UL LLC, UL Solutions medical regulatory services

Program requirements

LET'S GO

At of the date of issuance of this document, UL LLC is accredited by the following accreditation bodies for its medical and regulatory certification services. The scope of accreditation can be obtained directly from the website of the accreditation body, and this information may be used by registered customers to fulfill supplier qualification of UL LLC.

United Kingdom Accreditation Service
ISO 13485 and ISO 9001
https://www.ukas.com

UKAS is a member of the International Accreditation Forum (IAF) Multilateral Recognition Arrangement
https://iaf.nu/

Medical Device Single Audit Program
Recognized Auditing Organization
https://www.fda.gov/medical-devices/cdrh-international-programs/medical-device-single-audit-program-mdsap

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UK Conformity Assessed Approved Body
https://www.gov.uk/government/publications/medical-devices-uk-approved-bodies

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1.0 Scope

1.1
Program requirements provided by UL Solutions medical regulatory services, hereafter referred to as "UL Solutions," are designed to support customers' compliance with the services listed below in accordance with contracted certifications:

- ISO Management System Certification Services for ISO 13485 and ISO 9001
- Medical Devices Single Audit Program (MDSAP) Management System Certification Services
- UK Conformity Assessed (UKCA) certification under the Medical Devices Regulations 2002 UK Approved Body Services

1.2
These program requirements supplement the Global Services Agreement (GSA) program's specific services terms and conditions, which can be viewed here.

1.3
The objective of these program requirements is to provide, by evaluation and applicable audits — i.e., registration audits, surveillance audits, recertification audits — conformity assessments and independent verification of a customer's quality management system's (QMS) capability to consistently provide products and/or services that conform to given specifications.

1.4
This document identifies and describes the requirements for our certification services, including the use of our Marks, and ongoing activities to maintain certification.

1.5
By following these program requirements, customers allow UL Solutions to support the relevant certification programs. Additional applicable regulatory requirements also apply that may not be defined in this document.

1.6
UL Solutions certified customers must adhere to requirements of this document and applicable regulatory requirements as a condition of certification. The requirements stated in this document are expected to be implemented within the customer's QMS and are considered auditable criteria.

1.7
These requirements may be modified or supplemented by UL Solutions at any time. For the most up-to-date version of UL Solutions' medical regulatory services program requirements (Customer Support Guidance-ULID-000703), please check the UL Solutions website at Quality Management System (QMS) Audit Service | UL or contact your UL Solutions representative.

2.0 Applicable documents

- ISO 9000:2015, Quality Management Systems – Fundamentals and Vocabulary
- ISO 9001:2015, Quality Management Systems – Requirements
- ISO 9004:2018, Quality Management Systems – Quality of an Organization – Guidance to Achieve Sustained Success
- ISO 17021-1:2017, Conformity Assessment – Requirements for Bodies Providing Audit and Certification of Management Systems, Part 1: Requirements
- ISO 19011:2018, Guidelines for Auditing Management Systems
- ISO 13485:2016, Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
- MDSAP audit model – MDSAP AU P0002
- UL Solutions Global Services Agreement, Program-Specific Service Terms and other certification contracts between UL Solutions and the customer

3.0 Terms and definitions

3.1 Quality management standards
The standards for quality systems published by the International Organization for Standardization (ISO); the certificate of registration may also denote conformance with equivalent series standards such as European Norm (EN), American National Standards Institute (ANSI) and Canadian Standards Association (CSA) standards.

3.2 Quality management system
The organizational structure, responsibilities, procedures, processes and resources for implementing a quality management system

3.3 Customer
The party that is responsible for the product, process or service and can ensure that quality assurance is exercised; this definition may apply to manufacturers, distributors, importers, assemblers, service organizations, etc. A customer that is granted certification by UL Solutions is a legal entity — an incorporated or unincorporated body — that has been issued a certificate. This customer subscribes to UL Solutions medical regulatory services and is therefore responsible for complying with UL Solutions requirements and for UL Solutions invoices associated with the certification and associated audits.

3.4 Management representative
A member of the customer's management who represents the evaluated facility and is responsible for the customer's QMS as it pertains to the relevant products and/or services covered in the customer's scope of registration

3.5 Certification
A decision by UL Solutions that a customer's QMS meets the requirements of a specific management system standard and UL Solutions program requirements; a certificate is issued to the customer to indicate acceptance into the UL Solutions medical regulatory services program.

3.6 Certificate scope
A certificate scope describes the type of activities, products and services as applicable at each physical site without being misleading or ambiguous. The scope describes the relevant process, product and/or service areas that are provided under the customer's quality system. Proposed certificate scopes are agreed on prior to the certification audit. All sites and off-sites must be included in the applicable certificate scope for QMSs.

3.7 Site
Any physical location that is associated with design and/or production of the product

3.8 Off-site
Any physical location that provides QMS activities other than design and/or production, i.e., warehousing, customer service, etc.

3.9 Certificate
A document recognizing that the scope and QMS implemented by the customer and audited by UL Solutions is in accordance with a specific management system standard and UL Solutions program requirements; all certificates are issued electronically by UL Solutions.

3.10 Certification audit
The initial evaluation performed by UL Solutions to determine the compliance of the customer's QMS with the applicable standard(s) and/or regulations; certification audit activity consists of a Stage 1 Readiness Audit and a Stage 2 Certification Audit.

3.11 Surveillance audit

An audit performed by UL Solutions to determine a customer's continued compliance with the applicable standard and the requirements listed in this document following certification; these audits are typically scheduled three (3) to six (6) months in advance of an audit due date set in relation to the certification audit activity and certification cycle. Audit agendas are provided at least two (2) weeks prior to the audit start date. UL Solutions also reserves the right to perform unannounced and/or short-notice for-cause surveillance audits to investigate complaints, changes, concerns or as follow-up on suspended certificates.

