

THE MEDICAL DEVICES REGULATIONS 2002 UK APPROVED BODY SERVICES SERVICE TERMS

These Service Terms shall govern The Medical Devices Regulations 2002 UK Approved Body Services to be performed by the UL Contracting Party (as identified in the Quotation or Project Confirmation) operating through its affiliate UL International (UK) Ltd. ("UL UK") as a UK Approved Body for The Medical Devices Regulations 2002 and also set out the responsibilities and obligations of the Client. These Service Terms and the terms of the Global Services Agreement ("GSA") are incorporated by reference into and are an integral part of each Service Agreement entered into by the Parties for The Medical Devices Regulations 2002 UK Approved Body Service. The conditions of the UL Solutions Medical Management System and UK Approved Body Program Requirements apply to these Service Terms. These terms are available under www.ul.com The capitalized terms in these Service Terms which are not defined herein shall have the same meaning as in the GSA.

1. **Scope of Service.** UL Contracting Party utilizing UL UK will undertake to assess Client's products, quality assurance systems, products, and/or reagents for compliance with the Medical Devices Regulations 2002), as amended and incorporated into applicable national law, and any applicable laws, regulations, and standards ("Applicable Requirements"), as may be requested by Client (the "Assessment Services"). This includes unannounced visit activity.- The Assessment Services requested by Client and to be provided by UL Contracting Party acting through UL UK for specific projects shall be set out in a Quotation or Project Confirmation.

Unannounced audits may take place at the client's premises, or the client's critical subcontractor premises or crucial supplier's premises at least once over a five-year cycle.

2. **Application.** Client agrees by accepting the Quotation that a formal application has been lodged with UL UK Client agrees there is no current or prior application with any other Approved Body for the same product within the same scope of service. Where there is a current or prior application with another Approved Body, the Client shall formally advise UL UK in writing before project begins. The Client shall inform UL UK if Emergo by UL is or has been used for consulting services for the devices under assessment in the three years before we begin with executing any Services. The Client shall inform UL UK if Emergo by UL is used as UK responsible person, before the project begins.
3. **Partial Assessment Services.** Client agrees that its ordering of partial assessment services (gap analysis, readiness review, early engagement or spin projects) from UL UK in accordance with the scope of service is considered lodging a formal application with UL UK and will be evaluated as such.
4. **Information, Data, and Materials.** Client agrees to provide UL Contracting Party with all relevant information, test data, products, and reagents, and unrestricted access to all locations necessary to complete the Assessment Services upon request from UL Contracting Party. Client agrees to give UL Contracting Party timely written notice of all material changes to the information disclosed to UL Contracting Party in connection with the Assessment Services. Significant changes requiring notification to UL UK are described in the UL Solutions Medical Management System and UK Approved Body Program Requirements available under <https://www.ul.com>.

To meet unannounced audits requirements of the Directives/Regulations:

i) unrestricted access is required to any locations, including the client's manufacturing locations, the client's critical subcontractor locations and the client's crucial supplier locations.

ii) the client is contractually obliged to provide invitation letters to needed locations. The invitation letters will leave the date of signature and visit open.

iii) the client need inform UL Contracting Party on periods when the devices falling under the Approved bodies' certificates will not be manufactured.

5. **Compliance.** UL Contracting Party and Client shall not deviate from the applicable laws, regulations, and standards governing the Assessment Services, unless Client has obtained an exemption from the relevant authority.
6. **Language Requirement.** Client shall provide all materials and information with respect to the Assessment Services in English, unless the parties have agreed in writing to the use of a different language, and Client agrees to pay any additional costs related to the Assessment Services, e.g., translation costs.
7. **Cancellation.** Client may elect to discontinue or postpone the Assessment Services at any time upon written notice to UL Contracting Party. Client shall be responsible for payment of all Assessment Services performed prior to UL Contracting Party's receipt of such notice and any fees associated with the termination or postponement. Neither UL Contracting Party nor UL UK shall be held liable for any errors or deficiencies in connection with the work already performed and Client shall not use either UL Contracting Party's or UL UK's name or Approved Body number in connection with Client's products or quality assurance systems.
8. **Fees.** Quotation will set forth the fees for UL Contracting Party's Assessment Services as provided through UL UK, including fees associated with preparation prior to the assessment activities, and the on-site assessments, reports, reviews, and activities following the assessments, but does not include expenses associated with travel and living which will be billed at cost as incurred. The fees set in the Quotation are subject to change in the event that UL Contracting Party determines that additional services are reasonably necessary to complete the Assessment Services. Annual fees for filing and maintenance of the Certificate and for additional copies of reports and Certificates will be billed separately.
Service provided under these Service Terms include and are subject to annual management fees. Annual management fees cover a period of one year from the placement of the order. The annual management fees support UL activities at external experts' programme, attendance with the UK's Medicines and Healthcare Products Regulatory Agency (MHRA), process and trainings resulting from and in support of the programme needs and expectations. The annual management fees will be renewed every year for the validity of the certificate.
Financial compensation will be needed for device acquisition, its testing and security arrangements associated to unannounced audits where required.
9. **Certificate.** If UL Contracting Party acting through UL UK finds that Client's product and/or quality system conforms to the applicable laws, regulations, and standards, Client shall be eligible to receive a UL UK Certificate(s). The maintenance of any UL UK Certificate is contingent upon the Client's continued adherence to the terms of the Agreement, including these Service Terms and UL Solutions Medical Management System and UK Approved Body Program Requirements available under <https://www.ul.com>. , UL Contracting Party and UL UK each shall have the right to cancel or withdraw the Certificate at any time if Client's product and/or quality system fails to conform to the applicable laws, regulations, and standards, or if the information , materials, or data Client provides to UL Contracting Party contain any misrepresentation or omission.
UL Contracting Party and UL UK will end this contract where permanent unannounced access to client premises or its critical subcontractors or crucial suppliers in no longer assured.
10. **References to UL Contracting Party or UL UK.** Unless otherwise authorized in writing by UL Contracting Party, UL Contracting Party will only permit the use of appropriate references to UL Contracting Party or UL UK in the form or text as specified by UL Contracting Party. UL Contracting Party will permit Client to use such references in promotional or advertising material provided that, in the opinion of UL Contracting Party, the promotional or advertising material does not conflict with UL UK's findings on UL Contracting Party's behalf or create a misleading impression as to the nature of those findings.

