



UL LLC Medical Management System Registration Program Requirements





At the date of issuance of this document, UL LLC. is accredited by the following Accreditation Bodies for its Medical Quality Management System Registration programs. The scope of accreditation can be obtained directly from the website of the Accreditation Body, this information may be used by registered organizations to fulfill supplier qualification of UL.



<p>United Kingdom Accreditation Service ISO 9001 and ISO 13485</p> <p>http://www.ukas.org</p>	
<p>Medical Device Single Audit Program Recognized Auditing Organization</p> <p>https://www.fda.gov/medical-devices/cdrh-international-programs/medical-device-single-audit-program-mdsap</p>	



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1. Introduction

UL's Medical Quality Management System (MMS) Registration Program is designed to evaluate and register organizations to the standard ISO 13485 Medical Devices – Quality Management Systems. The program also provides for optional registration to ISO 9001 and registration to the Medical Devices Single Audit Program (MDSAP).

The objective of this program is to provide, by audit and subsequent follow-up audits (i.e. surveillance audits), independent verification of an organization's quality management system's (QMS) capability to consistently provide products and/or services that conform to given specifications. UL MMS registered firms must adhere to requirements of this document as a condition of registration.

Upon application to the program, UL provides these *Medical Management System Registration Program Requirements* to prospective organizations. These requirements may be modified or supplemented by UL at any time. This document identifies and describes the QMS scope for the goods or services that are the subject of Registration, specifies certain requirements for the registered QMS, specifies the particular type and form of UL mark which may be used in connection with the quality management system and the scope that is the subject of registration, the use of the marks, and the conduct of surveillance service.

This document contains basic requirements for all UL MMS Registration Program requirements, which apply to all registered organizations and additional requirements for organizations additionally registered to ISO 13485 under the MDSAP program. Any changes to program specific requirements shall be communicated to registered and pending clients.

For the most up to date version of UL's Medical Quality Management System Registration Program Requirements (00-MB-C0032) please check UL's web site at www.ul.com or contact your local UL representative.

2 Applicable Documents

- 2.1 ISO 9000: 2015 Quality Management Systems - Fundamentals and Vocabulary
- 2.2 ISO 9001:2015 Quality Management Systems - Requirements
- 2.3 ISO 9004: 2018 Quality Management Systems - Quality of an organization -- Guidance to achieve sustained success
- 2.4 ISO 17021-1: 2017 Conformity Assessment – General Requirements for Bodies Providing Audit and Certification of Management Systems
- 2.5 ISO 19011:2018 Guidelines for Quality and/or Environmental Management Systems Auditing
- 2.6 ISO 13485:2016 Medical Devices – Quality Management Systems
- 2.7 MDSAP Audit Model: MDSAP AU P0002
- 2.8 UL General Services Agreement and other certification contracts between UL and the client



3 Terms and Definitions

- 3.1 *Certificate of Registration* - A certificate recognizing the scope of registration that the quality management system, implemented by the organization having been assessed by UL, is in accordance with a specific management system standard and UL's Medical Quality Management System Registration Program requirements.
- 3.2 *Surveillance Audit* - An Audit performed by UL to determine an organization's continued compliance with the applicable standard and program requirements subsequent to facility registration. These Audits are typically scheduled 2 months in advance with agendas provided at least two (2) weeks prior to the visit date. UL also reserves the right to perform unannounced surveillance Audits.
- 3.3 *Registration* - A decision by UL that a facility's quality management system meets the requirements of a specific management system standard and UL's Medical Quality Management System Registration Program requirements. A certificate of registration is issued to the organization to indicate acceptance into the UL Medical Quality Management System Registration Program. An organization that has been granted registration by UL is a legal entity, an incorporated or unincorporated body that has been issued a certificate of registration. This organization subscribed to UL's Quality Management System Registration Program and is therefore responsible to comply with UL requirements and for UL invoices associated with the registration and associated Audits.
- 3.4 *Quality Management Standards* - The standards for quality systems published by the International Organization for Standardization. The certificate of registration may also denote conformance with equivalent series standards such as European Norm, American National Standards Institute and Canadian Standards Association standards.
- 3.5 *Management Representative* - A member of the organization's management who represents the evaluated facility and is responsible for the facility's quality management system as it pertains to the relevant products and/or services covered in the organization's scope of registration.
- 3.6 *Organization* - The party that is responsible for the product, process or service and is able to ensure that quality assurance is exercised. This definition may apply to manufacturers, distributors, importers, assemblers, service organizations, etc.
- 3.7 *Quality Management System (QMS)* - The organizational structure, responsibilities, procedures, processes and resources for implementing a quality management system.
- 3.8 *Recertification Audit* - The evaluation performed by UL to confirm compliance of the organization's quality management system with the requirements of the applicable QMS standard(s) at the end of the organization's registration cycle.
- 3.9 *Registration Audit* - The evaluation performed by UL to determine the compliance of the organization's quality management system with the requirements of the applicable QMS standard(s).



- 3.10 *Scope of Registration* - A synoptic description outlining the relevant process, product and/or service areas that are provided under the organization's registered quality system. Proposed scope of registration is agreed on prior to the Registration Audit.
- 3.11 *UL* - UL LLC® and its affiliates.
- 3.12 *UL Online Certification Directory* - A listing of the facilities that have been issued certificates of registration to at least one of the QMS standards by UL. Descriptions shall define a facility's name, address, , facility scope of registration and the registration issue date. This is available electronically on UL's web site at www.ul.com.
- 3.13 *UL Registered Firm Mark* - The UL mark which is used by registered organizations in accordance with UL's registration agreements and Appendix A of these requirements to publicize their facility registration.

4 **UL's Quality Management System Program Requirements**

4.1 **General**

- 4.1.1 UL is the sole authority by which UL certificates of registration may be issued.
- 4.1.2 An organization capable of demonstrating a legitimate business that complies with the ULMMS Program Requirements shall be entitled to a certificate of registration that shall remain the property of UL. The certificate must be returned to UL upon request.
- 4.1.3 All organizations audited under UL's scope of accreditation shall be given the opportunity to have the mark of one or more of those Accreditation Bodies appear with UL's Registered Firm mark on their certificate.
- 4.1.4 A separate certificate shall be issued for each registration for which an application is submitted.
- 4.1.5 Certificates are renewed as indicated on the Certificate of Registration unless cancellation, suspension or withdrawal occurs. If an organization does not intend to renew its registration, it must notify UL in writing of its intentions not less than sixty days prior to its renewal.
- 4.1.6 An organization's right to use the Certificate of Registration is not transferable to any other person, organization or corporation without UL's written authorization.
- 4.1.7 The organization agrees that it shall comply with all applicable laws, statutes and regulations (e.g. state, region, province, country, etc.).
- 4.1.8 The organization shall report incidents to respective Regulatory Authorities in-line with the local country's laws and Directives.



