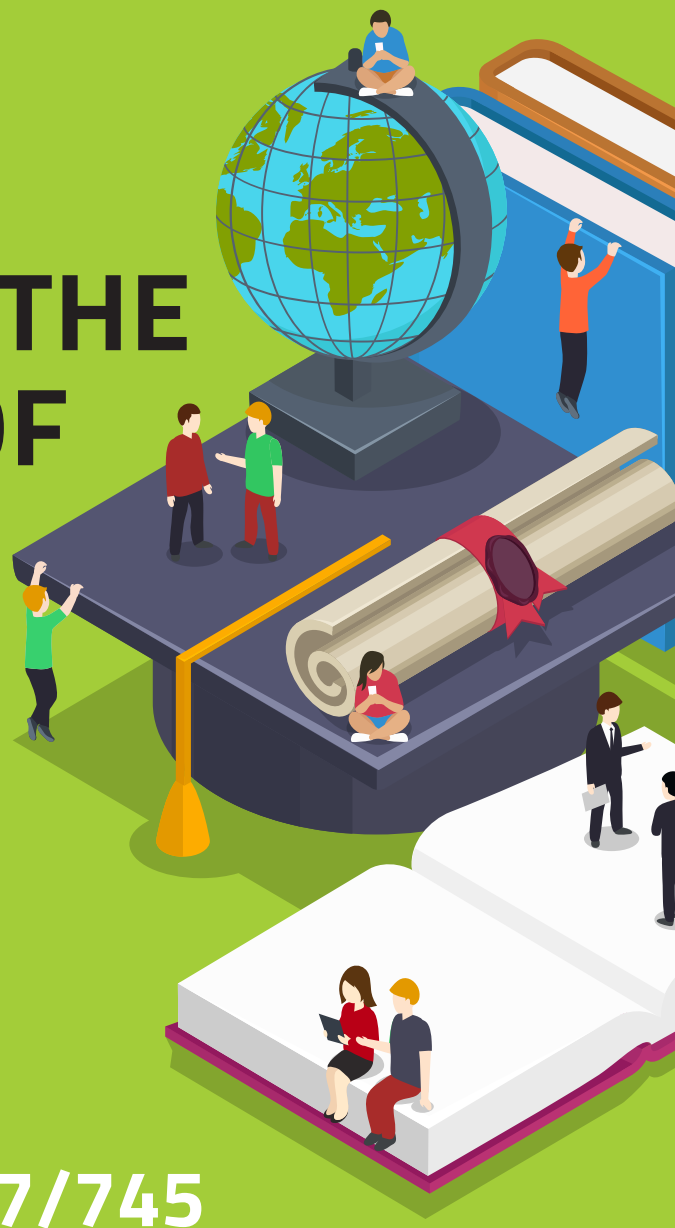
TEMPLATE FOR THE DECLARATION OF CONFORMITY TO COMPLY WITH:



REGULATION (EU) 2017/745 ON 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

The EC declaration of conformity must contain the following elements:

1. Name, registered trade name or registered trade mark and, if already issued, SRN as referred to in Article 31 of the manufacturer, and, if applicable, its authorised representative, and the address of their registered place of business where they can be contacted and their location be established;
2. A statement that the EU declaration of conformity is issued under the sole responsibility of the manufacturer;
3. The Basic UDI-DI as referred to in Part C of Annex VI;
4. Product and trade name, product code, catalogue number or other unambiguous references allowing identification and traceability of the device covered by the EU declaration of conformity, such as a photograph, where appropriate, as well as its intended purpose. Except for the product or trade name, the information allowing identification and traceability may be provided by the Basic UDI-DI referred to in point
5. Risk class of the device in accordance with the rules set out in Annex VIII;
6. A statement that the device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity;
7. References to any CS used and in relation to which conformity is declared;
8. Where applicable, the name and identification number of the notified body, a description of the conformity assessment procedure performed and identification of the certificate or certificates issued;
9. Where applicable, additional information;
10. Place and date of issue of the declaration, name and function of the person who signed it as well as an indication for, and on behalf of whom, that person signed, signature.

2.

Template of form of declaration of conformity

Supplier's declaration of conformity (DoC)
Unique identification number of this DoC: XXXXX

We (manufacturer or authorised representative):

Business name: .....

Registered trade name or trade mark: .....

SRN manufacturer: .....

Address: .....

Country: .....

declare under our sole responsibility that the device:

Basic UDI-DI: .....

Device name/Trade name: .....

Product code: .....

Catalogue number: .....

Intended purpose: .....

Object (colour image):

to which this declaration relates is classified as risk class [class], according to the rules as set out in Annex VIII

is in conformity with the following relevant Union harmonisation legislation:

- ✓ Regulation (EU) 2017/745 relating to medical devices
- ✓ (example) Directive 2014/35/EU on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits

and that the device is in conformity with the following standards and/or other normative documents:

- ✓ EN 794-3:1998+A2:2009 Lung ventilators - Part 3: Particular requirements for emergency and transport ventilators

and that the following Notified Body performed the intervention as described below and issued the EU-type examination certificate:

Notified Body name: .....

Address: .....

Country: .....

Identification number: .....

Description of intervention: .....

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

Date EU-type examination certificate: .....

Duration and conditions of validity of the examination certificate: .....

Place and date of issue (of this DoC):

.....

Signed by or for the manufacturer:

.....

Name: .....

Function: .....

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