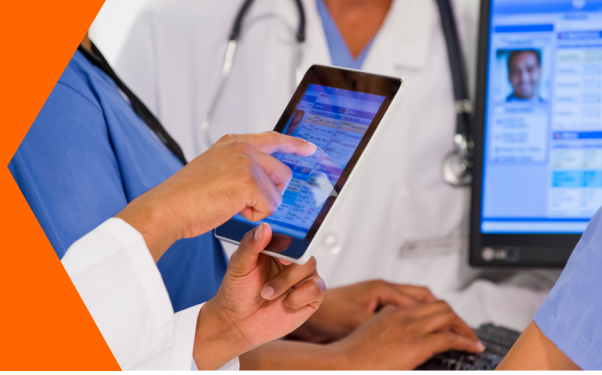
# Medical devices pre-audit client questionnaire

***** FOR USE UNDER BOTH MDD AND MDR *****



You are required to inform SGS of any changes or regulatory actions that may affect the validity of your certification or the scope of an audit. This should be done as soon as the information is known, using the Medical Devices Notification of Changes and Regulatory Actions form. This is available on our website (https://www.sgs.com/en/our-services/health-and-nutrition/health-science/eu-medical-devices-regulations-information-center).

This Medical Devices Pre-Audit Client Questionnaire, which is available on our website (https://www.sgs.com/en/our-services/health-and-nutrition/health-science/eu-medical-devices-regulations-information-center), is not intended to notify SGS of significant changes and regulatory actions not notified to SGS before. If done, a proposal for supplementary review or audit time may be required and the notified significant change cannot be implemented without prior written approval by SGS.

SGS clients are required to confirm information before each scheduled audit at least one month in advance. Audits cannot be undertaken without completing this Medical Devices Pre-Audit Questionnaire and delays in auditing can lead to certificate suspension, so returning this document to your medical device officer is very important.

A Notified Body shall be organized and operated to safeguard the independence, objectivity and impartiality of its conformity assessment activities. For this purpose, we have included some questions that enable us to identify particular circumstances in which a conflict of interest may arise, caused by the involvement of SGS or its representatives during the last three years, through consultancy services, customized training services and clinical assessments, etc.

The person shown below is responsible for the accuracy and completeness of the information given on behalf of the client.

Please return this completed questionnaire, confirming there is no new information or providing any new information. Please complete it electronically and keep a copy for the audit.

| | |
|---|---|
| Company (client) name: | Date: |
| Person completing this questionnaire: | |
| Person responsible for regulatory compliance*: | |
| Contact tel: | Email: |
| SGS contract number (if known): | Audit dates: |
| Current SGS certificate number(s): | |

*Mandatory under MDR (EU) 2017/745

Please review all current SGS certificates and the last SGS audit report, sections 0, (Manufacturer/Organization), section 3 (Scope of Certification) and section 4 (Audit Findings), especially those entitled Additional Information about the Manufacturer and Information on Critical Suppliers.

Check one of the following responses:

| |
|---|
| There have been no significant changes or regulatory actions since the last SGS audit |
| We have previously notified SGS of all significant changes and regulatory actions |
| We are notifying you of the changes and regulatory actions detailed below |

*Client, please return to local SGS Office*
*Local SGS office, please send changes and regulatory actions as a MED to MDO via (CertIQ)*

| CHANGE TO (CHANGES CAN BE ADDITIONS AND DELETIONS): |
|---|
| *Please check all relevant categories of change and provide details in the details of change and effective date box below.* |
| The certified name and address or other site addresses, or site activities/scopes/ownership: |
| Number of employees covered by the scope of certification or shift pattern: |
| Relevant subcontractors and suppliers (please provide an updated list of relevant subcontractors and suppliers, available on the SGS website): |
| The structure of the quality management system or links with related companies: |
| Major processes or activities: |
| Major production, testing or inspection processes: |
| Medical device generic types manufactured or classifications: |
| Change in sterilization process(es) that required revalidation or addition of a sterilization process: |
| Other (please give details): |
| DETAILS OF CHANGE AND EFFECTIVE DATE (ATTACH ADDITIONAL DOCUMENTS IF REQUIRED): |

| REGULATORY ACTIONS AND APPROVALS: |
|---|
| *Please check relevant boxes and give further information below.* |
| New regulatory approvals obtained or stopped (e.g. US, Brazil, Japan, Australia): |
| Regulatory actions by any Regulatory Authority that have required you to take action, supply information or restrict the sale of your medical devices in any market: |
| Incident reports (vigilance), which have required you to take actions that you have not previously informed SGS about (please attach vigilance report): |
| DETAILS OF REGULATORY ACTIONS AND APPROVALS: |

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| **CONSULTANCY AND OTHER SERVICES RENDERED CONCERNING MEDICAL DEVICES, IN VITRO DIAGNOSTIC DEVICES OR ACTIVE IMPLANTABLE MEDICAL DEVICES DURING THE LAST THREE YEARS (PLEASE COMPLETE WITH 'YES' OR 'NO'):** (This data, as with all customer-related data, is treated as confidential. The Notified Body needs it to avoid any potential conflicts of interest.) | | |
|---|---|---|
| *Please check relevant boxes and give further information below in the section Details.* | | |
| Consultancy services in the field of medical devices, in vitro diagnostic devices or active implantable medical devices: | Yes | No |
| Training activities in the field of medical devices, in vitro diagnostic devices or active implantable medical devices: | Yes | No |
| Internal audits: | Yes | No |
| Consultancy services, as regards EU requirements for the design, construction, marketing or maintenance of the products under assessment: | Yes | No |
| Services related to preclinical studies, clinical evaluation, clinical investigations, performance studies: | Yes | No |
| Laboratory testing services (e.g. testing for electro-medical devices): | Yes | No |
| Clinical research: | Yes | No |

| DETAILS OF CONSULTANCY AND OTHER SERVICES: |
|---|
| Please provide the name of the organization/person(s) that delivered services in the field of medical devices for any box that has been checked with "Yes": |

| **PLEASE ALSO COMPLETE THE BELOW SECTION:** |
|---|
| If you are located outside of Europe, please supply the name, address and activities undertaken by any EU Authorized Representative that you have appointed, including the name of the person responsible for regulatory compliance*: |
| If you are undertaking clinical investigations under the MDD 93/42/EEC (requiring ethics approval) or MDR (EU) 2017/745, either within or outside of the EU, please check the box: |
| If yes, please provide details below, indicating whether they are pre-market or post-CE marking, and attach summaries and/or protocols and current status of the clinical investigations: |

*Mandatory under MDR (EU) 2017/745

| REVIEW OF CHANGE OR REGULATORY ACTION BY SGS (FOR COMPLETION BY MDO): |
|---|
| *Check appropriate response.* |
| Review at next audit (no charge): |
| Proposal for an extension to scope: |
| Comments to auditor/CWS raiser: |

| CHANGES AND REGULATORY ACTIONS REVIEWED BY CWS APPROVER | Date: |
|---|---|
| CWS approver name: | |
| QUESTIONNAIRE REVIEWED BY SGS LEAD AUDITOR | Date: |
| Auditor name: | |

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