3.12 Recertification audit

The evaluation performed by UL Solutions to confirm compliance of the customer's QMS with the applicable standard and the requirements in this document at the end of the customer's certificate cycle; a recertification audit is also known as a triennial audit.

3.13 Recertification assessment

The evaluation performed by UL Solutions to confirm compliance under the UKCA program at the end of the customer's UKCA certificate cycle

3.14 UL Solutions

UL LLC, UL Solutions medical regulatory services and its affiliates

3.15 UL Product iQ®

An online certification directory containing a list of the customers that are issued certificates of registration by UL Solutions to at least one of the QMS standards; descriptions define a customer's name, address, scope of registration and the certificate issue date. This information is available electronically on the UL Solutions website at www.UL.com or in the Product iQ database. A login account may need to be created to access information on the Product iQ site.

3.16 UL Solutions Management System Enhanced Mark

The UL Solutions Management System Enhanced Mark is displayed on UL Solutions-issued management system program certificates only.

3.17 UL Solutions Management System Promotional Badge

Customers may use the UL Solutions Management System Promotional Badge in accordance with UL Solutions certification agreements to promote their facility registration.

Information and marketing guidelines are available from the Marks and Label Hub. No use on products/product packaging. No other use of marks/badges is permitted.

UL Solutions Management Systems Promotional Badge example

Marks and Label Hub | UL Solutions

4.0 UL Solutions Management System Certification Services Program requirements

4.1 General

4.1.1 UL Solutions is the sole authority by which UL Solutions certificates may be issued.

4.1.2 Customers capable of demonstrating a legitimate business that complies with these program requirements shall be entitled to a certificate that remains the property of UL Solutions. All UL Solutions certificates are provided electronically and must be destroyed upon termination.

4.1.3 All customers certified under UL Solutions' scope of accreditation will have one or more accreditation body marks appear with the UL Solutions Management System Enhanced Mark on their certificate.

4.1.4 A separate certificate is issued for each program following application and successful evaluation to confirm compliance.

4.1.5 Certificates are renewed in accordance with the expiry date indicated on the certificate unless cancellation, suspension or withdrawal occurs. If a customer does not intend to renew an issued and active certificate, notification must be sent to UL Solutions in writing detailing such intentions no later than 60 days prior to certificate expiry renewal.

4.1.6 A customer's right to use certificates issued by UL Solutions is not transferable to any other person, customer or corporation without UL Solutions' written authorization.

4.1.7 The customer agrees to comply with all applicable laws, statutes and regulations, e.g., state, region, province, country, etc.

4.1.8 The customer shall report incidents to respective regulatory authorities in line with the local country's laws and regulations.

4.1.9 UL Solutions is required to be notified of the reported incident where the device is CE certified under any UL Solutions partner notified body as applicable.

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

4.1.11 Should a UL Solutions representative identify items that are not in compliance with this document or the applicable standard and other applicable criteria, the customer shall either correct such items or cancel registration and immediately refrain from any further reference to UL Solutions and the certification program.

4.1.12 If it is reported that the customer's QMS for goods or services under the applicable certificate scope is not in compliance with this document or applicable standards, the customer shall cooperate with and assist UL Solutions in obtaining the relevant information. This includes sharing any information the customer acquires concerning the reported noncompliance and reporting to UL Solutions concerning corrective actions taken to address any noncompliance within an agreed period of time.

4.2 The customer shall:

4.2.1 Comply with UL Solutions program requirements at all times.

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 QMS (or any parts thereof) upon UL Solutions' request.

4.2.3 Notify UL Solutions in writing of significant changes to the management system. Please use the Manufacturers' Significant Change Notification Form, Form-ULID-000717 (formerly 00-MB-F0853), available upon request.

Significant changes requiring notification to UL Solutions include:

- Increases/decreases in staff that exceed 20% of total headcount reported during previous audit
- Change of management representative or 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 certificate(s); addition/removal of sites or off-sites
- Expansions or reductions to certificate scope(s)
- 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 the change becomes effective or the start of that activity. UL Solutions shall evaluate whether additional audit activity is necessary for verifying certification conformance in relation to any changes.

All such notifications shall be made by email to Inform.Regulatory@UL.com using the Manufacturer's Significant Change Notification Form (Form-ULID-000717).

4.2.4 Discontinue any use of the UL Solutions Management System Promotional Badge that is unacceptable to UL Solutions and any form or statement of reference that in the opinion of UL Solutions might be misleading. The customer shall not use certification in such a manner as to bring into disrepute or cause loss of public trust to UL Solutions, its affiliates, representatives or the certification system.

4.2.5 Ensure that any purchased finished products, processes or services covered under the customer's certificate scope comply with the assessed capability of the program by UL Solutions. If any finished products, processes or services are produced or provided external to the customer's QMS, the external producer or provider may also be evaluated during the certification process. This may require an on-site audit of the external producer or provider by the UL Solutions Audit team. In cases where products described in the certificate scope are not traceable to a QMS certification that is recognized by UL Solutions, the customer shall establish and operate a procedure for notifying the prospective customer that the items in question have not been produced or provided within UL Solutions' certification program.

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

4.2.7 Extend all necessary privileges and assistance to UL Solutions representatives and observers, including health and safety conditions, so the representatives may properly perform their function under UL Solutions' certification or surveillance audit service, and make all written material utilizing the UL Solutions Management System Promotional Badge and other means of displaying UL Solutions certification available for audit by a UL Solutions 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 certification.

4.2.9 Refrain from using any report or certificate issued as the result of a UL Solutions audit to indicate that a product is Listed, Classified or Recognized by UL Solutions, 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 Solutions.

