UL LLC Medical Management System Registration Program Requirements

At of 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.

United Kingdom Accreditation Service ISO 9001 and ISO 13485 https://www.ukas.com UKAS is a member of IAF Multilateral Recognition Arrangement https://iaf.nu/	UKAS MANAGEMENT SYSTEMS 4426 MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF
Medical Device Single Audit Program Recognized Auditing Organization https://www.fda.gov/medical-devices/cdrh-international-programs/medical-device-single-audit-program-mdsap	MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

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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, registration to the Medical Devices Single Audit Program (MDSAP), and the United Kingdom Conformity Assessment (UKCA) Program.

These Program Requirements supplement the Global Services Agreement (GSA) Program Specific Services Terms and Conditions, which can be viewed at https://www.ul.com or GSA Services Terms | UL.

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. The requirements stated in this document are expected to be implemented within the Organization's QMS and is considered auditable criteria.

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 (Client/Customer Support Guidance-ULID-000703 (Formerly 00-MB-C0032)) please check UL's web site at Quality Management System (QMS) Audit Service | UL 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 *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.

3.2 *Quality Management System (QMS)* - The organizational structure, responsibilities, procedures, processes and resources for implementing a quality management system.

3.3 *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.

3.4 *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.

3.5 *Registration* - A decision by UL that an Organization'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.

3.6 *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. All sites and off-sites must be included in the scope of registration.

Site – any physical location that is associated with design and/or production of the product.

Off-site – any physical location that provides QMS activities other than design and/or production (i.e., warehouse, customer service, etc.).

3.7 *Certificate of Registration* - A certificate recognizing the scope of registration and quality management system implemented by the Organization and assessed by UL is in accordance with a specific management system standard and UL's Medical Quality Management System Registration Program requirements. All certificates are issued electronically by UL.

3.8 *Registration Audit* - The initial evaluation performed by UL to determine the compliance of the Organization's quality management system with the requirements of the applicable QMS standard(s). Registration Audit activity consists of a Stage 1 Readiness Audit and a Stage 2 Certification Audit.

3.9 *Surveillance Audit* - An Audit performed by UL to determine an Organization's continued compliance with the applicable standard and program requirements subsequent to registration. These Audits are typically scheduled 3-6 months in advance of an Audit Due Date. The Audit Due Date is set 3 months prior to the anniversary of the Certificate Expiry Date. Audit agendas are provided at least two (2) weeks prior to the start date. UL also reserves the right to perform unannounced surveillance Audits.

3.10 *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.

3.11 *UL* - UL LLC® and its affiliates.

3.12 *UL Product iQ*™ - An online certification directory containing a list of the organizations 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, or UL Product iQ. A log-in account may need to be created to access information on UL Product iQ.

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 UL MMS Program Requirements shall be entitled to a certificate of registration that shall remain the property of UL. All UL certificates are provided electronically and must be destroyed upon the request of UL should the registration be terminated.

4.1.3 All Organizations audited under UL's scope of accreditation will have one or more Accreditation Body Marks 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 in accordance with the expiry date 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 regulations.

4.1.9 UL is required to be notified of the reported incident where the device is CE Certified under any UL partner Notified Body.

4.1.10 Where incidents occur to products covered outside of CE Certification, the Organization is required only to inform UL of any incidents leading to product recall, advisory notices, and where the incident leads to a significant change in processes. This includes products covered under the UKCA Mark.

4.1.11 Should a UL representative identify items which are not in compliance with this document or the applicable standard and other applicable 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 is not in compliance with this document or applicable standards, the Organization shall cooperate with and assist UL in obtaining the relevant information. This includes sharing any information the Organization acquires concerning the reported noncompliance and reporting to UL concerning corrective actions taken to address any noncompliance within an agreed upon period of time.

4.1.13 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, applicable standards, and other applicable 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 under 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 6.1.4 of this document.

4.1.15 UL Audit Teams may include UL trainee auditors, provisional auditors, surrogate auditors, technical experts, observers from UL and/or accreditation bodies, regulatory authorities, and/or other UL staff. As a condition of registration, the Organization must permit such persons to accompany the UL Audit Team. UL does not charge the Organization for any time or expenses where such persons attend an Audit.

