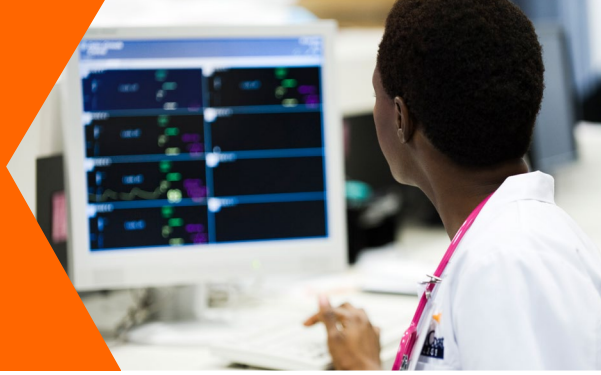
MDR client questionnaire

***** FOR UNANNOUNCED AUDIT YEAR *****



BACKGROUND INFORMATION FOR SGS CLIENTS

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

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 by the end of each calendar year, at the latest. 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. SGS will assume that there is no unavailability period for an unannounced audit of 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 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:

SECTION 2: SITE INFORMATION – FOR UNANNOUNCED AUDITS

Guidance notes: Unannounced audits will be carried out at the site(s) where the specific product range has its final manufacturing stage, acceptance testing and final inspection carried out.

If you have multisite certification, these activities may be carried out at more than one of your sites, so please provide information on all the relevant sites and activities at each.

If you use a relevant subcontractor for the final manufacturing, acceptance testing or final inspection, please provide information on those relevant sites and activities at each.

For virtual manufacturers, the site of the relevant subcontractor that is supplying the final device (including any relevant subcontractors holding the rights to the design development of the medical device(s) supplied) will be the location of the unannounced audit. You must provide the information on the site(s) where the subcontractors have their final manufacturing, acceptance testing and final inspection for the devices, for which you are the virtual manufacturer, as you are obliged to know this information. Please state if you are the virtual manufacturer of the product next to its name in the product range column below.

PRODUCT RANGE (as on the current certificate, state if you are the virtual manufacturer):	**SITE ADDRESS** (your site address or name of critical subcontractor and site address. For relevant subcontractors, give a local contact name):	**ACTIVITIES:**
Please list the further site addresses as a separate page if necessary.		

SECTION 3: MANUFACTURING INFORMATION – FOR UNANNOUNCED AUDITS

Guidance notes: Each client may specify a maximum of six weeks each year when unannounced audits cannot audit manufacturing activities due to the closure of the manufacturing site, stocktaking, extensive holidays, planned audits from other bodies, etc. It is then judged that an unannounced audit cannot take place. Please specify the dates of periods of unavailability below.

Any changes to these dates must be notified to SGS at least two weeks in advance.

PERIODS OF UNAVAILABILITY: Please list any dates for the following year when an unannounced visit cannot take place (up to a maximum of six weeks each year):	
Site address:	Period of unavailability:

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, 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 office to discuss how unannounced audits may be undertaken.