4.2.10 Refrain from releasing any information referencing UL Solutions' audit acceptance, certification and/or certification of the facility before it is established and confirmed in writing by UL Solutions.

4.2.11 Make available to UL Solutions, when requested, the records of all complaints and corrective action taken, in accordance with the requirements of the QMS standards or other normative documents.

4.3 As a certificate holder under UL Solutions' MDSAP Management System Certification Services, the customer shall:

4.3.1 Receive an audit report specific to each site under the QMS.

4.3.2 Agree that the audit report generated is shared to all jurisdictions participating in the MDSAP where the customer has market access. Additionally, the customer agrees 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 to cover provisions for protecting proprietary information and trade secret information.

4.3.3 Agree that the audit findings generated from any audit will be shared among all jurisdictions where the customer has market access in the MDSAP.

4.3.4 Agree to the nonconformity grading system per the International Medical Device Regulators Forum (IMDRF) Global Harmonization Task Force (GHTF) Study Group 3 (SG3), document GHTF/SG3/N19:2012.

4.3.5 Agree to the composition of the Audit team per the requirements of IMDRF/MDSAP WG/N3 Final:2016 (Edition 2).

4.3.6 Agree that the MDSAP does not absolve the customer of potential unannounced audits by a regulatory authority (U.S. Food and Drug Administration (FDA), Health Canada, Agência Nacional de Vigilância Sanitária (ANVISA), Therapeutic Goods Administration (TGA), Pharmaceuticals Medical Devices Agency (PMDA), etc.) as determined per the requirements of GHTF/SG3/N19:2012 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 on site.

If specific information provides reasons to suspect serious nonconformities of the devices or if a regulatory body requests that UL Solutions 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 at the customer premises or the premises of the contracted critical suppliers. If a visa is needed to visit the country where the customer is located, the contractual arrangements shall contain, as an annex, an invitation to visit the customer or the contracted critical supplier at any time and an invitation that 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 organization to end the contract as soon as permanent unannounced access to the premises of the customer or the contracted critical suppliers are no longer assured. The contractual arrangements shall furthermore cover the measures to be taken by the auditing organization to ensure the security of their auditors, and shall provide for financial compensation for the unannounced audits, including security arrangements.

4.3.7 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 customer end the relationship for the MDSAP and/or manufacturing site(s) with UL Solutions.

4.4 As a UKCA certificate holder under UL Solutions' UK Approved Body Services in compliance with the Medical Devices Regulations 2002, the customer shall:

4.4.1 Implement and maintain a quality system to ensure conformity with the applicable directives and regulations.

4.4.2 Immediately notify the Medicines and Healthcare Products Regulatory Agency (MHRA) and UL Solutions of any incident involving product safety or noncompliance with the applicable directive and/or regulation. Information on the investigations, corrective actions taken and the final report must be provided.

4.4.3 Submit notifications to Inform.Regulatory@UL.com.

4.4.4 Retain documentation and reports relating to the products covered by UL Solutions 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, U.K. approved body certificates and decisions. These documents are required to be available to the MHRA for the period of time stated.

4.4.5 Establish processes to ensure availability of relevant personnel to support unannounced audits of the customer's facilities and/or any critical subcontractors/suppliers. Notifications of facility shutdowns or changes in shift patterns potentially affecting the execution of an unannounced audit shall be sent to Inform.Regulatory@UL.com.

4.4.6 Establish appropriate arrangements with suppliers to ensure that UL Solutions auditors will gain access to the facilities in a timely manner to conduct an unannounced audit.

4.4.7 Promptly inform the UL Solutions 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. The customer shall inform the approved body that issued the UKCA design examination certificate of any significant change made to the approved design (including manufacture and final inspection).
- 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. The customer shall inform the approved body that approved the quality system of any plan for substantial changes to the quality system or the product range covered.

4.4.8 For product changes, the matters that are considered when deciding whether changes are significant include the following:

- Does the change introduce a new device, device variant, 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 design or details of an existing device regarding overall design solutions or significant changes to the manufacture or supply of essential components of the device, and/or affect compliance with the essential requirements given in the device master record submitted to UL Solutions?
- Does the change alter the intended purpose, indications for use, or method of use of the device?
- 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 impact the performance claims of the device or require new clinical or other performance studies to support continued compliance with requirements?
- Are there major changes to the manufacture of the device, for example: change of manufacturing site, new manufacturing technologies, major changes to the manufacturing processes that require significant validation to establish equivalence, or changes to product release procedures and/or specifications?

4.4.9 For quality system changes, the matters that are considered when deciding whether changes are significant include the following:

- Does the change alter the manufacturing technologies?
- Does the change affect the 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, e.g., verification, validation, etc.?
- Does the change require that manufacturing processes and controls are revalidated?

4.4.10 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
- The reason for the changes/modifications
- In the case of design/device changes, a statement on the relevance to its compliance with the essential requirements of the directive

4.5 UL Solutions shall:

4.5.1 Issue an electronic certificate to the customer valid for an appropriate period of time (no more than three to five years maximum, depending on the program) as determined by applicable requirements and the final review certification decision.

4.5.2 Send an auditor or audit team to the customer at its discretion — not less than once per year — to all sites in which the customer is manufacturing goods, operating processes or offering a service for which it is certified for the purpose of verifying that the obligations imposed by the certificate are being carried out.

4.5.3 Conduct annual surveillance audits to monitor the maturity and continued effectiveness of the QMS, 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 references to certification.

4.5.4 Refrain from disclosing any information concerning the customer that is of a confidential nature without the customer's prior authorization in writing other than information that has been made publicly accessible by the customer. 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 Solutions shall inform the supplier of the information provided.

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

4.5.6 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.

