

MDR & IVDR client questionnaire

*** FOR UNANNOUNCED AUDIT YEAR

BACKGROUND INFORMATION FOR SGS CLIENTS

As a requirement of Regulation (EU) 2017/745 and Regulation (EU) 2017/746, SGS NB 1639 must undertake unannounced audits, usually at the location of the physical manufacturing site of the device. To allow notified bodies to accurately plan such audits and to undertake other aspects of the recommendation, information must be supplied by clients certified under MDR (EU) 2017/745 or IVDR (EU) 2017/746.

INFORMATION AND DEADLINE FOR COMPLETION

This questionnaire must be completed yearly. Please provide the questionnaire to your local SGS delivering office as soon as possible and at the latest by the end of the calendar year. Please answer the following questions fully, and if you have any questions contact your local SGS delivering office.

If the questionnaire is not received, unannounced audits must still be planned and consequently SGS will assume that there is no unavailability period for unannounced audit for your company, or that the information you declared during your last scheduled audit for the location(s) of the critical processes for your device(s) is still valid, and that these locations can be audited at any time.

SECTION 1: CONTACT INFORMATION

Guidance notes: Please confirm the current information that SGS has for your company and primary contact. Please provide a second contact person. This is new information needed for someone who will deputize for the primary contact, in the case of unannounced audits and urgent regulatory queries.

Company name (legal entity):	
Main address:	
Person completing this questionnaire:	
Contact tel:	Email:
Primary contact person:	
Position	
Contact tel:	Email:
Secondary contact person:	
Position	
Contact tel:	Email:
PRRC name:	
Position	
Contact tel:	Email:

NORMAL WORKING WEEK AND HOURS:

Please confirm which days are included in your normal working week, and the normal working hours when the site is fully manned and supervised (for example: Monday to Friday inclusive, 08:00 to 17:00 hours). Please indicate the days and hours for each site.

SHIFT OPERATIONS:

If the site operates a shift system, please indicate the site, the number and times of the shifts and a description of the activities per shift:

If manufacturing at your site or that of your subcontractor is intermittent, please contact your local SGS delivering office to discuss how unannounced audits may be undertaken.

