

**SUPPLEMENTARY
REGULATIONS SPECIFIC TO
CERTIFICATION OF PERSONAL
PROTECTIVE EQUIPMENT (PPE)**

INTRODUCTION

One of the conditions placed on all holders of Sira Certificates is that they shall accept and comply with the current version of 'Regulations Applicable to the Holders of Sira Certificates' (SCS/SF/053) and any applicable supplementary regulations.

These supplementary regulations are applicable to manufacturers of personal protective equipment certificates issued under directive 89/686/EEC and regulation 2016/425

Definition of Terms

'Manufacturer' An organisation, situated at a stated location or stated locations, that carries out or controls such stages in the manufacture, assessment, handling and storage of a product that enables it to accept responsibility for continued compliance of the product with the relevant requirements and undertakes all obligations in that connection.

'Certificate Holder' The party responsible for ensuring that certificated products meet and continue to meet the requirements on which the certification is based.

'Personal Protective Equipment' (PPE) means: (a) equipment designed and manufactured to be worn or held by a person for protection against one or more risks to that person's health or safety; (b) interchangeable components for equipment referred to in point (a) which are essential for its protective function; (c) connection systems for equipment referred to in point (a) that are not held or worn by a person, that are designed to connect that equipment to an external device or to a reliable anchorage point, that are not designed to be permanently fixed and that do not require fastening works before use.

This means that a **'certificate holder'** (and therefore the **'manufacturer'**) of a certificated **'PPE'** is responsible for ensuring that the **'PPE'** meets and continues to meet the requirements on which the certification is based. Both the Regulation and Directive cover PPE which is new to the Union market when it is placed on the market; that is to say it is either new PPE made by a manufacturer established in the Union or PPE, whether new or second-hand, imported from a third country. Articles 8 through to 12 of the Personal Protective Equipment Regulation 2016/425 of 09 March 2016, specify obligations for manufacturers, authorised representatives, importers and distributors

These supplementary regulations summarise the various conditions, requirements and guidance contained in the following publications:

- Regulations applicable to the holders of Sira certificates (SCS/SF/053)
- The National Accreditation Logo & Symbols – Conditions for Use by UKAS and UKAS Accredited Organisations – February 2017
- Personal Protective Equipment (PPE) Directive 89/686/EEC of 21 December 1989
- Personal Protective Equipment (PPE) Regulation 2016/425 of 09 March 2016
- ISO/IEC 17065 : 2012 – Conformity assessment – Requirements for bodies certifying products, processes and services
- ISO/IEC Guide 23 : 1982 – Methods of indicating conformity with standards for third-party certification systems
- Guidelines on the application of Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of member states relating to Personal Protective Equipment
- Guideline document on the PPE transition from Directive 89/686/EEC to Regulation (EU) 2016/425
- The Blue Guide on the implementation of EU Product Rules 2016
- CE Marking Principles Regulation 765/2008

CERTIFICATES ISSUED UNDER DIRECTIVE 89/686/EEC (only applicable until 20 April 2018)

Directive Annex/Article	Certificate
Article 10: EC type-examination certificate	EC type-examination Certificate
Article 11A: EC quality control system for the final product (periodic testing)	EU type-examination Certificate
Article 11B: System for ensuring EC quality production by means of monitoring (periodic auditing)	Conformity to Type Certificate

CERTIFICATES ISSUED UNDER REGULATION 2016/425 (only applicable on or after 21 April 2018)

Regulation Annex	Certificate
Annex IV: Internal Control of Production	Type-examination Certificate (voluntary)
Annex V: EU type-examination certificate	EU type-examination Certificate
Annex VI: Conformity to Type based on Internal Production Control	Conformity to Type Certificate
Annex VII: Conformity to Type based on Internal Production Control and Supervised Product Checks at Random Intervals (periodic testing)	Conformity to Type Certificate
Annex VIII: Conformity to Type based on Quality Control of the Production Process (periodic factory audit)	Conformity to Type Certificate

Holders of EC type-examination certificates and/or EU type-examination certificates for complex equipment (category 3), are required to comply with surveillance requirements defined in Article 11A and 11B of the Directive, and Annexes VII and VIII of the Regulation.

Modifications to certificated products

Certificate holders are required to inform Sira of any modification that affects any of the documents, drawings, technical file contents or other information referred to in the certificate. Modifications to a certificated product are not permitted until a new certificate or certificate variation has been issued by Sira.

