



Area of application: basic principles

CE conformity procedure for machines, partly completed machinery and personal protective equipment against falls from a height

Accredited Certification Body SCESp 0008
European notified body,
identification number 1246

Order no. CE08-18.e
Date of issue 05.02.2018

Suva
Swiss National Accident Insurance Fund
Section Technology
Accredited Certification Body SCESp 0008
European notified body, identification number 1246
P. O. Box 4358
CH-6002 Lucerne
Switzerland

Telephone +41 58 411 12 12
<http://www.suva.ch/certification-e>

**CE conformity procedure for machines, partly
completed machinery and personal protective
equipment against falls from a height**

Author : Mauritius Bollier, Ivo Maurer
Issued : 05.12.2018
Order no. : **CE08-18.e (Available only as a pdf file)**

Contents

	Page
General remarks	4
Construction of machines according to the Machinery Directive	5
Comment: scope of the Machinery Directive	6
Comment: consideration for the requirements of the Low-Voltage Directive	6
Additional procedure when constructing machines with electrical equipment acc. to the Electromagnetic Compatibility (EMC) Directive	7
Construction of partly completed machinery acc. to the Machinery Directive (Article 1, §1, g)	8
Construction of personal protective equipment against falls from a height acc. to the Regulation on personal protective equipment	9

General remarks

During the development phase, manufacturers of technical products are often faced with issues connected with the application of vital regulations, standards or rules of technology. The purpose of the following explanations is to help manufacturers take the right direction from the very start in order to ensure that they are not confronted with legal requirements when the machine or installation has already been completed. The individual steps for the procedure to be followed when constructing machines, partly completed machinery and personal protective equipment against falls from a height are summarised on the following pages. There are also references to other documents provided by Suva CERTIFICATION. These documents can be accessed on the Internet at <http://www.suva.ch/certification-e> or <http://www.suva.ch/waswo>.

The individual steps are usually structured according to the following matrix independent of the product.

1. Inspection of the relevant regulations

Prior to starting construction, the manufacturer must clarify which regulations apply to the product.

2. Construction according to the essential health and safety requirements

The technical products mentioned in this publication may only be put in circulation if they comply with the essential health and safety requirements. This principle must be adhered to as far as possible where partly completed machinery is concerned.

3. Technical file

The purpose of the technical file is to substantiate the product's compliance with the essential health and safety requirements.

4. Conformity evaluation

This determines whether all the relevant regulations have been complied with.

5. Declaration of conformity

Declaration by the manufacturer that the product complies with the relevant regulations.

6. CE marking

The marking of a product with the letters "CE" (= Communautés Européennes) is the manufacturer's notification to the authorities that the product complies with the requirements of a European directive.

Our certification body will be pleased to help you acquire CE conformity.

Construction of machines according to the Machinery Directive

Dependent on the design of the machine, compliance is necessary with additional regulations.

No.	Activity	Regulations		Supporting documents by certification body SCESp 0008
		(Swiss) Machinery ordinance	Machinery Directive 2006/42/EC	
1	Inspection of the relevant regulations 1. Comparison of the machine design with the scope of reference of the regulations	Article 1	Article 1 Article 2 Article 3	CE96-7.e
2	Construction according to essential health and safety requirements - Produce a risk assessment and risk reduction - Adhere to essential health and safety requirements - Construction acc. to standard (voluntary) - State-of-the-art implementation - Mark the machine - Instructions	Article 2 Article 3	Article 5, §1a Annex I: General principles, §1 Section 1, poss. Section 2, 3, 4, 5, or 6 Article 7 Annex I: General principles, §3 Section 1, §1.7.3 Article 5 §1c, Annex I Section 1, §1.7.4	66037.e Sec. 1: CE08-8.e Sec. 2 to Sec. 6: CE08-9.e CE93-1.e
3	Technical file Substantiation of compliance with all the requirements; this must be submitted if requested by the executive body.	Article 2	Article 5, §1b Annex VII, Part A	CE08-7.e CE08-10.e
4	Conformity evaluation Examination into whether the requirements have been complied with.	Article 2	Article 5, §1d, Article 12	
4a	Machine not in 2006/42/EC Annex IV: Internal check on the manufacture of machinery Type examination is voluntary	Article 2	Article 12, §2, Annex VIII	CE08-1.e CE08-2.e CE08-3.e CE08-7.e
4b	Machine in 2006/42/EC Annex IV, manufactured in accordance with the harmonised standards and these standards cover all of the relevant essential health and safety requirements*: - Internal check on the manufacture of machinery - Type examination and internal check on the manufacture of machinery or - Full quality assurance	Article 2	Article 12 Article 12, §3a, Annex VIII Article 12, §3b, Annex IX Annex VIII, No. 3 Article 12, §3c, Annex X	CE08-1.e CE08-3.e CE08-7.e
4c	Machine in 2006/42/EG Annex IV, not manufactured in full accordance with the harmonised standards or these standards do not cover all the relevant essential health and safety requirements*: - Type examination and internal check on the manufacture of machinery or - Full quality assurance	Article 2	Article 12 Article 12 §4a, Annex IX Annex VIII, No. 3 Article 12 § 4 b Annex X	CE08-1.e CE08-3.e CE08-7.e

