



EC Type Examination  
of PPE  
in catheterology II and III,  
for CE-marking according to Directive 89/686/EEC

## Introduction

This information, made up by SP, is meant to be used as a support when putting together an application and appurtenant documentation.

## Basis for the EC Type Examination

To perform the EC Type Examination process according to Directive 89/686/EEC, we need an application together with a technical file from the client. The application shall be made on our application form. The information below explains in general terms what the application shall contain. In this information, we assume that the product is tested according to a harmonized European Standard (EN)

## General data

### Applicant and product data

Specify:

- The name and address of the applicant
- The products complete designation
- The number and designation of the harmonized standard(s) used
- If the applicant and manufacturer is not the same, the name and address of the manufacturer

Note, if the applicant is another than the manufacturer, an agreement from the manufacturer that the applicant is his authorized representative within EC is necessary. The applicant shall also confirm that the same product has not already been applied for an EC Type Examination Certificate for, neither by the manufacturer himself or by another representative.

*Comment:*

*Normally the certificate is issued to the manufacturer. The manufacturer is not necessary the “real” manufacturer. It can be a person/company who assembles a product or who design a product and has it manufactured by one or several suppliers. Anyhow, he/she put his/her own label to it and has the full responsibility for the products, as if he/she was the “real” manufacturer.*

## Technical file

To the application, a technical file shall be applied containing at least:

- Test report from an accredited laboratory (please check with SP if the actual laboratory is OK)
- Drawings and specifications  
*The drawings are intended to clear and unambiguous identify the products. Drawings can be supplemented by photos or other illustrations.*
- Specifications on materials in all components, including quality and make  
When components are bought from a supplier, the name of the manufacturer/supplier, designation, quality etc shall be declared.  
NOTE! The manufacturer shall also convince himself, and declare, that materials coming in direct contact with the wearers skin are free from substances that can be harmful to the wearer or cause allergy or irritation

- A sample of the information to the user (users manual) which shall accompany the product. In some cases the minimum content of the information is specified in the actual standard. If not, one has to follow the requirements of the Directive. Besides this, the Directive requires that the name of the Notified Body issuing the EC-Type Examination Certificate is declared (This is not mentioned in the standards, but it is a requirement of the Directive's annex 2, point 1.4 i). See also appendix 1 to this information.

*Comment: At the examination, we normally check the information in one language, Swedish or English. Please note that it is the manufacturers or his representative's obligation to see to that the information is presented in the official language which is valid on the market where the product is marketed.*

- A sample of the marking which is intended to be permanently affixed to the product, including the CE-mark. If there are specified requirements in the applied standard, these requirements shall be followed. If the marking is in form of text, the text shall be translated to the official language which is valid on the market where the product is marketed.

*Comment: We accept a draft ready for printing*

All documents shall have a designation and a issue number and/or issue date. A document .....

A listing of documents is preferred

*See example, appendix 2*

### **Subsequent Factory Production Control**

The manufacturer shall also in the technical documentation describe his factory production control. This factory production control shall guarantee that the continuous produced samples fulfils the requirement, i.e. are compatible with the type approved samples.

*Comment*

*The production phase of Category II products are not supervised by a Notified Body. The manufacturer has the responsibility to have a quality assurance system preventing non-conforming products to reach the market. Anyhow, this system shall be described (summary) and annexed to the application.*

### **Requirements on PPE category III**

(Fall protection equipment; protective clothing protecting against chemical hazards, heat, cold; some helmets and more)

PPE of category III have to be EC type examined at the same way as category II products. In addition, the production stage of category III products must be supervised by a Notified Body. The manufacturer can chose between two alternatives: article 11A or 11B of the Directive. The manufacturer can also chose which Notified Body shall supervise the production. SP is notified for both 11A and 11B.

Notes:

- Article 11B presumes a Quality Management System. Even if the manufacturer has a certified ISO 9000 system, this is not enough. A Notified Body has to be involved in any case.
- Category III products shall in addition to the CE-mark show the identification number of the Notified Body responsible for the supervising part.

*See an example in appendix 2*

### **Comments regarding harmonized standards**

By attaching the CE-mark, the manufacturer declares that the product fulfils the requirements of Directive 89/686/EEG. When using a harmonised standard as a basis, presumption of conformity can be assumed.