4.5.7 Demonstrate responsibility for ensuring that all relevant and applicable information, scientific principles and ethical standards in determining the acceptability of information are upheld in all dealings with customers, accreditation bodies, regulatory authorities and other stakeholders.

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

4.5.9 Provide transparency regarding audits and methodology to customers with certificates or that are seeking certification.

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

4.5.11 Direct its representative(s) to exercise due care in complying with any safety regulations that may be applicable generally to the customer's facility personnel who are implementing the QMS.

5.0 Compliance with UL Solutions program requirements

5.1
If a customer is temporarily unable to comply with these program requirements, UL Solutions may require the customer to discontinue use of the UL Solutions Management System Promotional Badge and any claim to certification under a certificate suspension as described in Section 6.7. In this event, customers must notify their end customers of the suspension until the conditions of certification are achieved again or pending the result of an appeal as described under Section 6.10.

5.2
If the customer fails to comply with these program requirements, UL Solutions may, subject to the provisions in Section 6.7, as appropriate:

- Withdraw the certificate.
- Refuse to issue or renew the certificate.
- Change/limit the certificate scope.
- Notify vendors, regulatory authorities and potential users of improper or unauthorized use of the UL Mark or badge or improper or unauthorized reference to UL Solutions.

5.3
UL Solutions may, at its discretion and subject to the provisions in Section 6.7, withdraw or refuse to issue or renew a certificate if the customer becomes subject to bankruptcy laws or makes any arrangements or composition with its creditors; enters into liquidation, whether compulsory or voluntary (but not including liquidation for the purpose of reconstruction); has a receiver of its business appointed; or is convicted of an offense tending to discredit the customer's reputation and good faith as a trader. Such decisions and the grounds for them shall be communicated to the customer in writing.

5.4

In the event that UL Solutions makes changes to its program requirements that affect the certification of customers, UL Solutions shall:

- Specify an effective date for the changes that shall allow sufficient time for customers to amend their quality system.
- Formally notify all customers affected by the new requirements of the effective date of the change and new action required of them.
- Where appropriate, afford the opportunity for customers to submit comments on the proposed changes.

5.5

The customer shall take any required action by the specified effective date. If the agreed action is not found to be acceptable, certificate suspension or withdrawal may occur (see Section 6.7). If a special audit of the system is necessary to evaluate the customer's system due to the revised requirements, the customer shall be responsible for the cost of the evaluation.

6.0 UL Solutions medical regulatory services

6.1 Prior to the on-site visit:

6.1.1 UL Solutions shall provide the customer notification of an audit, 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 Solutions within two weeks of an audit notification; otherwise, UL Solutions will proceed to book the arrangements as specified. Customers requiring a purchase order for invoicing should also provide a purchase order document in response to an audit notification.

6.1.2 If there are significant changes, the customer shall provide information to UL Solutions about those changes by completing the Manufacturer's Significant Change Form (ULID-000717) (see Section 4.2.3) and responding to the questions listed in the audit notification for planning the audit. Upon receipt of information concerning the change, UL Solutions shall evaluate and confirm any adjustment to the scheduled activity. Any applicable forms must be completed and returned to UL Solutions prior to commencement of the scheduled on-site visit.

6.1.3 The customer shall accept any quote for the audit, which may include additional costs to verify changes that have been communicated by the customer.

6.1.4 UL Solutions shall provide confirmation of the audit arrangements to the customer concerning the finalized visit dates and name(s) of the assigned Audit team. Background information may be provided for each member of the Audit team upon request.

6.2 Audits

6.2.1 Pre-assessment audit, i.e., gap assessment:
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 Solutions representative(s) shall summarize the audit results and provide the facility representatives with a report of the Audit team's findings/gaps. In this report, UL Solutions will not draw any conclusions as to the eligibility of the evaluated facility for certification under UL Solutions' certification programs. The number of pre-assessment audits conducted at one facility may not exceed two. UL Solutions cannot offer pre-assessment audits for customers with existing certifications.

6.2.2 Pre-audit planning
UL Solutions representatives shall enhance a customer's understanding of the QMS standard and explain the mechanics and structure of the certification program. Discussions may include topics such as global quality standardization activities and the advantages provided by UL Solutions accreditations. Other customer-specific topics such as certificate scope, selection of facilities to be registered, organizational structure and proposed schedules for audit can also be discussed.

6.2.3 Certification audit activity

The certification audit activity is scheduled when a facility is determined to be eligible for audit. The certification audit activity is conducted in two stages:

- Stage 1 Readiness Audit – Allows the UL Solutions Audit team to evaluate the customer's readiness and preparedness for the Stage 2 Certification Audit; the UL Solutions 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 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 customer may elect to have the Stage 1 Readiness Audit conducted on site.
- Stage 2 Certification Audit – The UL Solutions Audit team shall evaluate the effective implementation of the subject QMS. The Stage 2 Certification Audit shall cover all processes included in the scope of the QMS and shall be conducted at the customer'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.

  Certification cannot be granted with open major nonconformities. A full re-audit of the affected areas will be required before certification 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 Solutions Audit team that the QMS continues to fulfill requirements and objectives. Surveillance audits are conducted on a biannual or annual frequency. The lead auditor may recommend that the customer be placed on biannual visits based on several factors including type and number of nonconformities and immature QMS. The first annual surveillance audit following certification shall be conducted within 12 months of the last day of the Stage 2 Certification Audit. The second annual surveillance audit shall be performed approximately 12 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 entire QMS over the previous cycle of surveillance audits and examine its continued ability to meet the certificate scope. Recertification audits shall be conducted at the customer's site(s) on a three-year cycle. Recertification audits are planned sufficiently in advance (usually three months prior to the certificate expiry date) to enable recertification to occur without interruption of the customer'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 that 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, customer 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 Solutions customer requests to expand their certificate scope to include other standards, operations, etc., or to assess a change of physical location. Scope expansion audits 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 (which can include individual auditor restrictions to travel), UL Solutions may deliver the audit remotely or semi-remotely (as a hybrid or blended audit). All deviations from normal audit processes must be approved by UL Solutions.