- 4.1.9 UL is required to be notified of the reported incident only where the device is CE Certified under any UL partner Notified Body;
- 4.1.10 Where incidents occur to products covered outside of i) above, the organization is required only to inform UL of any incidents leading to product recall, advisory notices and where leading to significant change in processes.
- 4.1.11 Should UL's representative identify items, which are not in compliance with this document or the applicable standard and other criteria, the organization shall either correct such items or cancel registration and immediately refrain from any further reference by UL and this program.
- 4.1.12 If it is reported that the organization's QMS for goods or services under their scope of registration are not in compliance with this document or applicable standards, the organization shall cooperate with and assist UL in obtaining the facts, including sharing such information as the organization acquires regarding the reported noncompliance, and to take and report to UL on such corrective action necessary to correct any noncompliance found to exist within a specified time period of time.
- 4.1.13 The Surveillance Audit service of UL and any other Audits conducted by UL, are designed to serve only as a verification of continued compliance of the organization's quality management system, with this document, the applicable standards and other criteria. The organization is in no way relieved of its responsibility for its quality management system and its scope of registration for those goods or services that are subject to the certificate issued by UL.
- 4.1.14 Occasionally the Audit Team may include members that are external to (not directly employed by) UL. These individuals meet all of UL's current auditor qualification requirements and must comply with UL's criteria for confidentiality, conflict of interest and ethical standards. See also section 6.1.3 of this document.
- 4.1.15 Additionally, UL Audit Teams may include UL trainee auditors, observers from accreditation bodies, regulatory authorities and other UL staff. As a condition of registration the organization permits such persons to accompany the UL Audit Team. UL shall not charge the organization for any time or expenses of such persons being present on an Audit.
- 4.1.16 Quality system consultants contracted by the organization are limited to the role of an observer.

4.2 The Organization shall:

- 4.2.1 At all times comply with UL MMS Registration Program Requirements
- 4.2.2 Maintain and document a QMS in accordance with the requirements of the applicable standard(s) and make available copies of that documented quality management system (or any parts thereof) should UL require it for registration purposes.



- 4.2.3 Notify UL in writing of significant changes to the management system. [Please use the **UL Significant Change, Additional Registration and Vigilance Notification Form**; 00-MB-F0853] Such significant changes requiring notification to UL are:
- Increases/decreases in staff that exceed 20% of total
 - Change of management representative, change in any contact details especially for primary and secondary contacts.
 - Change of legal entity name
 - Change of address of sites or off-sites listed on the certificate of registration, Addition/removal of sites or off sites;
 - Expansions or reductions to scope of registration
 - New manufacturing technologies used
 - Significant changes to existing manufacturing processes
 - Significant changes to outsourced processes (whole product design, greater than 75% of product manufacturing, software design and development, sterilization)

For all items above, notification shall be provided at least 10 weeks in advance of the date of effect of the change or the start of that activity. UL shall evaluate if additional Audit activity is necessary for verifying registration conformance in relation to any changes. All such notifications should be made by email to Inform.Regulatory@ul.com

- 4.2.4 Discontinue any use of the UL Registered Firm mark that is unacceptable to UL and any form or statement of reference that in the opinion of UL might be misleading. The organization shall not use its certification in such a manner as to bring into disrepute or cause loss of public trust to UL LLC, its affiliates, representatives or the certification system.
- 4.2.5 Ensure that any purchased finished product, processes or services covered under the organization's scope of registration complies with UL MMS Registration Program assessed capability. If any finished products, processes or services are produced or provided external to the organization's quality management system, the external producer or provider may also be evaluated during the registration process. This may require an on-site audit of the external producer or provider by the UL Audit Team. In cases where products described in the scope of registration are not traceable to a QMS registration that is recognized by UL, the organization shall establish and operate a procedure for notifying the prospective customer that the items in question have not been produced or provided within UL's registration.
- 4.2.6 Give the representatives of UL and any such observers access (including but not limited to accreditation body representatives, regulatory body representatives, other UL observers and UL trainees) during normal working hours, for the purpose of examining systems, processes, methods of test, and records; or, if necessary, to establish that the procedures for the termination of registration described in sec. 4.2.9 below have been carried out;



- 4.2.7 Extend all necessary privileges and assistance to UL's representatives and observers, including health and safety conditions, so the representatives may properly perform their function under UL's Registration or Surveillance Audit service, and shall make all written material utilizing the UL Registered Firm Mark and other means of displaying the mark available for audit by UL's representative.
- 4.2.8 Nominate a management representative and one or more deputies authorized to act in the main nominee's absence (and replacement nominees as may be necessary) who shall be responsible for all matters in connection with the requirements of the Certificate of Registration.
- 4.2.9 Not use any report or certificate issued as a result of a UL MMS Audit to indicate that a product is Listed, Classified or Recognized by UL, or as the basis of any oral or written representation to suggest that any product or system has been, or is, Listed, Classified or Recognized by UL.
- 4.2.10 Not release any information referencing UL MMS Audit acceptance, certification and/or registration of the facility before it is established and confirmed in writing by UL.
- 4.2.11 Make available to UL, when requested, the records of all complaints and corrective action taken, in accordance with the requirements of the quality management system standards or other normative documents

MDSAP Program Specific Requirements

- 4.2.12 Agrees that the audit report generated is shared to all jurisdictions participating in the MDSAP program where the organization has market access. Additionally, Organizations agree that Regulatory Authorities to share all documents and records related to the audits with other Regulatory Authorities that have formal established confidentiality agreements between governments which covers provisions for protecting proprietary information and trade secret information.
- 4.2.13 Will receive an audit report specific to each site under the quality management system.
- 4.2.14 Agrees that the audit findings generated from any audit, will be shared amongst all jurisdictions where the organization has market access in the MDSAP program.
- 4.2.15 Agrees to the nonconformity grading system per GHTF/SG3/N19.
- 4.2.16 Will not object to the composition of the audit team per the requirements of IMDRF/MDSAP WG/N3.
- 4.2.17 That the MDSAP program does not absolve the organization from potential unannounced audits, either by the Regulatory Authority (FDA, Health Canada, ANVISA, TGA, PMDA, etc.), as needed per the requirements of GHTF/SG3/N19 for



one or more nonconformity(s) graded as a “5”; or more than two nonconformities graded as a “4.” The unannounced audit will minimally require two auditors for one day onsite.