Although the Directive add some requirements which are not found in the harmonised standards. This is for instance the requirements, that information shall be presented in the language where the product

is intended to be sold/used. There is also a requirement that the Notified Body responsible for the type examination shall be declared. (Those requirements appears in the Directive, Annex II, point 1.4.  
*An extract is presented in appendix 2 to this information*

## **EC Declaration of Conformity**

Before the manufacturer can put the CE-mark on his/her product, he/she have to set up an EC Declaration of Conformity, where he/she certifies that the product fulfils all requirements of the applicable Directive. This declaration shall be presented upon request, e.g. to authorities. Without this document, which shall be signed by the manufacturer or his representative, there is no basis for putting the CE-mark on the product. A template for an EC Declaration of Conformity can be found in appendix 6 to the Directive.

*A copy of this is also presented in appendix 3 to this information.*

Extract from Directive 89/686/EEG, amended by Directive 93/68 annex 2

#### **1.4. Information supplied by the manufacturer**

In addition to the name and address of the manufacturer and/or his authorized representative established in the Community, the notes that must be drawn up by the former and supplied when PPE is placed on the market must contain all relevant information on:

- (a) storage, use, cleaning, maintenance, servicing and disinfection. Cleaning, maintenance or disinfectant products recommended by manufacturers must have no adverse effect on PPE or users when applied in accordance with the relevant instructions;
- (b) performance as recorded during technical tests to check the levels or classes of protection provided by the PPE in question;
- (c) suitable PPE accessories and the characteristics of appropriate spare parts;
- (d) the classes of protection appropriate to different levels of risk and the corresponding limits of use;
- (e) the obsolescence deadline or period of obsolescence of PPE or certain of its components;
- (f) the type of packaging suitable for transport;
- (g) the significance of any markings (see 2.12).  
These notes, which must be precise and comprehensible, must be provided at least in the official language(s) of the Member State of destination.
- (h) where appropriate, the references of the Directives applied in accordance with Article 5 (6) (b);
- (i) the name, address and identification number of the notified body involved in the design stage of the PPE.

These notes, which must be precise and comprehensible, must be provided at least in the official language(s) of the Member State of destination.

(End of extract)

**Example, document list, tech file**

Specification	Designation	Issue date
Test Report from X	...	10 <sup>th</sup> March 2009
Photo(s)	...	10 <sup>th</sup> March 2009
Drawing(s)	...	10 <sup>th</sup> March 2009
	...	10 <sup>th</sup> March 2009
	...	10 <sup>th</sup> March 2009
Components	...	10 <sup>th</sup> March 2009
Material specifications and suppliers	...	10 <sup>th</sup> March 2009
Declaration from supplier	...	10 <sup>th</sup> March 2009
Instructions for the user	...	10 <sup>th</sup> March 2009
Labels for marking (exemple)	...	10 <sup>th</sup> March 2009
Description of the Factory Production Control	.....	10 <sup>th</sup> March 2009

**Suggested text in the information to the user regarding issuer of the EC Type Examination Certificate**

EC type examination by  
 SP Technical Research Institute of Sweden  
 Box 857  
 SE-501 15 Borås  
 Sweden  
 Notified Body No.0402

**Exemple marking on Category III product where SP performs the follow-up inspection**

**CE 0402**

MODEL EC DECLARATION OF CONFORMITY

The manufacturer or his authorized representative established in the Community (1):

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declares that the new PPE described hereafter (1)

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- is in conformity with the provisions of Council Directive 89/686/EEC and, where such is the case, with the national standard transposing harmonized standard N° ..... (for the PPE referred to in Article 8 (3))
- is identical to the PPE which is the subject of EC certificate of conformity N° ..... issued by (3) (4) .

- 
- is subject to the procedure set out in Article 11 point A or point B (%) of Directive 89/686/EEC under the supervision of the notified body (3) .

Done at ....., on.....

.....  
Signature (5)

(1) Business name and full address; authorized representatives must also give the business name and address of the manufacturer.

(2) Description of the PPE (make, type, serial number, etc.).

(3) Name and address of the approved body.

(4) Delete whichever is inapplicable.

(5) Name and position of the person empowered to sign on behalf of the manufacturer or his authorized representative.