6.3 Nonconformities

6.3.1 Nonconformities fall under two categories: major and minor. UL Solutions uses definitions for major and minor nonconformities adopted from the Global Harmonization Task Force. For MDSAP nonconformities, see Section 4.3.4.

A major nonconformity is:

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

6.3.2 Major nonconformities, MDSAP Grade 5 and multiple MDSAP Grade 4 nonconformities must be responded to within fifteen (15) calendar days from the last day of the audit where the nonconformity was raised.

- 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 nonconformities were raised.
- The major nonconformity must be resolved prior to the issuance or re-issuance of the applicable certificate(s).
- Following the review of the major nonconformity and the customer'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.
- Customers must provide evidence to UL Solutions of implementation of the remediation actions to address the major nonconformity within thirty (30) calendar days of the last day of the audit.
- Evidence of implementation of the remediation actions to address MDSAP Grade 4 and/or Grade 5 nonconformities must be provided to UL Solutions within thirty (30) calendar days of the last day of the audit.

6.3.3 Minor nonconformities are defined as quality system nonconformities that judgment and experience indicate are not likely to:

- Result in the failure of the quality system
- Reduce the quality system's ability to assure controlled processes
- Result in the probable shipment of nonconforming product

6.3.4 Minor nonconformities must be responded to within fifteen (15) calendar days of the last day of the audit where the nonconformity was raised.

6.3.5 All minor nonconformities must be resolved within sixty (60) calendar days of issuance. Customers must provide to UL Solutions evidence of the implementation of the corrections and corrective actions within 60 calendar days of issuance. UL Solutions 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 depend on the number and nature of the nonconformities raised.

6.4 Conformity assessments (UKCA)

These will be conducted in line with the relevant regulations.

6.5 Issuing certifications

6.5.1 At the completion of each audit, the UL Solutions Audit team shall provide the customer's management representative with any nonconformities or itemized discrepancies identified during the audit. Time limits for responses to nonconformities are determined by UL Solutions. The Audit team shall also provide a recommendation as to the customer's eligibility for certification, continued certification or recertification.

6.5.2 The Audit team's recommendation, provided at the end of the audit, and the entire audit package are 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 customer should there be a disagreement with the certification decision.

6.5.3 Certification 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 Solutions auditor. If the nonconformities are not satisfactorily resolved, UL Solutions shall provide an explanation of the reasons why the response did not resolve the nonconformity.

6.5.4 When certification is granted, UL Solutions shall issue an electronic certificate to the customer indicating that the customer's quality system complies with a given QMS standard for a specific group of products and/or services and recognizing the customer's certification with a validity not to exceed three (3) years. The certificate information shall also be published in UL Solutions' online certification directory, Product iQ.

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

6.6 Maintenance of certification

6.6.1 Upon initial issuance of a certificate, a program of surveillance audits is established. The establishment and maintenance of certification is contingent upon the continued adherence to the terms and conditions of this document by the customer. During these visits, UL Solutions shall verify that the customer continues to comply with the requirements of the subject QMS standard(s), other relevant program standards as applicable and these program requirements.

6.6.2 Surveillance audit visits are conducted annually. Annual surveillance audit(s) will cover approximately one-third to one-half of the QMS. 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 customer's certificate. The recertification audit duration will be approximately two-thirds of the time required for a Stage 2 Certification Audit.

6.6.3 Alternate audit methods may be used only when specifically authorized by UL Solutions in writing or where there are special or extraordinary circumstances beyond UL Solutions' or the customer's control.

6.7 Suspension or withdrawal of certificates

6.7.1 Certificates may be suspended by UL Solutions under any of the following conditions:

- The customer's quality system no longer complies with the requirements of the applicable QMS standard or program requirements.
- The customer's use of any UL Solutions symbol, marking or statement is determined by UL Solutions as unacceptable or misleading.
- The customer's use of any accreditation body's marking, symbol or statement is determined by UL Solutions and/or the accreditation body as unacceptable or misleading.

- The customer is delinquent in payments.
- The customer violates a signed UL Solutions agreement during the process of (or after) achieving registration.
- The customer has exhibited a lack of commitment to responding to nonconformities (action requests), including continued failure to provide adequate root cause analysis, or continues to fail to meet agreed response dates.
- The customer delays or refuses the scheduling of an audit, including delays in audit cost acceptance.
- The customer's management system continues to demonstrate an ineffective QMS by repetitive nonconformities (action requests) being issued and not resolved.
- The customer refuses to allow access to UL Solutions auditors or accreditation body observers, regulatory body observers or other UL Solutions observers for scheduled or unannounced audits.
- The corrective action to address minor nonconformities is not submitted to UL Solutions within sixty (60) calendar days or is not sufficient to address the nonconformity.
- The remediation action for any MDSAP Grade 4 and/or Grade 5 nonconformities is not submitted to UL Solutions within thirty (30) calendar days of the last day or is not sufficient to address the nonconformity.
- The quote for the supplemental project to review the evidence submitted to correct the nonconformities is not accepted by the customer and thus the nonconformities cannot be closed.

6.7.2 While the suspension is in effect, the customer's certification is invalid. The customer shall refrain from any further promotion of its certification and the UL Solutions Management System Promotional Badge.

