Pre-audit client questionnaire

*** For use under MDD, MDR and IVDR ***

It is a requirement to inform SGS NB 1639 of any planned 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 Action form, which can be found on the EU MDR Information Center and the EU IVDR Information Center on our website.

This Pre-Audit Client Questionnaire is not intended to notify SGS NB 1639 of planned changes and regulatory actions that have not been notified to SGS NB 1639 before. If done, an updated contract proposal for supplementary review or audit time may be required and the notified change cannot be implemented without prior written approval by SGS NB 1639.

SGS NB 1639 clients are required to confirm information before each scheduled audit at least one month in advance. MDR/IVDR audits cannot be undertaken without completion of this Pre-Audit Questionnaire and delays in auditing can lead to certificate suspension, therefore returning this document to your SGS Delivering Office is of significant importance.

A Notified Body shall be organized and operated as 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 involvement of SGS NB 1639 or its representatives in e.g. consultancy services, customized training services and clinical assessments during the last 3 years.

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 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 and under IVDR (EU) 2017/746

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 sections entitled Additional Information about the Manufacturer and Information on Relevant Suppliers.

Check one of the following responses:

	There have been no significant changes or regulatory actions since the last SGS NB 1639 audit
	We have previously notified SGS NB 1639 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 provide further information below in the section "Details of change and effective date"	
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 suppliers/subcontractors (please provide name, address and product/service supplied for new suppliers). Please provide an updated list of relevant subcontractors and suppliers (which is available on our 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/IVD 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 and provide further information below in the section "Details of Regulatory Actions and Approvals".	
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 to restrict sale of your medical devices in any market:	
Incident reports (vigilance), which have required you to take actions of which you have not previously informed SGS NB 1639 about (please attach vigilance report):	
DETAILS OF REGULATORY ACTIONS AND APPROVALS:	

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 is, as all client-related data, treated as confidential and is required by SGS NB 1639 to avoid any potential conflict of interest.)

Please check all relevant categories and provide further information below in the section "Details of consultancy and other services"		
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/performance 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 name of 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 the European Union, please supply the name, address and activities undertaken by any EU Authorized Representative you have appointed, including 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: Yes No
If you are undertaking Performance Studies under the IVDR (EU) 2017/746 either within or outside of the EU, please check the box: Yes No
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 or performance studies:

*Mandatory if MDR (EU) 2017/745 or IVDR (EU) 2017/746 is applicable.

REVIEW OF CHANGE OR REGULATORY ACTION BY SGS NB 1639 (FOR COMPLETION BY MDO):

Check appropriate response.	
Review at next audit (no charge):	
Proposal for extension to scope:	
Comments to auditor/Delivering Office:	

CHANGES AND REGULATORY ACTIONS REVIEWED BY TECHNICAL COORDINATOR	Date:
Technical coordinator name:	
QUESTIONNAIRE REVIEWED BY SGS LEAD AUDITOR	Date:
Lead auditor name:	

When you need to be sure