



# 9.8 Years:

The average length of time an employee or freelancer stays with an employer before changing jobs in the European Union.



# Change of authorised representative

## Art. 12

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

The average employee in the EU is staying at their employer for 9,8 years, but what is to be done when the time has come for a change? In this Fast Fact Friday we look at the detailed arrangements that need to be done when your authorised representative changes.

If you need help or guidance regarding the change of authorised representative or need an authorised representative in the „European Union“ contact us!





## Change of authorised representative

The **detailed arrangements** for a **change** of authorised representative shall be **clearly defined** in an **agreement** between **the manufacturer**, where practicable the **outgoing authorised representative**, and the **incoming authorised representative**. That agreement shall address at least the following aspects:

- a) The **date of termination** of the **mandate** of the outgoing authorised representative and the **date of the beginning** of the **mandate** of the incoming authorised representative;
- b) The **date** until which the outgoing authorised representative may be **indicated in the information supplied** by the manufacturer, including **any promotional material**;
- c) The **transfer of documents**, including **confidentiality** aspects and **property** rights;
- d) The obligation of the outgoing authorised representative **after the end of the mandate** to **forward** to the manufacturer or incoming authorised representative **any complaints** or **reports** from healthcare professionals, patients or users about **suspected incidents** related to a device for which it had been designated as the authorised representative.

***For more information, please review:***

*Article 12: Change of Authorised Representative (Regulation (EU) 2017/745 on medical devices (MDR))*





## Takeaway

Change of staff is always hard, especially when the employee or the freelance partner has great responsibility and needs to correspond with regulatory authorities.

For the change of authorised representative, there are a few **basic rules** which include drawing up a **contract** between the **manufacturer** and the **outgoing and incoming authorised representative**. In the contract, you need to include **key dates** that are concerning the authorised representatives but also you are required to contractually manage the **transfer of documents**.

Furthermore, it must be clear, that the **outgoing** authorised representative still has **obligations** to the manufacturer, so it is required for them to **forward** any kind of **complaints/reports** concerning the product to the manufacturer **even after the mandate ends!**

*For more information, please review:*

*Article 12: Authorised Representative (Regulation (EU) 2017/745 on medical devices (MDR))*





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