6.7.3 The customer shall resolve any issues surrounding certificate suspension within a period of less than ninety (90) days. If the issues have not been resolved within this time frame, UL Solutions shall withdraw the certificate(s). The customer may also request withdrawal of certificate(s) at any time, subject to any notice period contained in this document or other agreements.

6.7.4 UL Solutions may reduce the certificate scope to exclude parts, services or sites that consistently fail to meet the certification requirements for the applicable parts of the certificate scope. UL Solutions shall update its certification directory and certification documents. The customer shall amend advertising and promotional material to remove references to UL Solutions certification or use the UL Solutions Management System Promotional Badge only for products or services covered by the reduced scope of certification.

6.7.5 Certificates shall be discontinued for any quality system or goods or services that, for any reason, are no longer eligible for certification.

6.7.6 Upon withdrawal of any rights or authority conferred by signed agreements, UL Solutions shall take one or both of the following actions:

- UL Solutions shall discontinue in whole or in part UL Solutions-issued certificates of the quality system and any goods or services covered.
- The UL Solutions representative shall have the right to acquire possession of any written material utilizing the UL Solutions certificate, UL Mark or badge, and any other form or reference to UL Solutions used in connection with any system, goods or services that are no longer subject to registration.

6.7.7 Upon the termination or withdrawal of the certificate, the customer shall immediately discontinue the use of the UL Solutions Management System Promotional Badge and any reference to UL Solutions as its certification body, including all materials that refer to certification status with UL Solutions. This does not in any way limit the actions that UL Solutions may take in the event of the termination of any rights or authority conferred by signed agreements.

6.7.8 In the event of certificate suspension or withdrawal, UL Solutions shall update the certificate information in UL Solutions' certification directory, Product iQ.

6.8 Complaints

6.8.1 Customers are encouraged to provide feedback concerning their experience with UL Solutions services by completing the Customer Experience Survey and/or emailing Inform.Regulatory@UL.com and/or emailing CustomerAdvocacy@UL.com. See also Customer Confidentiality and Complaint Process FAQ | UL Solutions.

6.8.2 Any complaints are requested to be submitted in writing and should include specific references, as applicable, for investigation, validation, documentation and UL Solutions' consideration for continuous improvement.

6.8.3 Submission, investigation and decisions made concerning any complaints shall not result in any discriminatory actions against the complainant.

6.8.4 All complaints received are entered into UL Solutions' complaint database by our Customer Advocacy team for tracking investigation and resolution.

6.8.5 Where possible, complaints are acknowledged within forty-eight (48) hours, with updates and results communicated to the complainant and, where possible, resolved within that time frame. If additional time is required, this is explained to the complainant and should not exceed thirty (30) days. If a complainant wishes to remain anonymous and does not request a response, the complaint is still evaluated and considered for possible corrective actions.

6.8.6 UL Solutions personnel handling complaints gather and verify all necessary information to validate the complaint and conduct a thorough review of the facts and information acquired from all available sources.

6.8.7 Decisions regarding complaints are made by or reviewed and approved by UL Solutions personnel not previously involved in the subject of the complaint and are based on the facts and information collected, also taking into consideration the resolutions and actions resulting from any prior similar situations.

6.8.8 Where possible, UL Solutions shall provide formal notice of the closure of the complaint-handling process to the complainant.

- If the complaint is determined to be invalid, UL Solutions shall communicate the results of the investigation to the complainant.
- If the complaint is determined to be valid, UL Solutions shall investigate for correction and corrective action.
- The results of the investigation and the corrective action plan are to be communicated to the complainant, including determining (with the customer and complainant) whether and to what extent the subject of the complaint and resolution shall be made public.

6.8.9 Upon resolution, the Customer Advocacy team and/or 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 are included within UL Solutions' corrective action system.

6.8.10 If the complainant is not satisifed with the results of the investigation and UL Solutions' corrective or preventive actions, and UL Solutions cannot come to an agreeable solution with the complainant, UL Solutions shall inform the complainant of their right to make their complaint to a higher UL Solutions management level.

6.8.11 The complainant may request information on the consideration of the complaint or on any corrective action at any time.

6.9 Complaints about UL Solutions certified customers

6.9.1 If UL Solutions receives a complaint about a certified customer, the confidentiality of the customer's files and any other associated information must be maintained in accordance with UL Solutions policy and the signed agreement with the customer.

6.9.2 If UL Solutions receives a complaint by a certified customer's end customer about the customer, the complaint shall be communicated to the customer if agreeable to the end customer and depending on the significance and impact on the system.

6.9.3 Only complainants who are willing to identify themselves to the UL Solutions certified customer will be made aware of their complaint's resolution, i.e., the resolution would be communicated by the UL Solutions customer during resolution. UL Solutions shall encourage its certified customer to work with the complainant through their quality system's complaint handling mechanism to resolve the issue. UL Solutions can follow up during the subsequent routine surveillance audit(s) by evaluating the certified customer's resolution of the complaint.

6.9.4 If the investigation into the complaint leads UL Solutions to determine that further investigation is necessary, yet without an on-site visit, it shall be requested that the certified customer provide a corrective action plan including root cause analysis, planned actions and timing.

6.9. If UL Solutions determines after review of the complaint and any other associated evidence that an on-site visit is required, the following shall be observed:

- 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.
- If a major nonconformity is found during the assessment of the complaint, it is to be documented in the audit report and a response by the customer shall be required within 10 days of the last day of the audit.

6.9.6 UL Solutions shall provide monthly progress reports to the complainant should the process take more than one month to conclude. The complainant may also enquire at any time the status of the complaint. However, UL Solutions shall not release any confidential information regarding the UL Solutions certified customer unless otherwise stated in the document.

6.9.7 UL Solutions shall determine, together with the certified customer and the complainant, whether and, if so, to what extent the subject of the complaint and its resolution shall be made public.