If specific information provides reasons to suspect serious nonconformities of the devices or if a Regulatory Body requests UL to conduct an unannounced audit, the audit shall focus on the specific information of the serious nonconformities or request of the Regulatory Authority.

The unannounced audits may occur on premises of the manufacturer or of the contracted critical suppliers. If a visa is needed to visit the country where the manufacturer is located, the contractual arrangements should contain, as an annex, an invitation to visit the manufacturer or contracted critical supplier at any time and an invitation which leaves the date of visit open. The contractual arrangements shall also contain, as an annex, similar invitations issued by the critical suppliers. The contractual arrangements shall authorize the auditing organizations to end the contract as soon as permanent unannounced access to the premises of the manufacturer or his contracted critical suppliers is no longer assured. The contractual arrangements shall furthermore cover the measures to be taken by auditing organizations to ensure the security of their auditors. It shall provide for a financial compensation for the unannounced audits including security arrangements.

4.2.18 If Organization ends the relationship for the MDSAP program and/or manufacturing site(s) with UL, that all documentation associated with the current certification cycle and valid certificates may be shared with the next Auditing Organization (Registrar) upon request.

4.3 UL shall:

4.3.1 After granting registration to an organization, UL shall issue a Certificate of Registration valid for a period not exceeding three years.

4.3.2 Send a representative to the organization at its discretion but not less than once per year to a site in which the organization is manufacturing goods, operating processes or offering a service for which it is registered for the purpose of verifying that the obligations imposed by the Certificate of Registration are being carried out. The scope and extent of any re-audit activity shall depend on the Surveillance Audit cycle and the performance and activities of the organization; The maturity and continued effectiveness of the quality management system is monitored through the Surveillance Audit process, including the audit of management review, complaint handling, internal audits, corrective action, preventive action, effectiveness of meeting quality objectives, continual improvement (where applicable), conformity of regulatory requirements and use of marks (including Accreditation Body marks) and other reference to certification.

4.3.3 Not disclose any information concerning the organization which is of a confidential nature, without the organization's prior authorization in writing other than information which has been made publicly accessible by the organization; Information about a particular product or supplier shall not be disclosed to a third party without the written



consent of the supplier except as required by regulatory authorities for matters of regulatory compliance or protection of public health. Where law requires information to be disclosed to a third party, UL shall inform the supplier of the information provided.

- 4.3.4 Ensure the safe handling of all customer confidential information by using secure facilities and systems for the storage and transmission of documents and records.
- 4.3.5 Conduct audits and maintain registration with the highest levels of impartiality. In our audits UL shall evaluate only the facts presented against the requirements of the audit criteria with regard to no other interest.
- 4.3.6 Demonstrate responsibility for ensuring that all relevant and applicable information, scientific principles and ethical standards in determining the acceptability of information in all dealings with clients, accreditation bodies, regulatory authorities and other stakeholders.
- 4.3.7 Ensure that persons carry out audits with demonstrated competence for the activities, which they are evaluating.
- 4.3.8 Provide transparency to organizations registered or seeking registration in regards to our audits and methodology.
- 4.3.9 Notify the organization at its discretion of customer complaints relating to the compliance of its product, process or service with the specified requirements.
- 4.3.10 Direct its representative to exercise due care in complying with any safety regulations which may be applicable generally to the organization's facility personnel effecting the quality management system.

5 Compliance with UL's Management System Program Requirements

- 5.1 If an organization is temporarily unable to comply with these UL Quality Management System Registration Program Requirements, UL may require the organization to discontinue use of the Registered Firm mark, any claim to registration under the Registration, and notify customers until the conditions of registration are again achieved or pending the result of an appeal as described under section 6.8.
- 5.2 If the organization fails to comply with these UL Quality Management System Registration Program Requirements UL may, subject to the provisions in section 6.5, as appropriate:
 - a) Revoke the Certificate of Registration
 - b) Refuse to issue or renew the Certificate of Registration
 - c) Change/limit the scope of registration
 - d) Notify vendors, regulatory authorities, and potential users of improper or unauthorized use of the UL mark or improper or unauthorized reference to UL

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- 5.3 UL may, at its discretion, and subject to the provisions in section 6, revoke or refuse to issue or renew a Certificate of Registration if the organization becomes subject to the bankruptcy laws or makes any arrangements or composition with its creditors, or enters into liquidation, whether compulsory or voluntary (but not including liquidation for the purpose of reconstruction), or has a receiver of its business appointed, or is convicted of an offense tending to discredit the organization's reputation and good faith as a trader. Such decisions, and the grounds for them shall be communicated to the organization in writing.
- 5.4 In the event that UL makes changes to its Quality Management System Program and/or requirements that affect the registration of registered organizations, UL shall:
- a) Specify an effective date for the changes, which shall allow sufficient time for the UL registered organizations to amend their quality system,
 - b) Formally notify all UL registered organizations affected by the new requirements of the effective date of the change and new action required of them.
 - c) Where appropriate, afford the opportunity for UL registered organizations to submit comments on the proposed changes,
- 5.5 The registered organization is required to take required action by the effective date. If agreed action is not acceptably taken, withdrawal or suspension of Registration may occur (see sec. 6.5). If a Special Audit of the system is necessary to evaluate the organization's system due to the revised requirements, the registered organization shall be responsible for the cost of the evaluation.

