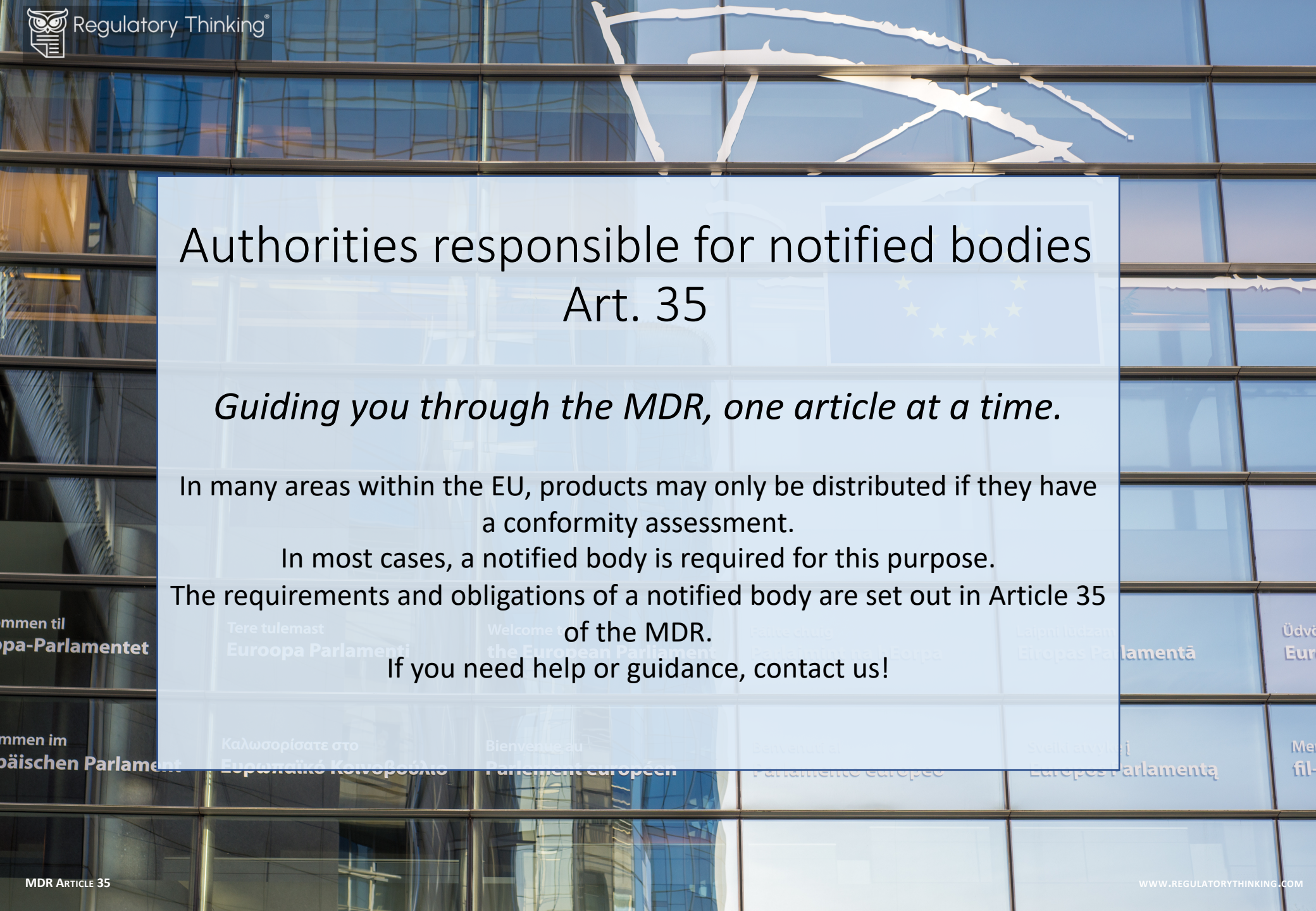

Authorities responsible for notified bodies Art. 35

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

In many areas within the EU, products may only be distributed if they have a conformity assessment.
In most cases, a notified body is required for this purpose.
The requirements and obligations of a notified body are set out in Article 35 of the MDR.
If you need help or guidance, contact us!

Authorities responsible for notified bodies

1. Any Member State that intends to designate a conformity assessment body as a notified body, or has designated a notified body, to carry out conformity assessment activities under this Regulation **shall appoint an authority** (‘authority responsible for notified bodies’), which **may consist of separate constituent entities** under national law and shall be responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, including subcontractors and subsidiaries of those bodies.

For more information, please review:

Article 35 MDR

Authorities responsible for notified bodies

2. The authority responsible for notified bodies shall be established, organised and operated so as to safeguard the objectivity and impartiality of its activities and to **avoid any conflicts of interests with conformity assessment bodies**.

For more information, please review:

Article 35 MDR

Authorities responsible for notified bodies

3. The authority responsible for notified bodies shall be organised in a manner such that each decision relating to designation or notification is taken by **personnel different from those who carried out the assessment**.

For more information, please review:

Article 35 MDR

Authorities responsible for notified bodies

4. The authority responsible for notified bodies shall not perform any activities that notified bodies perform on a commercial or competitive basis.

For more information, please review:

Article 35 MDR

Authorities responsible for notified bodies

5. The authority responsible for notified bodies **shall safeguard the confidential aspects of the information** it obtains.

However, **it shall exchange information on notified bodies with other Member States**, the Commission and, when required, with other regulatory authorities.

For more information, please review:

Article 35 MDR

Authorities responsible for notified bodies

6. The authority responsible for notified bodies **shall have a sufficient number of competent personnel permanently available** for the proper performance of its tasks.
Where the authority responsible for notified bodies is a different authority from the national competent authority for medical devices, it **shall ensure that the national authority responsible for medical devices is consulted on relevant matters**.

For more information, please review:

Article 35 MDR

Authorities responsible for notified bodies

7. **Member States shall make publicly available general information** on their measures governing the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and on changes which have a significant impact on such tasks.

For more information, please review:

Article 35 MDR

Authorities responsible for notified bodies

8. The authority responsible for notified bodies shall participate in the peer-review activities provided for in Article 48.

For more information, please review:

Article 35 MDR

Takeaway

Article 35 of the MDR clearly defines the structure and duties of a notified body.

The main points are:

- Objectivity and impartiality
- Confidentiality
- Availability of a sufficient number of staff
- Conflicts of interest must be avoided

For more information, please review:

Article 35 MDR


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