6.10 Disputes and appeals

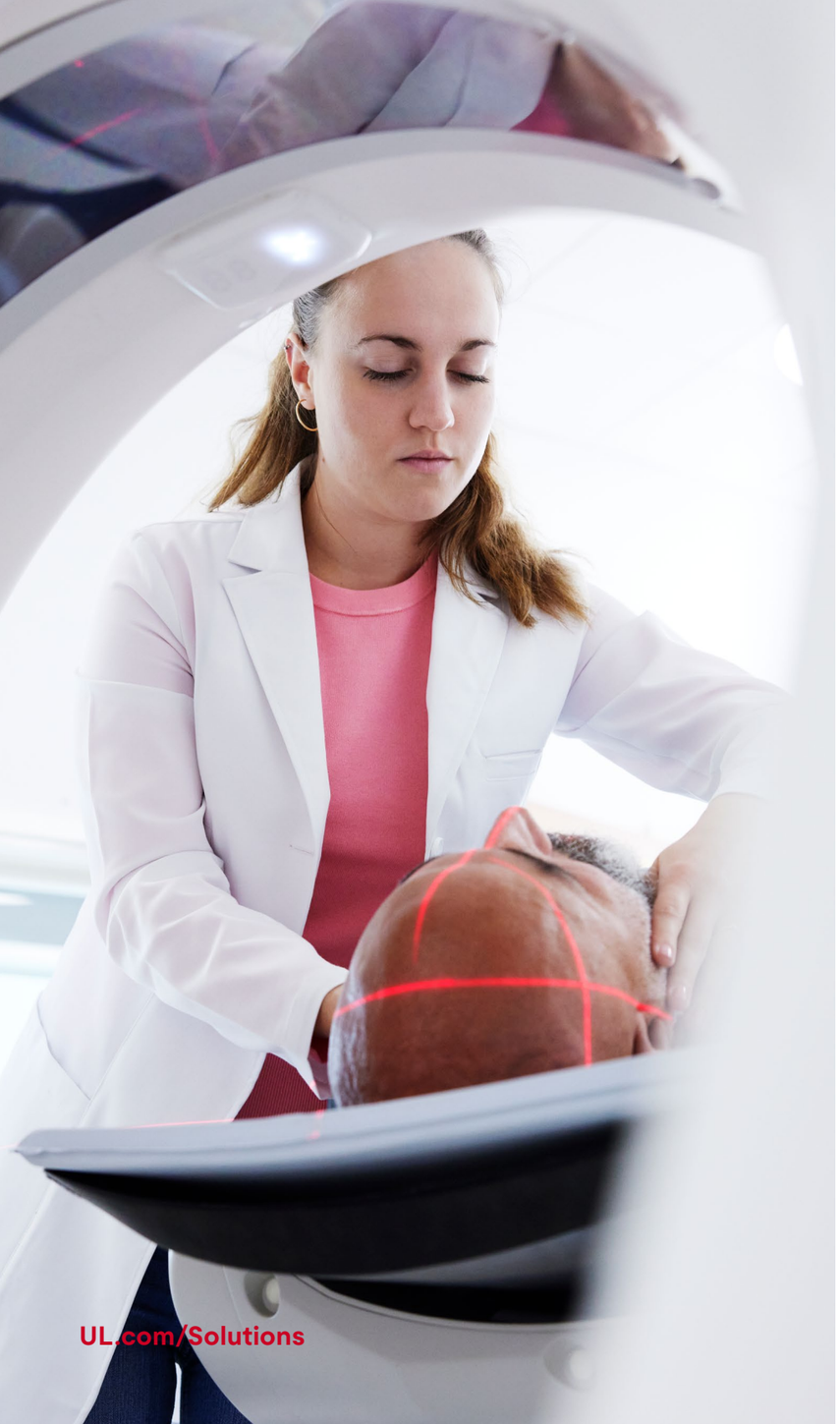
6.10.1 Customers may dispute the issuance or classification of any nonconformity issued by the UL Solutions Audit team. Any dispute shall be raised with the lead auditor of the Audit team first. If the customer is not satisfied, the dispute can be raised with a UL Solutions certification decision maker for further review and decision. If an agreement still cannot be reached and the nonconformity will likely result in registration withdrawal, the customer is invited to make a formal appeal.

6.10.2 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 6.3.2 and 6.3.4 above.**

6.10.3 The UL Solutions 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.

6.10.4 Appeals are generally not complaints. An appeal is made when there is a disagreement with a UL Solutions decision to not grant or to withdraw registration.

6.10.5 Appeals should be documented by the customer and submitted in English to UL Solutions 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 to 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.



6.10.6 Upon receipt of the appeal, UL Solutions' lead reviewer shall acknowledge their receipt of the appeal to the appellant. An appeals panel shall then be convened to assess the validity of the recommendation not to grant or to withdraw registration. The appeals panel shall include additional UL Solutions auditors independent of both the audit recommendation and the review of the audit where a recommendation not to grant or to withdraw registration was made.

6.10.7 Once an appeals panel is formed, it shall be verified with the appellant to ensure that 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 Solutions and the appellant agree to abide by the decision formed by the appeals panel.

6.10.8 The chair of the appeals panel shall verify that all facts are equally presented to the individual UL Solutions auditors on the appeals panel. Each UL Solutions auditor shall be requested to independently weigh the customer's appeal with records generated from the audit. Additional requests for information from either the UL Solutions Audit team or the customer shall be requested through the chair of the appeals panel.

6.10.9 The UL Solutions 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 customer.

6.10.10 A majority decision of the panel assessors shall be carried forth as the final decision of the panel.

6.10.11 The appellant may request of UL Solutions' lead reviewer the status of any application at any time during the appeals process or in relation to UL Solutions' corrective action, should the appeal be successful.

