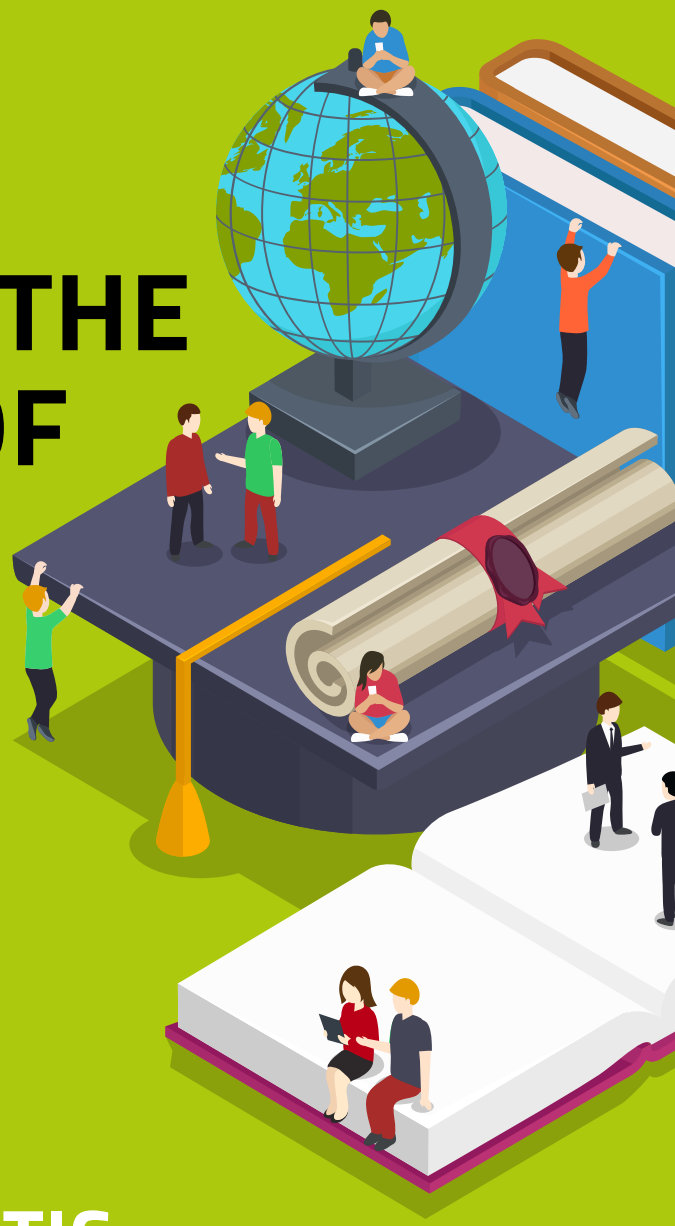
TEMPLATE FOR THE DECLARATION OF CONFORMITY TO COMPLY WITH:



DIRECTIVE 98/79/EC ON IN VITRO DIAGNOSTIC MEDICAL DEVICES

INSTRKTIV

USER INSTRUCTIONS

Important information before using your template

Thanks for your interest in INSTRKTIV's Declaration of Conformity Template Method. We at INSTRKTIV help our clients create compliant and user-friendly user instructions (user manuals, online help, operating instructions etc). The nature of our work means that we are often involved in the CE marking process, risk analysis, technical files and also in compiling declarations of conformity.

I hope that the Declaration of Conformity Template Method will be useful to you. If so, I would appreciate you making a comment on our website or social media share. Do give us a call if we can help you create compliant and user-friendly user instructions.

A few points to keep in mind:

- Read through and make sure you understand the **full post** and the relevant directives before simply using the template(s).
- As well as the specific requirements on the content, the relevant directives also give requirements whether to **translate** the declaration of conformity or not, to deliver the declaration of conformity with the product (or to keep in the technical file only), or to draw up a single declaration of conformity for all applicable directives. Read through and ensure you understand all relevant directives for more information. My **blog post** tells you how to search for the relevant articles in the directives.

Best regards,
Ferry Vermeulen, director at **INSTRKTIV**

1. Contents of the declaration of conformity

There are no special requirements on the contents of the declaration of conformity. This means the harmonised standard NEN-EN-ISO/IEC 17050-1 (en) Conformity assessment - Supplier's declaration of conformity - Part 1: General requirements (ISO/IEC 17050-1:2004-10,IDT) can be used.

A. unique identification of the declaration of conformity;
B. the name and contact address of the issuer of the declaration of conformity;
C. the identification of the object of the declaration of conformity (e.g. name, type, date of production or model number of a product, description of a process, management system, person or body, and/or other relevant supplementary information);
D. the statement of conformity;
E. a complete and clear list of standards or other specified requirements, as well as the selected options, if any;
F. the date and place of issue of the declaration of conformity;
G. the signature (or equivalent sign of validation), name and function of the authorized person(s) acting on behalf of the issuer;
H. any limitation on the validity of the declaration of conformity.

And additionally the following could be mentioned:

I. Used quality system
J. The notified body … (name, number) performed … (description of intervention) and issued the certificate…

2. Template of form of declaration of conformity

Supplier's declaration of conformity on in vitro diagnostic medical devices (DoC)

Unique identification number of this DoC: ……..

We (manufacturer):

Business name: ……..

Address: ……..

Country: ……..

declare under our sole responsibility that the device:

Device name: ……..

Trade name: ……..

Type or model: ……..

Quality system: ……..

to which this declaration relates is in conformity with the essential requirements and other relevant requirements of Directive 98/79/EC on in vitro diagnostic medical devices. The product is in conformity with the following standards and/or other normative documents:

- (example) EN 13532:2002 General requirements for in vitro diagnostic medical devices for self-testing

Additional information:

Notified body involved:

Notified Body name: .....

Address: .....

Country: .....

Identification number: .....

Description of intervention: .....

Number EU-type examination certificate: .....

Technical file held by:

Business name: .....

Address: .....

Country: .....

Name: .....

Position: .....

Place and date of issue (of this DoC):

.....

Signed by or for the manufacturer:

.....

Name: .....

Title: .....

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