4.1.16 Quality system consultants contracted by the Organization are limited to the role of an observer during an Audit.

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) upon UL request.

4.2.3 Notify UL in writing of significant changes to the management system. [Please use the **Manufacturers' Significant Change Notification Form;** Form-ULID-000717 (formerly: 00-MB-F0853)]

Significant changes requiring notification to UL are:

- Increases/decreases in staff that exceed 20% of total headcount reported during previous audit
- Change of management representative, primary, or secondary contacts – and any changes to contact details
- 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 using the Manufacturer's Significant Change Notification Form [Form-ULID-000717 (formerly: 00-MB-F0853)].

4.2.4 As a certificate holder under UL's UKCA Program:

- Implement and maintain a quality system to ensure conformity with the applicable directives and regulations.
- Immediately notify the Medicines and Healthcare Products Regulatory Agency (MHRA) and UL of any incident involving product safety or non-compliance with the applicable directive and/or regulation. Information on the investigations, corrective actions taken, and the final report must be provided.
- Notifications should be submitted to Inform.Regulatory@ul.com
- Retain documentation and reports relating to the products covered by UL UKCA certification for the design life of the product, and in any case not less than five years after the last product has been manufactured. This specifically includes, but

is not limited to technical documentation, declarations of conformity, UK Approved Body certificate and decisions. These documents are required to be available to the MHRA for the period of time stated.

- Establish processes to ensure availability of relevant personnel to support unannounced audits of the Organization's facilities and/or any critical subcontractor/suppliers.
- Establish appropriate arrangements with suppliers ensuring UL Auditors will gain access to the facilities in a timely manner to conduct an unannounced audit.
- Promptly inform the UL Approved Body of any significant changes where:
    - for product changes, the change would affect conformity with the essential requirements and/or the conditions prescribed for the intended use of the device.
    - for changes to the quality system, either the change would affect compliance of the devices covered by the quality system with the essential requirements or the approved type / design; or the change means additions to the product-range covered by the quality system.

Product Changes:

The matters that are considered when deciding whether or not particular changes are significant include the following:

- does the change introduce a new device, or new hazards which have not been previously addressed?
- does the change adversely affect the risk associated with existing hazards?
- does the change alter the details on intended use and/or compliance with the essential requirements given in the Device Master Record submitted to UL?
- does the change mean that the device will have different end users or be used in a different manner or for a different purpose?
- does the change mean that the clinical data for the original device is not sufficient to confirm conformity of the changed device with the required characteristics and performance?

Changes to the Quality System:

The matters that are considered when deciding whether or not particular changes are significant include the following:

- does the change alter the manufacturing technologies?
- does the change affect product conformity route?
- does the change affect the continued compliance of the quality system with the relevant harmonized standards against which it has been approved?

- does the change affect the arrangements for ensuring continued compliance with the requirements of the directive for example verification, validation etc.?
- does the change require that manufacturing processes and controls are re-validated?

A notification of any significant change in the design / device as well as in the quality system will include, as necessary:

- a brief description of the modifications compared to the approved design / device or the approved quality system and
- the reason for the changes / modifications and
- in the case of design / device changes, a statement on the relevance to the compliance with the essential requirements of the directive.

4.2.5 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, its affiliates, representatives, or the certification system.

4.2.6 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.

4.2.7 Give the representatives of UL and any observers (including but not limited to accreditation body representatives, regulatory body representatives, other UL observers and UL trainees) appropriate access during normal working hours, for the purpose of examining systems, processes, methods of test, and records.

4.2.8 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.

4.2.9 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.

4.2.10 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.

4.2.11 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.

4.2.12 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

The Organization shall:

4.2.13 Receive an audit report specific to each site under the quality management system.

4.2.14 Agree 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 may 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.

4.2.15 Agree that the audit findings generated from any audit, will be shared amongst all jurisdictions where the Organization has market access in the MDSAP program.

4.2.16 Agree to the nonconformity grading system per GHTF/SG3/N19.

4.2.17 Agree to the composition of the Audit Team per the requirements of IMDRF/MDSAP WG/N3.

4.2.18 Agree 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 determined 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.”

An 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.

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

4.3 *UL shall:*

4.3.1 Issue a Certificate of Registration valid for a period not exceeding three years after granting registration to an Organization.