6 UL's Quality Registration Services

6.1 *Prior to the On-site Visit*

- 6.1.1 UL shall provide the organization an Audit Notification which advises scheduled dates, assigned Audit Team and cost details for the audit. Any concerns regarding, or significant changes impacting, the audit arrangements must be raised to UL in response within 2 weeks of the Audit Notification, otherwise UL will proceed to book the arrangements as specified. Organizations requiring a Purchase Order for invoicing should also provide a Purchase Order document in response to the Audit Notification.
- 6.1.2 If there are significant changes, the organization shall provide UL information about those changes to their organization by completing the Significant Change Form and responding to the questions listed in the Audit Notification for planning the audit. Upon receipt of information concerning the change, UL shall evaluate and confirm any adjustment to the scheduled activity. Any application forms must be completed and returned to UL prior to commencement of the scheduled on-site visit
- 6.1.3 The organization shall accept any quote for the audit, which may include additional costs to verify changes that have been communicated by the manufacturer.



- 6.1.4 UL shall provide an Audit Confirmation to the organization concerning the finalized visit dates and name(s) of the assigned Audit Team. Background information may be provided by UL upon request for each member of the Audit Team.

6.2. On Site Visits

- 6.2.1. **Pre-assessment Meeting** – UL representatives shall enhance a company's understanding of the QMS standard and to explain the mechanics and structure of the registration program. Discussions may include topics such as global quality standardization activities and the advantages provided by UL's accreditations. Other company specific topics such as scope of registration, selection of facilities to be registered, organizational structure and proposed schedules for audit can also be discussed.
- 6.2.2. **Pre-Assessment Audit** – A Pre-assessment Audit of each facility can be performed in accordance with the requirements of the program. At the conclusion of the evaluation, the UL representative(s) shall summarize the audit results and provide the facility representatives with a report of the Audit Team's findings. In this report, UL will not draw any conclusions as to the eligibility of the evaluated facility for registration under UL's Quality Management System Registration Program. The number of Pre-assessment Audits conducted at one facility may not exceed two. UL cannot offer Pre-assessment Audits for customers with existing registrations.
- 6.2.3. **Registration Audit** - The Registration Audit is scheduled when a facility is determined to be eligible for audit based on the review of the preliminary information described above. The Registration Audit is conducted in two stages:
- **Stage 1 Readiness Audit:** Allows the UL audit team to evaluate the client's readiness and preparedness for the Stage 2 Certification Audit. The UL Audit Team shall also obtain information regarding the scope of the subject QMS, site operations, processes, regulatory requirements and associated risks to provide a focus for the planning for the Stage 2 Certification Audit including allocation of resources. Depending on the complexity of the QMS, the Stage 1 Readiness Audit may be conducted on-site or off-site. However, the organization may elect to have the Stage 1 Readiness Audit conducted on-site.
 - **Stage 2 Certification Audit:** The UL Audit Team shall evaluate the effective implementation of the subject QMS. The Certification Audit shall cover all processes included in the scope of the QMS and shall be conducted at the organization's site(s). The Stage 2 Certification Audit must be conducted within six months of the completion of the Stage 1 Readiness Audit for the conclusions of the Stage 1 Readiness Audit to remain valid.
- 6.2.4. **Surveillance Audit** – An onsite audit shall assess key processes of the subject QMS to provide confidence to the UL Audit Team that the QMS continues to fulfill requirements and objectives. Surveillance Audits are conducted on bi-annual or annual frequency. The Lead



Auditor may recommend that the organization be placed on biannual visits based on a number of factors including type and number of nonconformities and immature quality management system. The First Annual Surveillance Audit following certification shall be conducted within nine to twelve months of the last day of the Stage 2 Certification Audit. The Second Annual Surveillance Audit shall be performed approximately twelve months thereafter. For customers on biannual surveillance, audits shall be conducted approximately every six months.

- 6.2.5. **Recertification Audit** – Recertification shall include the continued performance of the QMS as a whole over the previous cycle of Surveillance Audits and examine its continued ability to meet the scope of registration. Recertification Audits shall be conducted at the organization's site(s) on a three-year cycle. Recertification Audits are planned sufficiently in advance (usually three months prior to certificate expiry date) to enable recertification to occur without interruption of the organization's certification.
- 6.2.6. **Special Audit** - A Special Audit is an additional evaluation to determine continued conformance to findings against requirements that were determined to be significant and required corrective action. An Audit Team shall be scheduled to perform a Special Audit in addition to the regular scheduled surveillance Audits to verify the implementation of major corrective actions. Clauses audited during a Special Audit shall be determined based on the Audit finding, field data, complaints, client requests, major organizational or system changes, etc. Special Audits may not be considered as part of Surveillance or Recertification Audits or for deferment of such Audits.
- 6.2.7. **Scope Expansion Audits** - A Scope Expansion Audit is scheduled when a UL client requests to expand their scope of registration to include other standards, operations, etc. This can be scheduled in conjunction with a Surveillance Audit or separate from the Surveillance Audit schedule. A Scope Expansion Audit normally results in additional Audit time.

6.3. Issuing Registration

- 6.3.1. At the completion of the Audit, and prior to leaving the facility, the UL Audit Team shall provide the organization's Management Representative with an Audit Report and any Action Requests generated during the evaluation that itemize discrepancies uncovered during the Audit. Time limits for Action Request responses are to be determined by UL. The Audit Team shall also provide a recommendation as to the organization's eligibility for facility registration.
- 6.3.2. The Audit Team's recommendation provided at the end of the Audit, and the entire Audit Report is later subject to review for a certification decision. Upon concurrence of the Audit Team and Reviewers, the Audit result and certification decision shall be finalized. An appeals process is available to the organization should they disagree with the certification decision.
- 6.3.3. Nonconformities fall under two categories, "major" and "minor". UL uses definitions for major and minor nonconformities adopted from the Global Harmonization Task Force.



A major nonconformance is either:

- a) Any unjustifiable exclusion or failure to address an applicable requirement in the medical device regulations such as Part 1 of the Canadian Medical Devices Regulations, Medical Devices Directive or In-Vitro Diagnostic Devices Directive
- b) Failure to implement an applicable element of the quality systems standard
- c) An excessive number of minor nonconformities against an element of the regulatory requirements for quality systems that indicates trend or absence of control.
- d) Failure to implement appropriate corrective and preventative action when an investigation of post market data indicates a pattern of product defects;
- e) Products which are put onto the market which cause undue risk to patient and/or users when the device is used according to the manufacturer's instructions;
- f) The existence of products which clearly do not comply with the manufacturer's specifications and/or the regulatory requirements due to defective elements in the quality system;
- g) Failure to inform UL of significant changes (see section 4.2.3)
- h) Repeated nonconformities from previous audits.

