Medical Devices Pre-Audit Client Questionnaire

It is a requirement 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 ***GPMD1007 Medical Devices Notification of Changes and Regulatory actions form***.

SGS clients are required to confirm information before each scheduled audit. Audits cannot be undertaken without completion of this Pre-Audit Questionnaire and delays in auditing can lead to certificate suspension so the **return of this document to your local SGS office is very important.**

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

Please return this completed Pre-Audit Questionnaire confirming there is no new information or providing any new information. Please complete electronically and keep a copy for the audit.

Client Name		Date
Person completing this questionnaire		
Contact Tel:	Fax:	E-mail:
SGS Contract number (If known)	Audit Dates	
Current SGS Certificate Numbers		

Please review all current SGS certificates and the last SGS audit report, sections 0, **(Manufacturer/Organisation**), section 3 (**Scope of Certification**), and section 4 (**Audit Findings)**, especially the sections 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	☐

Change to: (Changes can be additions and deletions**)**

Please check all relevant categories of change and then give 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	☐
Critical suppliers (give name, address, and product/service supplied for new suppliers)	☐
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	☐
Other (please give details)	☐

Details of Change and effective date (attach additional documents if required)

Client please return to local SGS office
Local SGS office please send changes and regulatory actions to GMDO via Epack (Applaudd)

Regulatory Actions and Approvals

Please check relevant boxes and give further information below	
New Regulatory approvals or approvals stopped (e.g. USA, Brazil, Japan, Australia)	☐
Regulatory actions by any Regulatory Authority that have required you to take action, supply information or to restrict sale of your medical devices in any market	☐
Adverse Event Reports (vigilance) which have required you to take actions of which you have not previously informed SGS (please attach vigilance report)	☐

Details of regulatory actions and approvals

For clients with CMDCAS certification please also complete this section

A complete list of all current Health Canada medical device licence numbers (note: List only required – please do not send copies of licences)
Medical devices generic types you intend to sell into Canada in the future:
If relevant the name, address and activities undertaken by any Regulatory Correspondent you have appointed in Canada
Location of QMS records if not available at or from the locations being audited

For clients with MDD or IVDD certification please also complete this section

If you are located outside of Europe, please supply the name, address and activities undertaken by any EU Authorised Representative you have appointed	
If you are undertaking clinical investigations under the MDD 93/42/EEC (requiring ethics approval) 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	
If you are undertaking Performance Evaluations under the IVDD 98/79/EC (Annex VIII) either within or outside of the EU, please check the box	☐
If yes, please provide details below, including summaries and/or protocols and current status of the performance evaluation	

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Review of Change or Regulatory Action by SGS [for completion by **GMDO**]

Check appropriate response.	
Review at next audit.(No charge)	☐
Proposal for Extension to Scope	☐
Comments to Auditor / PWS Raiser	

Changes and Regulatory actions reviewed by GMDO GMDO name :	Date
Questionnaire reviewed by SGS auditor Auditor name :	Date

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