

Application by conformity assessment bodies for designation

Art. 38

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

For conformity notified bodies to be allowed to operate, they must apply for their designation to the competent authority.

Article 38 of the MDR regulates everything necessary for this designation.

If you need help or guidance, contact us!



Application by conformity assessment bodies
for designation

1. Conformity assessment bodies shall **submit an application for designation to the authority responsible for notified bodies.**

*For more information, please review:
Article 38 MDR*



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2. The application shall **specify the conformity assessment activities** as defined in this Regulation, and the **types of devices for which the body is applying to be designated**, and shall be supported by documentation demonstrating compliance with Annex VII.

In respect of the organisational and general requirements and the quality management requirements set out in Sections 1 and 2 of Annex VII, a valid accreditation certificate and the corresponding evaluation report delivered by a national accreditation body in accordance with Regulation (EC) No 765/2008 may be submitted and shall be taken into consideration during the assessment described in Article 39. However, **the applicant shall make available all the documentation** referred to in the first subparagraph to demonstrate compliance with those requirements upon request.

For more information, please review:

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3. The **notified body shall update the documentation** referred to in paragraph 2 **whenever relevant changes occur**, in order to enable the authority responsible for notified bodies to monitor and verify continuous compliance with all the requirements set out in Annex VII.

*For more information, please review:
Article 38 MDR*



Takeaway

Article 38 of the MDR states that conformity assessment bodies must apply to the competent authority for their designation. Furthermore, the requirements and documents that must be submitted for this designation are clearly defined. The notified body also undertakes to update the required documents, for example, when relevant information is changed.

For more information, please review:
Article 38 MDR



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