6.3.4. Major non-conformances must be responded to within ten days of the last day of the audit where the nonconformity was raised.

- i) A major nonconformity may result in a Special Audit to verify effective implementation of the corrective actions.
- ii) The major nonconformity must be resolved prior to the issuance or re-issuance of the applicable Certificate of Registration.
- iii) A billable project will be opened within 30 days of the issuance of the major nonconformity to cover the time needed to review the information and records required to close out the nonconformity.
- iv) Manufacturers must provide evidence of implementation of the remediation actions to UL within 30 calendar days of the last day of the audit.
- v) Evidence of implementation of the remediation actions to address MDSAP Grade 4 and/or Grade 5 nonconformities, must be provided to UL within 30 calendar days of the last day of the audit.

6.3.5. Minor nonconformities defined as a quality system non-conformance that judgment and experience indicates is not likely to:

- a) Result in the failure of the quality system, or
- b) Reduce its ability to assure controlled processes, or
- c) Result in the probable shipment of nonconforming product

6.3.6. Minor nonconformities must be responded to within fifteen days of the last day of the audit where the nonconformity was raised.

6.3.7. All minor nonconformities must be resolved within 60 days of the issuance. Manufacturers must provide to UL evidence of correction and corrective action within 60 days of issuance. UL will open a supplemental project to conduct the evaluation of the evidence submitted to



address the correction and corrective actions. The amount of time to be quoted for this project will be dependent on the number and nature of the nonconformities raised.

- 6.3.8. Registration is granted only if the facility evaluated fully complies with the requirements of the selected standard. The Management Representative must respond to any Action Requests generated during the audit directly to the UL auditor. If they are not satisfactorily resolved, UL shall provide an explanation of the reasons why the response did not resolve the nonconformance.
- 6.3.9. When Registration is granted a Certificate of Registration shall be issued to the facility indicating that the facility's quality system complies with a given QMS standard, for a specific group of products and/or services and to recognize the organization's registration under UL's Quality Management System Registration Program. The name of the facility and a copy of the certificate shall also be published in UL's Online Certification Directory.

6.4. Maintenance of Registration

- 6.4.1. Upon issuance of a UL Certificate of Registration, a program of Surveillance Audits shall be established. The establishment and maintenance of UL registration is contingent upon the continued adherence to the terms and conditions of this document by the organization. During these visits, UL shall verify that the facility continues to comply with the requirements of the applicable QMS standard and other program standards, as applicable, and UL's MMS Registration Program.
- 6.4.2. Surveillance Audit visits shall be conducted annually. Annual Surveillance Audit(s) will cover approximately one third to one half of the quality management system. A Recertification Audit covering all clauses of the applicable standard(s) is conducted every third year as part of an ongoing program designed to maintain the organization's registration. The Recertification Audit duration will be approximately two-thirds of the time required for a Registration Audit.
- 6.4.3. Alternate Audit methods may be used only when specifically authorized by UL in writing.

6.5. Suspension or Withdrawal of Registration

- 6.5.1. Registration may be suspended by UL under any of the following conditions,
 - a) The organization's quality system no longer complies with the requirements of the applicable Quality Management System standard or UL MMS Registration Program Requirements.
 - b) The organization's use of any UL symbol, marking, or statement that is determined by UL as unacceptable or misleading.
 - c) The organization's use of any accreditation body marking, symbol or statement that is determined by UL and/or the Accreditation Body as unacceptable or misleading.
 - d) The organization is delinquent in payments.
 - e) The organization violates a signed UL agreement during the process of, or after, achieving registration.



- f) The organization has exhibited a lack of commitment in responding to Nonconformities (action requests) including continued failure to provide adequate root cause analysis or continues not to meet agreed response dates.
 - g) The organization delays or refuses the scheduling of an Audit.
 - h) The organization's management system continues to demonstrate a non-effective QMS by repetitive nonconformances (action requests) being issued and not resolved.
 - i) The organization refuses to allow access to UL Auditors or Accreditation Body observers, Regulatory Body observers or other UL observers to any facility referred to in section 4.3.2 of this document.
 - j) The corrective action to address minor nonconformities is not submitted to UL within 60 days, or is not sufficient to address the nonconformity.
 - k) The remediation action for any MDSAP Grade 4 and/or Grade 5 is not submitted to UL within 30 calendar days of the last day, or is not sufficient to address the nonconformity.
 - l) The quote for the supplemental project, to review the evidence submitted to correct the nonconformities, is not accepted by the organization and thus the nonconformities cannot be closed.
- 6.5.2. While the suspension is in effect, the organization's certification is invalid. The client should refrain from any further promotion of its certification and the UL registered firm mark.
- 6.5.3. The Organization shall resolve any issues surrounding registration suspension within a period of less than 90 days. If the issues have not been resolved within this timeframe, UL shall withdraw registration. The organization may also request withdrawal of registration at any time subject to any notice period contained in this document or other agreements.
- 6.5.4. UL may reduce the scope of registration to exclude parts, services or sites that consistently fail to meet the certification requirements for those parts of the scope of the registration. UL shall update its certification directory and certification documents and the organization shall amend its advertising and promotional material to remove references to UL certification or use the UL Registered Firm Mark to only products or services covered by the reduced scope of certification.
- 6.5.5. UL's registration shall be discontinued for any quality system or goods or services which, for any reason, are no longer eligible for registration.
- 6.5.6. Upon withdrawal of any rights or authority conferred by signed agreements, UL shall take one or both of the following actions:
- a) Discontinue in whole or in part UL registration of the quality system and any goods or services covered, and
 - b) UL's representative shall have the right to acquire possession of any written material utilizing the UL certificate, mark, and any other form or reference to UL, which were used in connection with any system, goods or services which are no longer subject to registration.



- 6.5.7. Upon the termination or withdrawal of the Certificate of Registration the organization shall immediately discontinue the use of the UL Registered Firm mark and all matter which contains reference to it or its certification status. This does not in any way limit the actions that UL may take in the event of the termination of any rights or authority conferred by signed agreements.
- 6.5.8. In the event of suspension or withdrawal of registration, UL shall update the registration information in the Online Certification Directory by denoting the status as suspended or withdrawn.

