is carried out on site at the client.

In total, two surveillance audits are conducted within the 3-year cycle

6. RECERTIFICATION

Three years after the initial certification is performed the recertification audit, the purpose of which is to verify the overall effectiveness of the management system with regard to internal and external changes, its continued relevance and applicability to the subject of certification, a proven commitment to maintaining the effectiveness and improvement of the management system throughout the scope of the standard.