

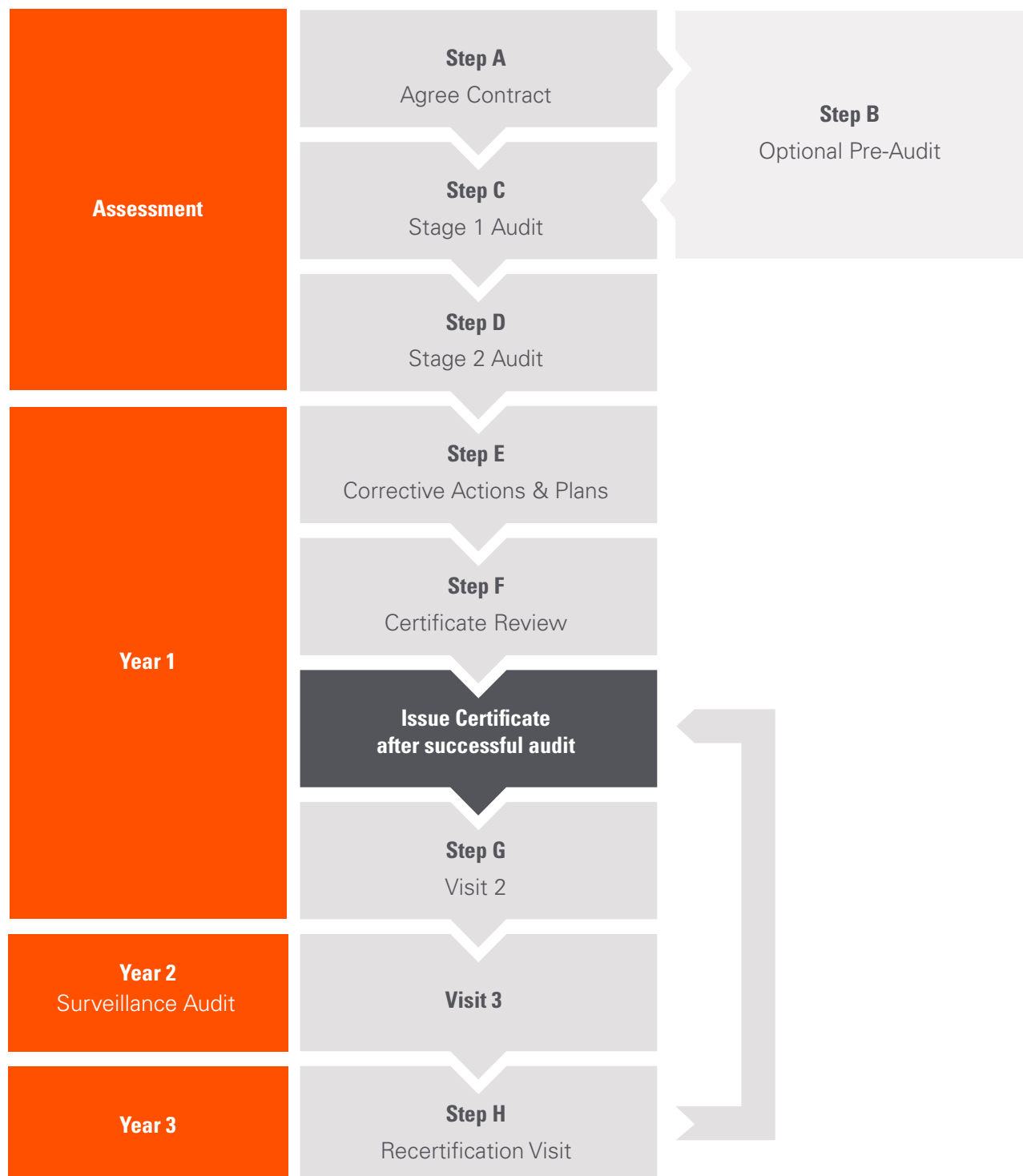
# Certification Process

PERSONAL PROTECTIVE EQUIPMENT REGULATION  
2016/425 MODULE D

SGS

# Notified body status

We are Approved Body 0120 and the Regulations for which we are approved include the Personal Protective Equipment Regulation 2016/425 Module D. On preparation of the proposal we have identified that your request falls within our Notified Body scope. This means you are entitled to use the UKCA 0120 logos on the completion of a successful audit.



## STEP A

### ACCEPTING THE SGS CONTRACT AND WHAT YOU NEED TO SEND US

A contract is submitted by SGS for consideration. We are happy to arrange a visit or discussion with a Sales Executive or an auditor to outline the process and discuss your requirements. This contract is valid for 60 days. Once the 60 days end, we will review the contract again and issue a new quote if necessary.

**Application:** To apply for registration the contract must be completed, signed and returned to the relevant SGS office before work can commence. Your application will be processed and one of our regional coordinators will contact you to arrange the next steps of the audit process.