Modifications to certificated quality management systems

Holders of Sira Quality Assurance certificates shall liaise with Sira with respect to any intended updating of their quality management system.

Verification of continued effectiveness of quality management systems

The certificate holder shall allow and facilitate access to the manufacturer's premises at intervals prescribed by Sira. Furthermore, Sira reserves the right to carry out unexpected, additional visits to the manufacturer. The certificate holder shall allow and facilitate access to manufacturing, testing, inspection and storage/distribution sites.

Conditions relating to the use of marks of conformity

The marking requirements for equipment and protective systems intended for use in potentially explosive atmospheres are defined in EU Directive 89/686/EEC, EU Regulation 2016/425 and in the appropriate harmonised European standards. Sira offers a certification service accredited by UKAS, and therefore additional conditions regarding the use and reproduction of the UKAS product certification mark apply. Additional conditions also apply to the use and reproduction of the CE marking **CE** and to the use of the Notified Body identification number 0518.

These supplementary regulations summarise the specific conditions, requirements and guidance for the use of all marks of conformity relating to Personal Protective Equipment (PPE). General conditions relating to the use of certification marks are given in the Regulations Applicable to the Holders of Sira Certificates (SCS/SF/053).

Where it is not possible to affix marks of conformity to the product because of the product's size or nature, they may be affixed to the packaging and accompanying documents.

All marks of conformity referred to in this document are available from Sira.

The CE marking

The CE marking is mandatory and must be affixed before any product is placed on the market or put into service within the European Union. The CE marking is affixed to the product on the sole responsibility of the manufacturer. Where a product is subject to more than one directive, which all provide for CE Marking, the marking indicates that the product conforms to the provisions of all these directives. It is the manufacturer's responsibility to ensure that the product conforms to all relevant directives. The CE Marking must take the form shown in Fig 1. If it is reduced or enlarged the proportions must be respected. It must be affixed visibly, legibly and indelibly to the product. The identification number of the notified body involved in the production control phase (0518 for Sira) shall follow the CE Marking. The minimum vertical dimension of the CE Marking shall not be less than 5 mm (this requirement may be waived for small-scale equipment). The CE Marking shall not be applied to Components.



Fig 1 - CE Marking

The Notified Body Identification Number

The Notified Body identification number, 0518 is assigned by the European Commission. The number is used by the manufacturer in the following ways

- marked next to the CE marking on product labels to indicate that Sira Certification Service is the Notified Body engaged in the production control phase (see Fig 1)
- included in manufacturer declarations of conformity to indicate that Sira Certification Service is the Notified Body that has issued an EC Type Examination Certificate or has stored a Technical File on behalf of the manufacturer

The Sira mark

The Sira name is registered under the Trade Marks Act 1994. The Sira mark is shown in Fig. 2. Holders of Sira certificates are licensed to use the Sira mark on certificated products providing that the serial number of the Sira certificate appears centrally under the Sira mark.



Fig 2 – Sira Mark – incorporating certificate serial number

The UKAS product certification mark

The UKAS product certification mark is shown in Fig. 3. Holders of Sira certificates are licensed to use the UKAS mark on certificated products. Only certificate holders having certificates bearing the UKAS mark may reproduce that mark on products. The Sira accreditation number (011) shall appear centrally under the UKAS mark. The Sira mark shall appear alongside the UKAS mark with the Sira certificate number appearing centrally under the Sira mark. Both marks shall be enclosed in a box.

Certificate holders are also permitted to use the UKAS mark on stationery and publicity material. Only certificate holders having certificates bearing the UKAS mark may reproduce that mark on stationery and publicity material. The Sira accreditation number (011) shall appear centrally under the accreditation mark. The UKAS product certification mark may be uniformly enlarged or reduced, but shall not usually be less than 20 mm in height. The UKAS mark and the Sira accreditation number shall be considered as a single entity for purposes of enlargement or reduction. Where the UKAS mark appears on products, stationery and publicity material, the Sira mark shall appear alongside the UKAS mark with the Sira certificate number appearing centrally under the Sira mark. Both marks shall be enclosed in a box.

The UKAS mark shall not be displayed on vehicles, buildings or flags.

The UKAS mark shall not be displayed without the Sira mark. Both marks shall be displayed in a box.

Holders of Sira certificates, which bear the UKAS mark, may use the Sira mark without the UKAS mark on products, stationery and publicity material.



Fig 3 – UKAS Product Certification mark