



## Conformity Assessment Procedures

Directive 94/9/EC includes seven Annexes which detail the conformity assessment procedures to be applied to equipment and protective systems. These Annexes are based on:

***“Council decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives”.***

This document is often referred to as “the modules directive” although it is a “Decision” rather than a “Directive”. Council decision 93/465/EEC is an amendment to decision 90/683/EEC of 13 December 1990.

Council decision 93/465/EEC forms the basis of the conformity assessment procedures to be applied throughout all “new approach” directives.

The following table cross-references the Annexes of 94/9/EC with the Modules of 93/465/EEC and the schedules referred to in the regulations which implement the directive in the UK.

Description	94/9/EC Annex	93/465/EEC Module	UK Regs' Schedule
EC Type-examination	III	B	6
Production Quality Assurance	IV	D	7
Product Verification	V	F	8
Conformity to Type	VI	C	9
Product Quality Assurance	VII	E	10
Internal Control of Production	VIII	A	11
Unit Verification	IX	G	12

A minimum of one and a maximum of two modules apply to any given product. The “Internal Control of Production” is undertaken by the manufacturer who can declare conformity without the intervention of a Notified Body, although in the case of some group I and II mechanical equipment, equipment (category M2 and 2), a design dossier must be communicated to a Notified Body.

All other modules are the responsibility of a Notified Body.

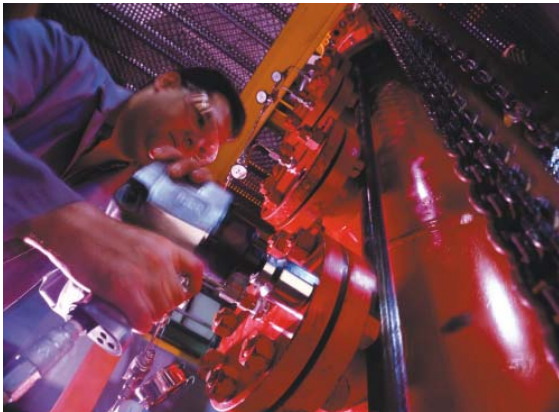


**Equipment in Group I and II,  
equipment category M1 and 1:**

Is subject to EC type-examination (Annex III) and **either** Production quality assurance (Annex IV) **or** Product verification (Annex V).

**Internal combustion engines or electrical  
equipment in Equipment Group I and II,  
equipment category M2 and 2:**

Is subject to EC type-examination (Annex III) and **either** Conformity to type (Annex VI) **or** Product quality assurance (Annex VII).



**Other equipment (not electrical equipment and  
not internal combustion engines) in  
Equipment Group I and II, equipment category  
M2 and 2:**

Is subject to Internal control of production (Annex VIII) and a design dossier is lodged with a Notified Body.

**Equipment Group II, equipment category 3:**

Is subject to Internal control of production (Annex VIII) without the necessity to lodge a design dossier with a Notified Body.

**Autonomous protective systems:**

Are subject to the same procedures as Equipment Group I and II, equipment category M1 and 1.

As an alternative to these procedures and for all Group I and II equipment and autonomous protective systems the Unit verification (Annex IX) procedure may be applied.

**Components**

Components are subject to the same conformity assessment procedures as **Equipment** except that the CE marking must not be affixed to the component. Instead, the manufacturer, on the declaration of conformity, must state the characteristics of the component and how the component must be incorporated into **equipment** or **protective systems** to assist compliance with the essential requirements applicable to finished equipment or protective systems.

**How Can Sira Help?**

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