No.	Activity	Regulations		Supporting documents by certification body SCESp 0008
		(Swiss) Machinery ordinance	Machinery Directive 2006/42/EC	
5	Declaration of conformity Attestation for customers and executive bodies that the requirements are met.	Article 2	Article 5, §1e, Annex II Part 1, §A	CE08-17.e
6	CE marking		Article 5, §1f Article 16, Annex I, §1.7.3, Annex III	
7	Marketing the machine	☺	☺	☺

Comment: area of application of the Machinery Directive:

Directive 2006/42/EC (Machinery Directive) applies in accordance with its Art. 1 to:

- a) Machinery
- b) interchangeable equipment
- c) Safety components
- d) Lifting accessories
- e) Chains, ropes and webbing
- f) Removable mechanical transmission devices
- g) partly completed machinery

According to Art. 2, a distinction is made in the remaining text of the Machinery Directive between “Machinery” and “partly completed machinery”. “Machinery” is understood to mean the products according to a) to f). Machinery in their closer definition are allotted to a). In contrast to the previous Directive 98/37/EC, safety components are no longer dealt with separately.

The precise definitions for a) to g) are also set forth in Art. 2.

Comment: consideration for the requirements of the Low-Voltage Directive

Directive 2006/42/EC (Machinery Directive) differs clearly from Directive 2006/95/EC (Low Voltage Directive). Products that are in the area of application of the Machinery Directive are not simultaneously included in that of the Low Voltage Directive. However, there is a compulsory requirement in Annex I, §1.5.1 that the protection goals of the Low Voltage Directive must be fulfilled. However, the regulations of the Machinery Directive apply to the conformity evaluation and the declaration of conformity.

N.B. For many types of machines, the essential requirements of Annex I, §1.5.1. are specified in EN 60204-1.

The Directive 2006/95/EC is replaced as from 20.04.2016 by Directive 2014/35/EU.

Additional procedure when constructing machinery with electrical and/or electronic equipment acc. to the Electromagnetic Compatibility Directive

No.	Activity	Regulations		Supporting documents by certification body SCESp 0008
		VEMV ¹⁾	Electromagnetic Compatibility Directive 2004/108/EC ²⁾	
1	Inspection of the relevant regulations Comparison of the machine design with the scope of reference of the regulations	Article 1	Article 1 and 2	CE96-7.e
2	Construction according to essential health and safety requirements³⁾ - Adhere to essential health and safety requirements - Construction acc. to standards ⁴⁾ (voluntary) - Operating instructions	Article 4 Article 5, Article 7	Article 5, Annex I Article 6 Article 9	CE93-1.e
3	Technical documentation Substantiation of compliance with all the requirements; this must be submitted if requested by the executive body.	Article 7, Article 8	Annex IV	CE08-10.e
4	Conformity evaluation Examination into whether the requirements have been complied with - Internal production check and possibly - Additional check by a named body ⁵⁾		Article 7 Annex II Annex III	
5	Declaration of conformity Attestation for customers and executive bodies that the requirements are met	Article 6	Annex IV	CE08-17.e
6	CE marking		Article 8, Annex V	
7	Marketing the machine	☺	☺	☺

1) (Swiss) ordinance on electromagnetic compatibility SR 734.5

2) The Directive 2004/108/EC is replaced as from 20.04.2016 by Directive 2014/30/EU.

3) Machinery manufacturers usually assemble the electrical equipment from bought-in components in accordance with the component manufacturers' instructions.

