



Area of application: basic principles

Document rules for the product certification of machinery and safety components by Accredited Certification Body SCESp 0008 Section Technology

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

Order no. CE23-3.e
Date of issue 01.09.2023

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>

**Document rules for the product certification
of machinery and safety components by
Accredited Certification Body SCESp 0008
Section Technology**

Author : Urs Bühlmann, Ivo Maurer
Issued : 01.09.2023
Order no. : **CE23-3.e (Available only as a pdf file)**

1. GENERAL

In the type-examination procedure, the certification body must assess the technical file. These document rules set out the requirements for the electronic provision of the technical file. This document preparation enables the type-examination to be carried out efficiently.

Deviations from the document rules are possible in consultation with the responsible expert.

2. PROCESS

After receiving the application for the type-examination procedure, the certification body sends the applicant the order confirmation with the details of the responsible expert.

The responsible expert then provides the applicant with the check lists and the electronic filing structure with the templates.

3. PREPARATION OF THE TECHNICAL FILE

The technical file is provided electronically to the certification body according to the scope in check list CE08-7, section 2 (www.suva.ch/CE08-7.e) and in compliance with the filing structure (tree structure) and designation defined in this document.

3.1 Filing structure

Naming of the file	Templates with explanatory notes	Section
■ 2.01 List of documents	Document directory	3.3.1
■ 2.02 List of directives and standards	Directives and standards list	3.3.2
■ 2.03 Description of the machinery	Description of the machinery	3.3.3
■ 2.04 Risk assessment	Risk assessment	3.3.4
■ 2.05 Description of safety devices		
■ 2.06 Plans or layout		
■ 2.07 Detailed plans with calculations		
■ 2.08 Circuit diagrams		
■ 2.09 Equipment list of the safety circuits	Validation plan for safety functions	3.3.5
■ 2.10 Test reports on electromagnetic compatibility, climate		
■ 2.11 Hydraulics/pneumatics		
■ 2.12 Health protection		
■ 2.13 Noise measurements		
■ 2.14 Original operating instructions		
■ 2.15 Installation notes		
■ 2.16 Mass production	Instructions and test report EN 60204-1	3.3.6
■ 2.17 Proof of accreditation		

The filing structure with the listed templates in the appropriate directory will be provided by the expert in ZIP format upon receipt of the application.

3.2 Naming of documents (identification)

The document name is compiled in such a way that it is clear, from the following details:

- filing location,
 - consecutive serial number (register/project level),
 - creation date,
 - description of the document's content,
- which document is current and where it must be filed.

Name format (example):

2.01_01_2023.01.20_Document list ... DoughMixer.pdf
2.02_11_2023.01.28_Standards list DoughMixer.pdf

The diagram shows two example document names with brackets underneath indicating their components:

- 1: Register number
- 2: Consecutive serial number
- 3: Date (YYYY.MM.DD)
- 4: Name (chosen by manufacturer)
- 5: File format

Legend

- 1 Register number according to file structure
- 2 Consecutive serial number in the register or project
- 3 Date (YYYY.MM.DD), issue date
- 4 Name (chosen by manufacturer)
- 5 File format; the following formats are preferred: .pdf, .jpg, xml, .ssm.

Naming the documents correctly reduces the time spent by the certification body on monitoring the documents.

3.3 Templates

The templates explained below can be found in the corresponding directory of the filing structure in section 3.1.

3.3.1 Document directory

A directory must be created for the documents and kept continuously up to date. Each document has a unique name according to the requirements in section 3.2. This template or an equivalent template must be used.

3.3.2 Directives and standards list

In order to establish the basis for testing in a binding manner, the applicable directives and standards must be identified. These principles must be documented in writing.

This template or an equivalent template must be used.

3.3.3 Description of the machinery

To help the expert get started with the certification of the specific product, it is recommended to fill in the attached template.

The supplied template is filled in by transferring the detailed information or by clear references (document name, section, page, etc.) in the technical file according to the identity in the document directory.

3.3.4 Risk assessment

The manufacturer is obliged to carry out a risk assessment in accordance with Directive 2006/42/EC, Annex I, "General principles".

This template or an equivalent template must be used.

3.3.5 Validation plan for safety functions

The manufacturer is obliged to prove that the requirements for safety functions have been fulfilled, e.g. on the basis of the validation requirements in EN ISO 13849-2.

The conformity and fulfilment of the requirements of each individual safety function must be demonstrated on the basis of the validation plan.

The following information is to be provided as a minimum:

- reference to the source of the required safety level
- description of the safety function with circuit diagram
- evidence of safety level achieved
- validation of the safety function

The supplied template is filled in at the level of each safety function by transferring the detailed information or by clear references (document name, section, page, etc.) in the technical file according to the identity in the document directory.

A central overview table provides information on the status of each individual safety function:

- number of safety function e.g. SF01 (unique identity)
- unique name
- clear reference to required safety level
- calculated safety level
- responsible person
- execution status

It is recommended to use the above-mentioned number of the safety function in all documents; in addition, the component designations from the circuit diagram should be used consistently in all documents to ensure clear identification.

This template or an equivalent template must be used.

3.3.6 Instructions and test report EN 60204-1

The manufacturer is obliged to prove that the requirements for the electrical equipment have been fulfilled in a routine testing report. The template is a guide with test report to prove that the requirements are met.

This template or an equivalent template must be used.

3.4 Electronic data transfer

If necessary, Suva can provide a data transfer platform for large amounts of data.