4.3.2 Send an Auditor or Audit Team to the Organization at its discretion, not less than once per year, to all sites 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.

4.3.3 Conduct annual surveillance audits to monitor the maturity and continued effectiveness of the quality management system, 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.

4.3.4 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.

4.3.5 Ensure the safe handling of all customer-confidential information by using secure facilities and systems for the storage and transmission of documents and records.

4.3.6 Conduct audits and maintain registration with the highest levels of impartiality, evaluating only the facts presented against the requirements of the audit criteria without regard to any other interest.

4.3.7 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.

4.3.8 Ensure that persons conducting audits have demonstrated competence for the activities they are evaluating.

4.3.9 Provide transparency to Organizations registered or seeking registration with regards to audits and methodology.

4.3.10 Notify the Organization at its discretion of customer complaints relating to the compliance of its product, process, or service with the specified requirements.

4.3.11 Direct its representative(s) 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) Withdraw 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

5.3 UL may, at its discretion, and subject to the provisions in section 6, withdraw or refuse to issue or renew a Certificate of Registration if the Organization becomes subject to 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 shall take any required action by the specified effective date. If the agreed action is not found to be acceptable, 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 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 applicable 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. Audits

6.2.1. **Pre-Audit Planning –** 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 Activity** - The Registration Audit activity is scheduled when a facility is determined to be eligible for audit. The Registration Audit activity 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.

Registration cannot be granted with open major nonconformities. A full re-audit of the affected areas will be required before registration can be granted.

6.2.4. **Surveillance Audit** – A surveillance 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 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.

6.2.8. **Alternate Audit Types –** During extraordinary circumstances and/or where travel is restricted (can include individual auditor restrictions to travel), UL may deliver the audit remotely or semi-remotely (hybrid or blended audit). All deviations from normal audit process must be approved by UL.

6.3. Issuing Registration

6.3.1. At the completion of each Audit the UL Audit Team shall provide the Organization's Management Representative with any non-conformities generated during the evaluation that itemize discrepancies uncovered during the Audit. Time limits for responses to non-conformities are to be determined by UL. The Audit Team shall also provide a recommendation as to the Organization's eligibility for QMS registration, continued certification, or recertification.

6.3.2. The Audit Team's recommendation, provided at the end of the Audit, and the entire Audit package is subject to review for the 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 Medical Devices Directive or In-Vitro Diagnostic Devices Directive, Medical Devices Regulation or In-Vitro Diagnostic Devices Regulation.
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, MDSAP Grade 5, and multiple MDSAP Grade 4 nonconformances must be responded to within fifteen (15) calendar days from the last day of the audit where the nonconformity was raised.

a) A major nonconformity will result in a Special Audit to verify effective implementation of the corrective actions. The Special Audit must be completed within ninety (90) days of the last day of the audit where the Major, MDSAP Grade 5 or multiple MDSAP Grade 4 nonconformances were raised.
b) The major nonconformity must be resolved prior to the issuance or re-issuance of the applicable Certificate of Registration.
c) Following the review of the major nonconformity and the Organization's response, the Reviewer will provide a letter notification for the Special Audit. A quote will be issued for the Special Audit to cover the time needed to review the information and records required to close out the nonconformity. The Special Audit may be conducted remotely.

d) Manufacturers must provide evidence of implementation of the remediation actions to address the major nonconformity to UL within thirty (30) calendar days of the last day of the audit.
e) Evidence of implementation of the remediation actions to address MDSAP Grade 4 and/or Grade 5 nonconformities, must be provided to UL within thirty (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 indicate 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 (15) calendar days of the last day of the audit where the nonconformity was raised.

6.3.7. All minor nonconformities must be resolved within sixty (60) calendar days of issuance. Manufacturers must provide to UL evidence of the implementation of the corrections and corrective actions within 60 calendar days of issuance. UL will initiate a cost limit increase to the audit project to cover the time to conduct the evaluation of the evidence submitted. 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 nonconformities 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 QMS Registration is granted a Certificate of Registration shall be issued to the Organization indicating that the Organization'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 with a validity not to exceed three (3) years. The name of the Organization and a copy of the certificate shall also be published in UL's online certification directory (UL Product iQ)

6.3.10. When UKCA conformity is verified, a certificate of conformance to the relevant part of UK MDR 2002 (as amended) is issued to the Organization, with a validity not to exceed five (5) years.