**What you need to send us:** You do not need to make any payments on application. The Stage 1 audit may be conducted on or off site; this will be agreed with you. It is therefore not necessary for you to send your system documentation at this stage; however, if you do enclose documents please make sure these are controlled. They will remain your property and we will return these to you when the audit process is complete.

### EU Regulations imposed the following conditions in addition to those set out in the SGS Code of Practice:

**On the Applicant:** No other application for this scope must be outstanding. The circumstances of any previous application must be documented and sent to SGS before an application can be accepted. The applicant undertakes to carry out all obligations arising from a certified quality control system and maintain its adequacy and efficiency.

The products require a combination of EU type-examination certificate and quality system certification. The applicant must only affix the UKCA Mark when all requirements of the Regulation are met.

**On SGS:** No information will be disclosed to a third party except to an enforcement authority, where they are entitled to be informed under national legislation. This includes notification of certificate withdrawal, suspension or cancellation to other Notified Bodies and Competent Authorities.

SGS retains the absolute right to amend the scope of registration by informing the organization and giving the reasons in writing.

Any critical subcontractors must have either acceptable third-party certification or be audited as part of this proposal.

## STEP C

### STAGE I AUDIT – PREPAREDNESS REVIEW

If your initial certification audit is being carried out for both the Regulation and the Quality Management System (ISO 9001 or ISO 13485) then it is recommended that this activity is conducted at your site once we have received your contract. The audit process includes an appraisal of your Quality Management System documentation and intended scope of certification, including processes and locations, related statutory and regulatory aspects and compliance. This stage will also include;

- an evaluation of your location and site-specific conditions, and discussions with you to determine the preparedness for the stage II audit.
- a review of your status and understanding regarding the requirements of the standard, with respect to the identification of key performance or significant aspects, processes, objectives, and operation of the management system.
- a review to ensure that internal audits and management review are being planned and performed, and that the level of implementation of the management system substantiates that you are ready for the stage II audit.

This is to determine compliance with the Standard and to prepare allocation of resources and working documentation for the Stage II audit.

You will receive a Stage I audit report outlining any shortfalls to enable immediate action prior to moving forward through the process. An itinerary for the on-site audit will also be forwarded to you at this stage.

If your Regulation certification is an additional certification to your existing accredited Quality Management System certification then the Stage 1 will be conducted offsite and will address those document procedures and technical information relevant to the Regulation.

## STEP D

### STAGE II AUDIT – ASSESSMENT PROCESS: ON-SITE AUDIT

This stage is usually conducted several weeks after the Stage I activity to ensure that you have time to implement any of our findings. We are led by you in relation to the amount of time between these stages; however, planning the required dates into the schedule is crucial.

The on-site audit determines compliance against your documented system and the Regulation. We would not conduct then Stage II Audit unless a valid EU type-examination certificate has been issued by an Approved Body.

All assessment conclusions are based on sampling of audit evidence, to demonstrate effective implementation of the quality system.

At SGS our audit approach is designed to contribute value to the process and ensure that your management system is achieving your goals.

On conclusion of the audit the auditor will make a recommendation dependent on findings. This recommendation will reflect the level of findings identified during the audit.

## STEP E

### CORRECTIVE ACTIONS AND PLANS – ASSESSMENT PROCESS

If a Major non-conformance is identified and is caused through a significant breakdown of system control, the certification decision will be deferred until corrective action has been taken.

This corrective action must be verified as effective by the auditor at a follow up visit, the date of which will be agreed at the Stage 2 closing meeting.

Minor non-conformance will not prevent recommendation for registration but may delay it, as planned action must be submitted to and reviewed by SGS, prior to the certification decision taking place. It is therefore recommended that, where possible, this is presented to the auditor at the closing meeting. Verification and closure of minor non-conformance will take place at the next routine surveillance visit.

## STEP F

### ISSUE CERTIFICATE AFTER SUCCESSFUL AUDIT – ASSESSMENT PROCESS

At the end of the Stage II audit the auditor will make their recommendation on site and talk through the findings. This will include confirmation of the recommended scope following assessment. The report is then compiled off site and reviewed and approved by an independent decision authority. Once the certification decision has been made, the certificate is processed and sent to you along with the formal guidance on the use of the UKCA 0120 logo. SGS can support you in the form of certificate presentations and arranging press releases to help you promote your achievement should this be required.

**UK  
CA  
0120**

Example mark

## STEP G

### ONGOING MAINTENANCE: SURVEILLANCE VISITS

Once issued certificates are only valid subject to satisfactory maintenance of your system. Ongoing audits (surveillance visits) are conducted annually to verify continued implementation of your quality management system in accordance with “planned arrangements” and the requirements within the Regulation. The first surveillance must be conducted within 12 months of the end of the Stage II audit. The choice of surveillance period will be agreed at the proposal stage and will depend on the scale, nature of your operations and scope of certification. Certain mandatory elements will be reviewed at every visit together with other pre-selected processes. We will work with you to identify areas that are not conforming to support opportunities for improvement. Itineraries will be forwarded in advance of the agreed audit date.

