GSA – MDR
05.06.2022

Medical Device Notified Body
Regulation Conformity Assessment and Assistance Services

These Service Terms shall govern the medical device notified body regulation conformity assessment and assistance services (the "Services") to be performed by the UL Contracting Party ("we", "us" or "our" as the context requires), as identified in the Quotation or Project Confirmation, in cooperation with and on behalf of DQS Medizinprodukte GmbH (the "Medical Notified Body") for the European Union Medical Devices Regulation (2017/745) (the "MDR"); and set out your responsibilities and obligations as a Client ("you" or "your" as the context requires). 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 Services.

The capitalized terms in these Service Terms which are not defined herein shall have the same meaning as in the GSA.

1. **Medical Notified Body Agreement.** Client shall enter into a separate application or agreement directly with the Medical Notified Body for Medical Notified Body CE Certification services relating to Client's products or quality systems ("Medical Notified Body Agreement"). and shall inform UL Contracting Party of such agreement. The Client's Medical Notified Body Agreement will directly apply to the Client and shall govern any CE Certification services performed by Medical Notified body for Client.

2. **Scope of Service.** The Medical Notified Body has authorized UL Contracting Party to perform certain activities and services on its behalf directly to Client in accordance with MDR Annex VII clause 3.4 in order to assist Client in seeking CE Certification from the Notified Body, which may include quality assurance system audits (initial or surveillance), product documentation review, and /or unannounced audits, for compliance with the MDR, as amended and incorporated into applicable national law, and any applicable laws, regulations, and standards ("Applicable Requirements"). Unannounced audits may take place at the Client's premises, or the Client's subcontractor or supplier premises at least once over a five year cycle. UL Contracting Party will not be responsible for issuing any certification for medical device compliance ("CE Certification") which shall exclusively be performed by the Medical Notified Body under the separate Notified Body Agreement directly with Client. The specific Services to be performed by UL Contracting Party for Client are set out in the Quotation or Project Confirmation.

3. **Information, Data, and Materials.** Client will provide UL Contracting Party with all relevant information, test data, products, reagents, and unrestricted access to all locations necessary to complete the Services upon request from UL Contracting Party. Client agrees that all such information, test data, products, reagents can be disclosed to the Medical Notified Body. Client agrees to give UL Contracting Party timely written notice of all material changes to the information disclosed hereunder and in connection with the Services.

   To meet unannounced audit requirements of the Regulations:

i) Unrestricted access is required to any locations, including the Client's manufacturing locations, the clients 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 needs to inform UL Contracting Party on periods when the devices falling under the Medical Notified Body's certificates will not be manufactured.

4. **Compliance.** UL Contracting Party shall not deviate from the applicable laws, regulations and standards governing the Services, unless Client has obtained an exemption from the relevant authority.

5. **Language Requirement.** Client shall provide all materials and information with respect to the Services in English, unless the parties have agreed in writing to the use of a different language. For Client related materials and information, the Client agrees to pay any additional costs related to the Services, e.g. translation costs.

6. **Cancellation**. Client may elect to discontinue or postpose the Services at any time upon written notice to the UL Contracting Party. Client shall be responsible for payment of all Services performed and any fees associated with termination or postponement.

7. **Fees.** Quotation will set forth the fees for UL Contracting Party's Services including fees associated with preparation prior to the initiation of Services, and the on-site assessments, travel time, 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 Client will pay all costs related to obtaining and transporting, including any security, any test samples to the test facilities where required as part of an Unannounced Audit. Fees may include pass through charges for Medical Notified Body's CE Certification if included in the Quotation. Notwithstanding that UL Contracting Party may invoice Client for such services Medical Notified Body performs for Client under its separate Medical Notified Body Agreement, UL assumes no liability and Client waives all liability against UL arising out of such Medical Notified Body services.

8. **Medical Notified Body Certificate.** The Medical Notified Body Agreement with Client shall apply to the management of the certificate with the Client. UL Contracting Party Services will provide recommendation of certification statuses to the Medical Notified Body, but the final decision regarding certification is made by the Medical Notified Body. UL Contracting Party makes no representation or guarantee that Client will receive certification from Medical Notified Body.

9. **References to UL Contracting Party.** 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 any of its affiliates in the form or text as specified by UL Contracting Party..

10. **Investigation of Noncompliance.** UL Contracting Party will communicate directly with Client on behalf of Medical Notified Body. Client will 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 Medical Notified Body's applicable requirements, or applicable

laws, regulations, and standards. Among other things, Client shall promptly share any information it acquires regarding the reported non-compliance, take any corrective action necessary to correct any noncompliance, and provide timely reports to UL Contracting Party on such corrective action.

11. **Claims.** Any claim by Client, or any third party claim, arising out of this Agreement, shall be filed within a period of two years from the date of UL Contracting Party's (or any of its affiliates) issuance of assessment documentation or recommendations or shall be forever waived.

12. **No Listing, Classification or Recognition.** Client understands and agrees that the Services performed by the UL Contracting Party (or any of its affiliates), shall not result in any authorization to use the Marks and will not indicate acceptability of a product or system for Listing, Classification or Recognition by UL Contracting Party, or any other UL Company. Client shall not in any manner or as basis of any oral or written representation convey the impression that any product or system has been or is so Listed, Classified or Recognized.

13. **Vigilance Reporting.** Client agrees to report serious incidents and field safety corrective actions occurring in the post-production phase affecting Medical Notified Body certificate devices, and also in accordance with Medical Notified Body Agreement. UL Contracting Party will receive, process and report to the Medical Notified Body on Client vigilances received. Client's reporting to UL Contracting Party shall include copies of notifications sent to the applicable competent authority where the vigilance incident took place. Additionally, Client shall report Field Safety Corrective Actions and Field Safety Notices related to Medical Notified Body CE certified devices to UL Contracting Party as required by References: Regulation 2017/745 Annex VII section 4.