6.6. Complaints

- 6.6.1. Any person may lodge a complaint regarding UL's auditors or services. All complaints received orally or in writing shall be investigated. If a complaint is communicated orally, the complainant will be encouraged to submit a documented complaint. If the complainant wants a formal response from UL regarding their complaint, they should document it and submit it to UL. Undocumented complaints do not require a formal response from UL.
- 6.6.2. Personnel handling complaints shall conduct a complete and thorough review of the facts and information acquired from all available sources. Decisions regarding all complaints shall be based on the facts and information collected and should take into account the resolutions and actions resulting from prior similar situations.
- 6.6.3. If a complainant wants to remain anonymous and does not request a response, the complaint shall still be evaluated and considered for possible corrective actions to be taken.
- 6.6.4. Upon its resolution, the individual(s) assigned to handling the complaint will communicate the actions taken to the complainant within the bounds of confidentiality as described more specifically below. Copies of documentation addressing the complaint and its resolution shall be included within UL's corrective action system.
- 6.6.5. All customer complaints shall be acknowledged within forty-eight hours and where possible, resolved within that time frame. If additional time is required, this shall be explained to the complainant and should not exceed thirty days.
- 6.6.6. If the complaint is determined to be not valid, the regional management involved shall communicate the results of the investigation to the complainant.
- 6.6.7. If the complaint is determined to be valid, the assigned individual shall take corrective action. The results of the investigation and the corrective action plan are to be communicated to the complainant including determining (with client and complainant) whether and to what extent the subject of the complaint and resolution shall be made public. If the complainant is not satisfied with the results of the investigation and UL's corrective/preventive actions, and the regional management cannot come to an agreeable solution with the complainant, regional management shall inform the complainant of their right to make their complaint to a higher UL management level.



- 6.6.8. The complainant may request at any time information on the consideration of the complaint or on any corrective action taken thereafter.

6.7. Complaints About UL Subscribers

- 6.7.1. When UL receives a complaint about a subscriber, confidentiality of the subscriber's files and any other associated information must be maintained in accordance with UL policy and the agreements UL has signed with the subscriber.
- 6.7.2. If UL receives a complaint(s) by a subscriber's customer(s) about that subscriber, regional management shall communicate the complaint to the subscriber if agreeable to the customer and depending on the significance and impact on the system.
- 6.7.3. Only complainants who are willing to identify themselves to the UL subscriber will be made aware of their complaint's resolution (i.e. the resolution would be communicated by the UL subscriber during resolution). UL shall encourage its subscriber to work with the complainant through their quality system's complaint handling mechanism to resolve the issue. UL can follow-up during the subsequent routine surveillance Audit(s) by evaluating the subscriber's resolution of the complaint.
- 6.7.4. UL shall enter all written complaints into UL's corrective action system so it may be investigated and the subscriber's resolution of the complaint tracked.
- 6.7.5. If the investigation into the complaint leads UL to determine that further investigation is necessary, yet without an on-site visit, regional management shall request that the subscriber provide a corrective action plan including root cause analysis, planned actions and timing.
- 6.7.6. If a representative of UL management determines after review of the complaint and any other associated evidence, that an on-site visit is required, the following shall be observed:
- a) Depending on the severity of the complaint, certain elements/systems may have to be evaluated at the next Surveillance Audit, or an immediate Audit of the subscriber may need to be scheduled.
 - b) If a major nonconformance is found during the assessment of the complaint, it is to be documented in the Audit Report and a response by the organization shall be required within 10 days of the last day of the Audit.
- 6.7.7. UL shall provide monthly progress reports to the complainant should the process take in excess of one month to conclude. The complainant may also enquire at any time the status of the complaint. However UL shall not release any confidential information regarding the UL subscriber unless as otherwise stated in the document.
- 6.7.8. UL shall determine, together with the subscriber and the complainant whether and, if so to what extent, the subject of the complaint and its resolution shall be made public.



6.8. Disputes and Appeals

- 6.8.1. An organization may dispute the issuance or classification of any nonconformity issued by the UL Audit Team. In the first instance the dispute should be raised to the Lead Auditor of the Audit Team. If the organization is not satisfied, then the dispute can be raised to a UL certification decision maker for resolution. If an agreement still cannot be reached, and the nonconformity shall likely result in registration withdrawal, then the organization is invited to make a formal appeal.
- 6.8.2. Disputes should be submitted in English by email or other written means to the Lead Auditor of the Audit Team for forwarding to a regional certification decision maker. The disputes **must be submitted within the allowable time frame for response to the nonconformity as per section 6.3.3 above.**
- 6.8.3. The UL certification decision maker shall confirm receipt of the dispute. While the dispute is being assessed no further action by the customer is required in regards to that specific nonconformity.
- 6.8.4. Appeals are generally not complaints. An appeal is made when there is a disagreement with a UL decision to not grant, or to withdraw registration.
- 6.8.5. Appeals should be documented by the organization and submitted in English to UL on company letterhead with the signature of an executive officer. The appeal must provide full details to support the overturning of a recommendation not to grant or withdraw registration. Appeals must be made within 30 days of the audit where certification was refused or within 30 days of the notice of certification withdrawal.
- 6.8.6. Upon receipt of the appeal, UL's Lead Regional Lead Reviewer shall acknowledge the receipt of the appeal to the applicant. An appeals panel shall then be convened to assess the validity of recommendation not to grant or withdraw registration. The appeals panel shall include additional UL Auditors independent of both the Audit recommendation and the review of the audit where a recommendation not to grant or withdraw registration was made. A member of UL's external impartiality committee, the Medical Management Systems Council, shall chair the appeals panel.
- 6.8.7. Once an appeals panel is formed, it shall be verified with the appellant to ensure they have no objection to the composition of the panel. The appellant may state objections to the composition of the appeals panel. Consequently the constitution of the panel may be amended accordingly in order to resolve those objections. Once both sides agree to the composition of the panel, both UL and the appellant agree to abide by the decision formed by the appeals panel.
- 6.8.8. The chair of the appeals panel shall verify that all facts are equally presented to the individual UL assessors upon the appeals panel. Each UL assessor shall be requested to independently weigh the organizations appeal with records generated from the audit. Additional requests for information from either the UL Audit Team of the organization shall be requested through the chair of the appeals panel.