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 Organization 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 or where there are special or extraordinary circumstances beyond UL or the customer control.

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 for any scheduled or unannounced audit.
j) The corrective action to address minor nonconformities is not submitted to UL within sixty (60) calendar 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 thirty (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 ninety (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, 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 any reference to UL as its Certification Body, including all matter which contains reference to certification status with UL. 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 UL's 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. UL shall enter all written complaints into UL's complaint database so they may be investigated, and the subscriber's resolution of the complaint tracked.

6.6.3. 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.

6.6.4. 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.

6.6.5. 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.

6.6.6. All customer complaints shall be acknowledged within forty-eight (48) 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 (30) days.

6.6.7. If the complaint is determined to be not valid, the regional management involved shall communicate the results of the investigation to the complainant.

6.6.8. 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.

6.6.9. 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. 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.

6.7.5. 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 sections 6.3.4 and 6.3.6 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 with 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 thirty (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 appellant. 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 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 or 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 RAs 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 Box 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's online certification directory.

7.2 UKCA PROGRAM

7.2.1 UK/MHRA Registration

Manufacturers wishing to place a device on the Great Britain market must register with the MHRA. All medical devices, including IVDs, custom-made devices and systems or procedure packs must be registered with the MHRA before being placed on the Great Britain market. In Great Britain (England, Wales and Scotland), devices must conform to the UK MDR 2002, the EU MDR (until 30 June 2023), or the EU IVDR (until 30 June 2023) in order to be registered with the MHRA.UK Responsible Person

Where a manufacturer is not established in the UK, they must appoint a UK Responsible Person to register and act on their behalf.

The UK Responsible Person acts on behalf of the non-UK manufacturer to carry out specified tasks in relation to the manufacturer's obligations. This includes registering the manufacturer's devices with the MHRA before the devices can be placed on the Great Britain

market. Note that the responsibilities of the UK Responsible Person are set out in the UK MDR 2002.

7.2.2 Post-market surveillance and vigilance

For Medical device (including self-declared) placed on the UK market, the manufacturer is required to submit vigilance reports to the MHRA (and the UK Approved Body if a certificate is issued) when incidents occur in the UK that involve their device.

7.2.3 Labelling requirements

Medical devices placed on the Great Britain market must have a UKCA marking *(or a CE marking, depending on which legislation the device has been certified under).* Where relevant, the number of the Approved Body (*or Notified Body*) must also appear on the label.

Devices with a valid CE marking are not required to re-label with a UKCA marking until 1 July 2023 for placement on the Great Britain market. Devices can have both the CE and UKCA markings present on the labelling prior to 1 July 2023, and dual marking will continue to be accepted on the Great Britain market after 1 July 2023. However, the name and address of the UK Responsible Person, where applicable, needs to be included on product labelling or the outer packaging, or the instructions for use in cases where the UKCA marking has been affixed (including when devices have been dual marked).

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. An electronic form of the logo is available from UL's web site (www.ul.com - UL Mark Artwork - UL Marks and Labels).

A.1.2 UL is the owner of the UL Registered Firm mark which incorporates the name, abbreviation or symbol of UL (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 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 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.

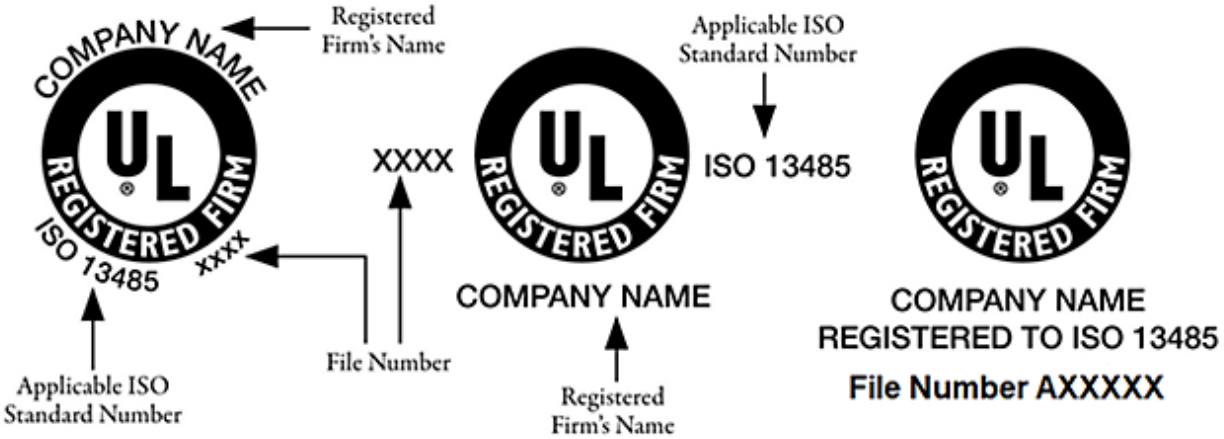
A.3 Composition & Elements:

