Regulatory Thinking®

23 Directives:

Number of different directives requiring a EU Declaration of Conformity

EU Declaration of Conformity Art. 19

Guiding you through the MDR, one article at a time.

Everything is set and done. Your product fulfils every requirement of the MDR. Now you just need to put the CE mark on it and you‘re ready to sell? Not too quickly. First, you have to draw up a declaration, that your device conforms to the corresponding directives.
In this fact, we will help you with that!

If you need help or guidance regarding the EU declaration of conformity, contact us!

EU Declaration of Conformity

1. The **EU declaration of conformity** shall state that the **requirements specified** in this **Regulation** have been fulfilled in relation to the **device** that is **covered**.
The manufacturer shall **continuously update** the EU declaration of conformity. The EU declaration of conformity shall, as a minimum, contain the information set out in **Annex IV** and shall be translated into an **official Union language** or **languages** required by the Member State(s) in which the device is made available.

2. Where, concerning aspects not covered by this Regulation, devices are subject to **other Union legislation** which also requires an EU declaration of conformity by the manufacturer that fulfilment of the requirements of that legislation has been demonstrated, a **single** EU declaration of conformity shall be drawn up in respect of **all Union acts** applicable to the device. The declaration shall contain all the information required for identification of the Union legislation to which the declaration relates.

For more information, please review:

Article 19: EU declaration of Conformity(Regulation (EU) 2017/745 on medical devices (MDR))

EU Declaration of Conformity

3. By drawing up the EU declaration of conformity, the manufacturer **shall assume responsibility** for compliance with the requirements of this Regulation and all other Union legislation applicable to the device.
4. The Commission is empowered to **adopt delegated acts** in accordance with Article 115 amending the **minimum content of the EU declaration of conformity** set out in Annex IV in the light of technical progress.

For more information, please review:

Article 19: EU declaration of Conformity(Regulation (EU) 2017/745 on medical devices (MDR))

Takeaway

For your medical device, it is necessary to draw up a declaration of conformity in which you state, that your device fulfils all requirements of the directives that cover your devices **(in most cases not only the MDR).** You need to keep your declaration up to date and may translate it into (other) Union languages.

Do you need to fulfil the requirements of other legislation? One declaration is sufficient.

For more information, please review:

Article 19: EU Declaration of Conformity (Regulation (EU) 2017/745 on medical devices (MDR))


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