- 6.8.9. The UL Auditors shall be asked to make their decision in writing and to document their rationale. The chair of the panel shall ensure that the decisions reached are consistent with the facts as presented by the organization.
- 6.8.10. A majority decision of the panel assessors shall be carried forth as the final decision of the panel.
- 6.8.11. The appellant may request to UL's Lead Regional lead Reviewer the status of any application at any time during the appeals process or in relation to UL's corrective action should the appeal be successful.
- 6.8.12. UL's Lead Regional lead Reviewer will provide in writing the decision and reasoning of the panel's final decision to the appellant. The final decision shall be provided within 45 days of the receipt of the written appeal.
- 6.8.13. The appellant is at liberty to bring the handling of their concern to the attention of an accreditation body if they believe the appeal has not been handled in accordance with UL's Medical Quality Management System Registration Program requirements.
- 6.8.14. UL shall ensure that no discriminatory action is taken against an organization in any way for the submission of a dispute, appeal or complaint.

7. UL's Regulatory Programs

7.1. **Medical Devices Single Audit Program**

- 7.1.1 UL provides registration to ISO 13485:2016 and the MDSAP program, as administered by the MDSAP Regulatory Authorities.
- 7.1.2 UL shall evaluate and register manufacturers to the requirements of the standard ISO 13485: 2016 and MDSAP program requirements.
- 7.1.3 In addition to sections 4.1.12 of this document, as a condition of registration under the MDSAP program the manufacturer agrees to allow UL's Audit Team to be observed by representatives from the MDSAP Regulatory Authorities during the onsite Audit at the manufacturer's location(s).
- 7.1.4 As condition of registration under the MDSAP program the manufacturer agrees to allow UL's release to the MDSAP Regulatory Authorities (RA) any document that RA's consider necessary to determine a medical device manufacturer's conformance to ISO 13485. These documents would include those that UL or its auditor's use to plan, perform or follow-up on an ISO 13485 investigation, and to record observations or report results of an ISO 13485 quality management system audit. All documents held by Regulatory Authorities shall be treated in accordance with appropriate



regulations and guidelines dealing with confidential and proprietary information. The documents required will be uploaded to the FDA REPS database as required under the MDSAP program to facilitate access to the participating Ras.

- 7.1.5 UL shall notify Regulatory Authorities in writing of any change in a manufacturer's registration certificate status relating to extension or reduction of scope, suspension or withdrawal of that certificate.
- 7.1.6 UL shall publish a list of manufacturers registered by UL under the MDSAP program with the manufacturer's address and scope of registration in UL online certification directory.



Appendix A - Conditions for Use of the UL Registered Firm Mark

A.1 General

- A.1.1 Upon acceptance of the following conditions, the registered organization is entitled to use the UL Registered Firm Mark illustrated below. Camera-ready artwork of the UL Registered Firm mark is available for photo reproduction from the UL office handling the registration. An electronic form of the logo is also available from UL's web site (www.ul.com).
- A.1.2 UL is the owner of the UL Registered Firm mark which incorporates the name, abbreviation or symbol of UL LLC (referred to as the "Mark") and which may, only under the conditions of this document, be used by the organization in connection with its quality system and the goods or services that are the subject of Registration to indicate that such goods or services are covered by UL and its registration. The organization shall not use such a Mark nor in any other way make use of UL's name, abbreviations, or symbols, or any other form or reference which may be interpreted to mean UL LLC, in connection with its quality system and goods or services not in compliance with this document and Requirements.
- A.1.3 In the opinion of UL the promotional or advertising material shall not be in conflict with the findings of UL and that the reference to UL LLC shall in no way create a misleading impression as to the nature of UL's findings and Registration. Except for the mark that is prescribed for use in Appendix A, no other UL mark may be used in the advertising and promotional material supplied unless otherwise specifically authorized in writing by UL. In those instances where a marking is used, any text, which is prescribed by this document, shall be used.
- A.1.4 The UL Certificate of Registration and Mark shall be used in the manner authorized by UL and subject to the control of UL. Requests for use of UL's Certificate of Registration and Mark shall be processed through UL. Notwithstanding that the cost of displaying UL's Certificate of Registration and Mark is not paid by UL, it is agreed that the right to control the display or other use of the Certificate of Registration and Mark shall be vested in UL. UL's representative shall have the right, on demand, to acquire possession of the UL Certificate of Registration and Mark and any or all advertising and promotional material, or other means of displaying the Certificate of Registration and Mark when in the judgment of UL's representative, such action is warranted.

A.2 Requirements

- A.2.1. The UL Registered Firm Mark may only be used on correspondence, advertising and promotional material and shall only be used in connection with the products and/or services described in the organization's scope of registration. The registered organization must identify the goods or services to which the Certificate of Registration applies when using the UL Registered Firm Mark in a context where the scope of application is open to interpretation.



- A.2.2. The UL Registered Firm Mark shall not be used on individual product containers or individual product packaging.
- A.2.3. The UL Registered Firm Mark may be used on bulk packaging only when specifically authorized in writing by UL, provided that in the opinion of UL, the mark's use in no way tends to create a misleading impression as to the nature of UL's quality management system registration.
- A.2.4. The UL Registered Firm Mark shall not under any circumstances be used directly on or closely associated with products or services in any way that may imply that the products or services themselves are Listed, Recognized, Classified, or in any way certified by UL. This includes laboratory test, calibration or inspection records.
- A.2.5. The registered organization agrees to discontinue any use of the UL Registered Firm Mark and any form of statement with reference to the authority of the registered organization to use the Mark, which is unacceptable to UL and that in the opinion of UL, might be misleading.
- A.2.6. Upon the termination of registration, for whatever reason, the organization must discontinue all use of the Mark immediately.