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 shall include the standard number with reference to the applicable QMS standard (i.e., ISO 13485, ISO 9001).

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 LLC to ISO 13485:2016."
- *"The quality systems of this facility have been registered by UL LLC 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.

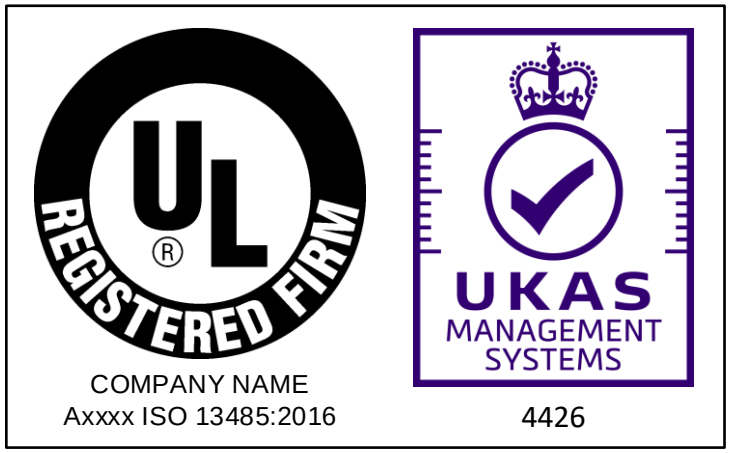
a) In exceptional circumstances, which are usually dictated by reason of space limitation or cost, the marks may be reproduced at a reduced height, but paragraph [B.1.9 (b)] must be satisfied
b) Irrespective of the height of reproduction, the mark must, in the opinion of UL, be legible, with no infilling.

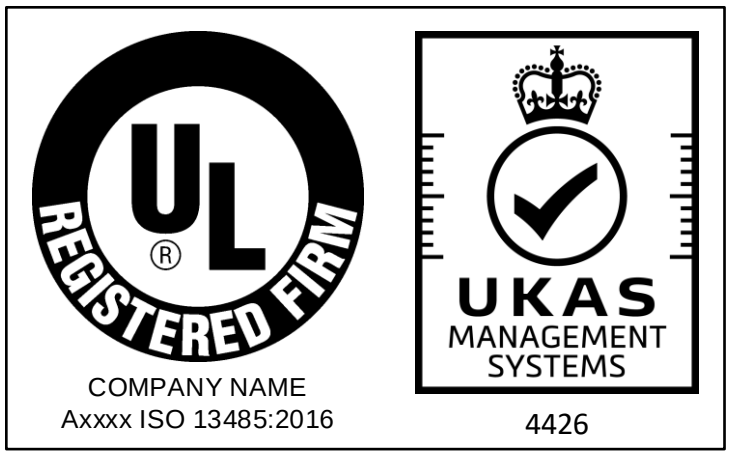
B.1.10. On unfolded stationery sized no greater than A4 the mark shall be no greater than 30mm. Authorized users shall ensure the form of the Accreditation Mark is legible.

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.





B.2 Requirements for use of the UKCA Mark

B.2.1 The UKCA marking must be clearly visible and legible when affixed to the product. the UKCA marking is at least 5mm in height

B.2.2 if marking is reduced or enlarged in size, the letters forming the UKCA marking must be in proportion to the version set out below

B.2.3 For dual marked devices CE and UKCA, manufacturer must ensure the legibility and visibility of the UKCA marking.