6.10.12 UL Solutions' 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.

6.10.13 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 Solutions' medical regulatory services program requirements.

6.10.14 UL Solutions shall ensure that no discriminatory action is taken against a customer in any way for the submission of a dispute, appeal or complaint.

7.0 UL Solutions' regulatory programs

7.1 Medical Devices Single Audit Program

7.1.1 UL Solutions provides registration to ISO 13485:2016 and the MDSAP, as administered by the MDSAP regulatory authorities (RA).

7.1.2 UL Solutions shall evaluate and register customers to the requirements of the ISO 13485:2016 standard and MDSAP requirements.

7.1.3 In addition to Section 4.1.15 of this document, as a condition of registration under the MDSAP, the customer agrees to allow UL Solutions' Audit team to be observed by representatives from the MDSAP RAs during the on-site audit at the customer's location(s).

7.1.4 As a condition of registration under the MDSAP, the customer agrees to allow UL Solutions to release to the MDSAP RAs any document that the RAs consider necessary to determine a medical device customer's conformance to ISO 13485 requirements and applicable regulations of the MDSAP member countries. These documents would include those that UL Solutions or its auditors use to plan, perform or follow up on an ISO 13485/MDSAP investigation and to record observations or report results of an ISO 13485 QMS audit. All documents held by RAs shall be treated in accordance with appropriate regulations and guidelines dealing with confidential and proprietary information. The documents required will be uploaded to the MDSAP REPS database as required under the MDSAP to facilitate access for the participating RAs.

7.1.5 UL Solutions shall notify RAs in writing of any change in a customer's registration certificate status relating to extension or reduction of scope, suspension or withdrawal of that certificate.

7.1.6 UL Solutions shall publish a list of customers registered by UL Solutions under the MDSAP with the customer's address and scope of registration in UL Solutions' certification directory, Product iQ.

7.1.7 Apart from appearing on the issued certificate, the MDSAP logo may not be used elsewhere.

7.2 UKCA program

7.2.1 U.K./MHRA registration:
Customers wishing to place a device on the Great Britain market must register with the MHRA. All medical devices, including in vitro diagnostic (IVD) devices, custom-made devices and systems or procedure packs must be registered with the MHRA before being placed on the Great Britain market.

Where a customer is not established in the U.K., they must appoint a UK Responsible Person (UKRP) to register and act on their behalf.

The UKRP acts on behalf of the non-U.K. customer to carry out specified tasks in relation to the customer's obligations. This includes registering the customer's devices with the MHRA before the devices can be placed on the Great Britain market.

7.2.2 Post-market surveillance and vigilance:
For medical devices (including self-declared devices) placed on the U.K. market, the customer is required to submit vigilance reports to the MHRA (and the U.K. approved body if a certificate is issued) when incidents occur in the U.K. 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 can have both the CE and UKCA markings present on the labelling. However, the name and address of the UKRP, where applicable, needs to be included on product labelling, 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 an accreditation body mark

A.1 Requirements for use of the UKAS mark

A.1.1 This section applies only to those customers with written authorization from UL Solutions to use the UKAS mark as evidenced by the UKAS mark on their certificate of registration.

A.1.2 Only customers authorized to use the UKAS mark are entitled to use the mark illustrated here.

A.1.3 Use of the UKAS mark must always be in conjunction with UL Solutions' relevant accreditation number: 4426.

A.1.4 The UKAS mark may be used on stationery and publicity material or other items relevant to the customer's ISO certificate(s) in connection with those goods and/or services listed on the certificate(s). 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 packaging, e.g., blister packs, and promotional products.

A.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 that may imply that the product, process or service itself is in any way certified or approved by UL Solutions or UKAS.

A.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.

A.1.7 The registered customer agrees to discontinue any use of the UKAS mark and any form of statement with reference to the authority of the registered customer to use the UKAS mark that is unacceptable to UL Solutions or that, in the opinion of UL Solutions, might be misleading.

A.1.8 Upon the termination of registration, for whatever reason, the customer must discontinue all use of the UKAS mark immediately.

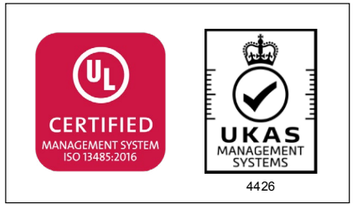
A.1.9 The UKAS accreditation mark shall normally have a minimum height (excluding the accreditation number) of 20 mm. Any enlargement or reduction shall retain the same proportions as those printed in this publication. The mark and the accreditation number shall be considered as a single entity for purposes of enlargement or reduction. In exceptional circumstances, which are usually dictated by reason of space limitation or cost, the marks may be reproduced at a reduced height, provided that, irrespective of the height of reproduction, the mark must, in the opinion of UL Solutions, be legible, with no infilling.

A.1.10 When printed on an unfolded portion of stationery sized no greater than A4, the UKAS mark shall be displayed no larger than 30 mm high. On larger portions of unfolded stationary, the size may be proportionately increased. Authorized users shall ensure that the form of the accreditation mark is legible.

A.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.

A.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 or flags. Marks may be displayed on internal walls and doors and on exhibition stands.

A.1.13 The UKAS national accreditation symbol shall always be used in conjunction with the UL Solutions Promotional Badge and shall be enclosed in a box as indicated below. The UL Solutions Promotional Badge may be used without the UKAS accreditation mark in accordance with guidelines on the UL Solutions website (see Section 3.17).



A.2 Requirements for use of the UKCA marking

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

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

UK
CA
0843

A.2.3 For devices dual-marked for CE and UKCA, the customer must ensure the legibility and visibility of the UKCA marking.

UL.com/Solutions