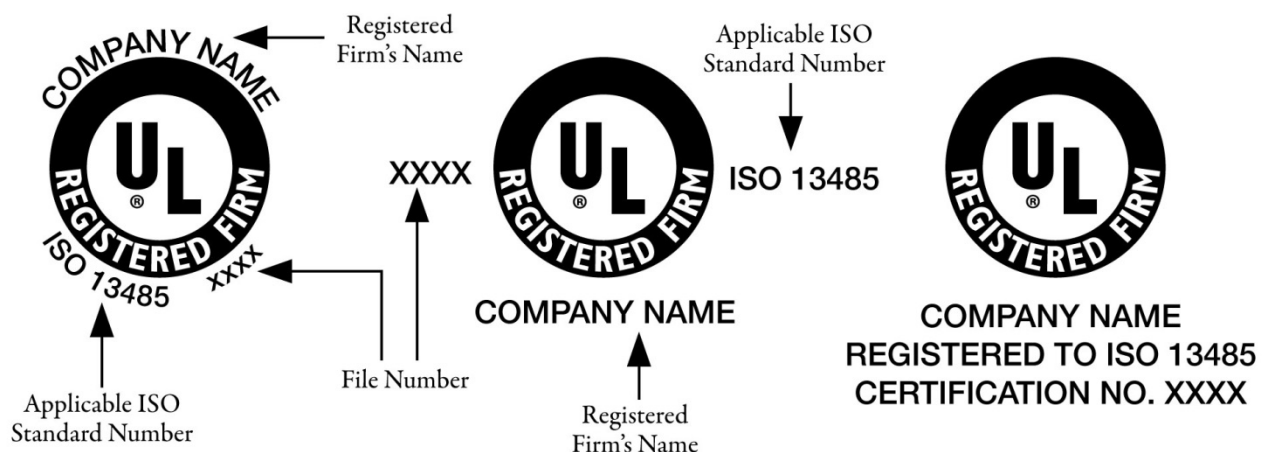
A.3 Composition & Elements:

- A.3.1. UL in a circle symbol encircled by the words "REGISTERED FIRM" in the bottom half as illustrated below:
- A.3.2. Use of the UL Registered Firm Mark, when used, must always be in conjunction with the following elements (as illustrated in the examples below):
 - a) Registered organization's name
 - b) File number
 - c) Applicable ISO standard to which the organization is registered





Examples of acceptable compositions:



A.4 Application

The following guidelines describe acceptable applications of the UL Registered Firm Mark:

- A.4.1. Minimum size is not specified as long as the words "REGISTERED FIRM" are clear and legible.
- A.4.2. Black on a white background, or a background in another color which clearly contrasts with black.
- A.4.3. White on a black background, or a background in another color which clearly contrasts with white.
- A.4.4. Contrasting colors where the foreground and the background allow the details of the UL Registered Firm mark to be clearly distinguishable and legible (consult UL for acceptability of color scheme).



- A.4.5. Embossed in such a way that the UL Registered Firm mark is clear and legible
- A.4.6 Where the organization has been registered to an accredited registration program, the organization may include the standard number with reference to the applicable QMS standard (i.e. AS-9100).

A.5 Preferred Text

Registered organizations may use the following pre-approved statements in connection with the mark to describe their registration:

- *The facility covered by this mark has been evaluated to international quality management system standards by UL LLC.*
- *"Our facility has been registered by UL LLC. to the International Organization for Standardization ISO 13485 Medical devices—Quality management systems. "Registered by UL to ISO 13485:2016."*
- *"The quality systems of this facility have been registered by UL to the ISO 13485:2016 Standard."*

Appendix B - Conditions for Use of an Accreditation Body Mark

B.1 Requirements for Use of the United Kingdom Accreditation (UKAS) Mark

- B.1.1. This section applies only to those organizations with written authorization from UL to use the UKAS mark as evidenced by the UKAS mark on their certificate of registration.
- B.1.2. Only organizations authorized to use the UKAS mark are entitled to use the mark illustrated below.
- B.1.3. Use of the UKAS mark must always be in conjunction with:
 - a) UL's Registered Firm mark
 - b) Registered firm's name
 - c) File number
 - d) Applicable ISO standard
- B.1.4. The UKAS mark may be used on stationery and publicity material or other items relevant to their certificate in connection with those goods and/or services listed on their certificate of registration. Publicity material shall not include notices, labels, documents or written announcements affixed to or otherwise appearing on goods or products unless the goods or products have been manufactured under an accredited product conformity scheme. This restriction shall also apply to primary (e.g. blister packs) packaging and promotional products.



- B.1.5. The UKAS mark shall not under any circumstances be used directly on or closely associated with any product, process or service in any way which may imply that the product, process or service itself is in any way certified or approved by UL or UKAS.
- B.1.6. Accreditation marks shall not be used in such a way to imply that UKAS accepts responsibility for activities carried out under the scope of accreditation and/or certification.
- B.1.7. The registered organization agrees to discontinue any use of the UKAS mark and any form of statement with reference to the authority of the registered organization to use the UKAS mark that is unacceptable to UL or which in the opinion of UL might be misleading.
- B.1.8. Upon the termination of registration, for whatever reason, the organization must discontinue all use of the UKAS mark immediately.
- B.1.9. The UKAS accreditation mark shall normally have a minimum height (excluding the accreditation number of 20 mm.) Any enlargement or reduction shall retain the same proportions as those printed in this publication. The mark and the accreditation number shall be considered as a single entity for purposes of enlargement or reduction.
 - (a) In exceptional circumstances, which are usually dictated by reason of space limitation or cost, the marks may be reproduced at a reduced height, but paragraph [B.5.9 (b)] must be satisfied
 - (b) Irrespective of the height of reproduction, the mark must, in the opinion of UL, be legible, with no infilling.
- B.1.10. On unfolded stationery sized no greater than A4 the mark shall be no greater than 30mm. Authorized users shall ensure the form of the Accreditation Mark is legible.
- B.1.11. Authorized users of the accreditation mark shall reproduce it in a single color only, which should be the predominant ink color of the document or, in the case of preprinted letterhead paper, the predominant color of the letterhead. Embossed, relief, or die-stamped versions may be used. The marks may be reproduced as watermarks.
- B.1.12. The accreditation marks shall not be displayed on vehicles, except in publicity material containing an accreditation mark as part of a larger advertisement, provided the mark is used in the publicity material in accordance with the conditions stated above. The accreditation mark shall not be displayed on buildings and flags. Marks may be displayed on internal walls and doors, and on exhibition stands.
- B.1.13. The Registered Firm's name, file number and applicable ISO standard to which the organization is registered, should appear below the UL Registered Firm mark as shown below.



COMPANY NAME
Axxxx ISO 13485:2016



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