## STEP H

### TRIENNIAL RE-CERTIFICATION

SGS operates a system of continuous certification. As part of this programme it is not necessary to conduct a complete assessment. Rather, we conduct a recertification visit which is more in-depth than a surveillance visits and will ensure that we review all aspects of your system. The recertification audit is the first visit of your new certification cycle. The recertification audit must be carried out and major non-conformances closed prior to the expiry of your current certificate.

Consequently, we look to conduct the audit approximately 3 months prior to the expiry date of your certificate.

We shall contact you approximately 6 months before the certificate expiry to make the necessary arrangements for this audit, including information on the costs for the next 3-year cycle, this can be provided earlier on request.



## PAYMENT TERMS

We will send you an invoice for the fees when we have carried out each stage. Once you receive an invoice, you must pay it within 30 days after the date of invoice (no matter what your company's payment terms) unless we agree otherwise in writing.

If you require a purchase order it is your responsibility to ensure this is supplied to SGS, either prior to the date of audit on the booking confirmation letter or given to the auditor during the on-site visit.

## CHANGES TO SCOPE

In the event of any developments that will alter your certification, e.g. site or scope additions, reductions, mergers, or acquisitions, it is important you inform us at your earliest convenience. Changes to scope can be covered at any time in the process. A revised contract would be issued in advance. The scheduling can take place at the same time as a surveillance/renewal visit, which is the most cost-effective method, or can be carried out between visits depending on your requirements and instructions. As this is personal to your individual business needs, it is anticipated this would need to be discussed between SGS and you, the client.



## SWITCH OF CERTIFICATION

If you have a current certification assessed by an accredited Approved Body, and this certification is up to date and in good standing, you can switch to SGS. We will conduct a review of your current certification and in order for us to do this you will need to send us a copy of your current certificate, previous visit reports, including the status of any outstanding corrective actions and the date of your last visit. Following the review, we will provide you with a contract to take over this certification. Once you have accepted our contract and dates have been arranged, we simply take over the next visit.

The process for reporting and certificate issue is the same as outlined above.



## ABOUT SGS

SGS are the world's leading inspection, verification, testing and Certification Company. SGS is recognised as the global benchmark for quality and integrity.

With more than 89,000 employees, SGS operates a network of over 2,600 offices and laboratories around the world.

We offer the following main services:

- **Customised Audit Solutions** – our diverse skills and experiences help organisations to exploit established management systems, by working in partnership to optimise efficiency and effectiveness, finding practical solutions to challenges related to: best practices in organisational operation, process efficiency and improvement, supply chain management, and Sourcing & Procurement.
- **Inspection services** – we inspect and check the quantity, weight and quality of traded goods. Inspection usually takes place when goods are moved from one type of transport to another.
- **Testing services** – we test quality and performance of products against various health, safety and regulatory standards. We use state-of-the-art laboratories on or close to customers' premises.
- **Certification services** – we confirm that systems or services meet the standards set by governments, standardisation bodies (for example, ISO 9001) or our customers' products. We also develop our own standards to meet our clients' needs. SGS as an accredited certification body can provide confidence to clients that professional, experienced auditors are used and standards are consistently applied.

- **Verification services** – SGS verification services ensure that products and services comply with global standards and local regulations. Combining global coverage with local knowledge, unrivalled experience and expertise in virtually every industry, SGS covers the entire supply chain from raw materials to final consumption.

In the UK, SGS employs over 1,800 staff based in over 30 regional offices. Our certification section provides independent certification and audits to a range of standards, including:

- Quality Management Systems (ISO 9001);
- Environmental Management (ISO 14001);
- Risk Management, IT Certification (ISO 20000);
- Information Security Management (ISO 27001, ISO 27701, BS10002, ISO 27017, ISO 27018);
- Business Continuity Management System (ISO22301)
- Energy Management Systems (ISO 50001)
- Asset Management Management Systems (ISO 55001)
- Customer Service Excellence;
- Occupational Health and Safety (ISO 45001)
- EC Directives (CE Mark) and other regulations;
- UKCA Mark for Medical, PPE and CPR
- Medical Device Certification (ISO 13485 and MDSAP);
- British Retail Consortium Global Standards;
- Food Safety Management Systems (ISO 22000);
- Aerospace

For more information on any of our services visit

[www.sgs.co.uk/certification](http://www.sgs.co.uk/certification)



**[WWW.SGS.CO.UK](http://WWW.SGS.CO.UK)**

WHEN YOU NEED TO BE SURE