11. **Use of Certificate and Approved Body number.** The UL UK Certificate and Approved Body number shall be obtained and used only when, and in the manner authorized by UL Contracting Party in consultation with UL UK. Notwithstanding that the cost of displaying UL UK's Certificate and Approved Body number is not paid by either UL Contracting Party or UL UK, Client agrees that UL Contracting Party and UL UK shall retain the right to control the display or otherwise use the Certificate and Approved Body number. UL Contracting Party's representative shall have the right, on demand, to acquire possession of the UL UK Certificate and any or all advertising and promotional material or other means of displaying the Certificate or other references to either UL Contracting Party or UL UK upon termination of this Agreement, or when such action is warranted in the judgment of UL Contracting Party's representative.

Client assumes full and sole responsibility for its use of UL UK 's Certificate and Approved Body number and agrees that its product and/or quality system will be in compliance with the Applicable Requirements at all times. Client agrees that its use of the UL UK Certificate and Approved Body number constitutes its declaration that UL Contracting Party operating through UL UK has assessed its product and/or quality system in accordance with the applicable laws, regulations and standards, and that the products and/or quality systems covered by the UL UK Certificate are in accordance with the Applicable Requirements.

Client agrees that the promotion of its product and/or quality system utilizing UL Contracting Party's or UL UK's name, Certificate, or Approved Body number, would mislead the public if such product and/or quality system is not covered by UL UK's Certificate; does not comply with the Applicable Requirements and applicable laws, regulations, and standards; or is used in any way not authorized by UL Contracting Party.

12. **Investigation of Noncompliance.** Client agrees that it will, at its expense, fully cooperate with and assist UL Contracting Party in ascertaining the facts if it is reported that Client's product and/or quality system are not in compliance with the Applicable Requirements, or applicable laws, regulations, and standards. Among other things, Client shall promptly share any information it acquires regarding the reported noncompliance, take any corrective action necessary to correct any noncompliance, and provide timely reports to UL Contracting Party on such corrective action.
13. **Surveillance Services.** Client agrees that UL Contracting Party's surveillance service as may be performed by UL Contracting Party through UL UK and any assessments conducted by UL Contracting Party are designed to serve only as a check on the means by which the Client determines compliance of its product and/or quality system with the applicable laws, regulations, and standards. Client also agrees that such surveillance service and assessments in no way relieve the Client of its responsibility for its product and/or quality system that are subject to the Certificate issued by UL UK. Client agrees to allowing third party witness audits of UL UK where audit supports UL UK Approved Body designation purposes.
14. **Claims.** Any claim by the Client, or any third party claim, arising out of this Agreement, shall be filed within a period of one year from the date of UL UK's issuance of a certificate to Client or UL UK's decision not to issue a certificate , or shall be forever waived.
15. **No Listing, Classification or Recognition of Product.** Client understands and agrees that any report, Certificate, or authorization, issued as a result of any assessment services performed by UL UK under this programme, shall not result in UL UK product safety certification or any authorization to use the Marks and will not indicate acceptability of a product for Listing, Classification or Recognition by UL Contracting Party, or any other UL Company. Client shall not use such report or Certificate in any manner or as the basis of any oral or written representation to convey the impression that any product or system has been or is so Listed, Classified or Recognized.
16. **Vigilance reporting.** Client understands and agrees to report issues occurring in the post-production phase affecting UL UK UKCA certified devices. Reporting shall include copy of notifications sent to the MHRA to UL UK. Additionally, the client shall report serious incidents, Field Safety Corrective Actions and Field Safety Notices related to UL UK CA certified devices to UL UK.

References: The Medical Devices Regulations 2002