4) Choice of standards for the fulfilment of the Low Voltage Directive:

EN 61000-6-2 Electromagnetic compatibility (EMC)
Part 6-2: Generic standard – Generic standard for interference resistance – Industrial sector

EN 61000-6-4 Electromagnetic compatibility (EMC)
Part 6-4: Generic standard – Generic standard for emitted interference – Industrial sector

5) EMC test centres can be found in the list from the Swiss Accreditation Service (SAS):
<https://www.sas.admin.ch/sas/en/home.html>

Construction of partly completed machinery acc. to Machinery Directive

Dependent on the design of the sub-assembly, compliance is necessary with additional regulations.

No.	Activity	Regulations		Supporting documents by certification body SCESp 0008
		(Swiss) Machinery ordinance	Machinery Directive 2006/42/EC	
1	Inspection of the relevant regulations Comparison of the design of partly completed machinery with the scope of reference of the regulations	Article 1	Article 1 §1g, Article 2 §g Article 3	CE96-7.e
2	Construction according to essential health and safety requirements, where possible: - Produce a risk assessment and risk reduction - Adhere to essential health and safety requirements - Construction acc. to standards (voluntary) - State-of-the-art implementation - Assembly instructions ¹⁾	Article 2 Article 3	Article 13 §1a Annex VII, Part B Annex I: General principles, §1 Section 1, poss. Section 2, 3, 4, 5, or 6 Article 7 Annex I: General principles §3 Article 13, §1b	66037.e Sec.1: CE08-8.e Section 2 to Section 6: CE08-9.e CE93-1.e
3	Relevant technical documentation Substantiation of compliance with all the requirements; this must be submitted if requested by the executive body.	Article 2	Article 13 §1a Annex VII, Part B	
4	Declaration of incorporation¹⁾ Reference to the user of the sub-assembly on the commissioning of the machine in which the sub-assembly is fitted.	Article 2	Article 13, §1c Annex II, Part 1, §B	CE08-17.e
5	CE marking²⁾			
6	Marketing partly completed machinery	☺	☺	☺

¹⁾ Assembly instructions and a declaration of incorporation must be included with partly completed machinery until its incorporation into a complete machine. These documents are then part of the technical file of the complete machine.

²⁾ Due to the Machinery Directive, a CE marking may not be applied to partly completed machinery; however, CE marking may be required due to other directives.

Construction of personal protective equipment against falls from a height acc. to the Regulation on personal protective equipment

No.	Activity	Regulations		Supporting documents by certification body SCESp 0008
		(Swiss) Ordinance on safety of personal protective equipment (PSAV) SR 930.115	(European) Regulation on personal protective equipment (EU) 2016/425	
1	Inspection of the relevant regulations	Article 1 § 1 + 2	Article 2 Article 3	CE96-7.e
2	Construction according to essential health and safety requirements - Adhere to essential health and safety requirements - Produce a risk assessment and risk reduction - State-of-the-art implementation - Construction acc. to standard (voluntary) - Mark the PPE - Instructions, information	Article 2 b Article 3 § 2 Article 3 § 3	Article 5 Article 8 § 1 Annex II Annex II 4. Prelim.Rem. Annex II 3. Prelim.Rem. Article 14 Annex II Section 2.12 Article 17 § 3, 4 Annex II Section 1.4	CE18-3.e 66037.e
3	Technical documentation Substantiation of compliance with all the requirements; this must be submitted if requested by the executive body.	Article 4 § 1 a	Article 8 § 2 Annex III	CE18-2.e
4	Conformity evaluation Examination into whether the requirements have been complied with: - Type examination - supervised product checks or quality assurance of the production process or - internal production control ¹⁾	Article 3 § 2	Article 14, Article 18, Annex I Article 19 c Annex V Annex VII Annex VIII Annex IV	CE08-1.e CE18-2.e
5	Declaration of conformity Attestation for customers and executive bodies that the requirements are met.	Article 3 § 2	Article 8 § 2 Article 15 Annex IX	CE08-17.e
6	CE marking ²⁾	Article 3 § 3	Article 16 Article 17	
7	Marketing personal protective equipment	☺	☺	☺
8	Product monitoring, corrective measures	Article 4 a	Article 8 § 9	

¹⁾ Only for PPE produced as a single unit to fit an individual user

²⁾ Attachment of the EC marking cannot be required for PPE units that are marketed in Switzerland. It is nonetheless advisable to attach the EC marking to PPE units before they are marketed in Switzerland.