2022-03-31

# Erfarenheter av anmälda organ – när tvist uppstår mellan anmält organ och tillverkare runt klassificering

**Sandra Brolin**

LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

## What says the regulation on handling of disputes between manufacturer and notified body on classification?

MDR, Article 51

Any dispute between the manufacturer and the notified body concerned, arising from the application of Annex VIII, shall be referred for a decision to the competent authority of the Member State in which the manufacturer has its registered place of business.

Where the notified body concerned is established in a Member State other than that of the manufacturer, the competent authority shall adopt its decision after consultation with the competent authority of the Member State that designated the notified body.

The competent authority of the Member State in which the manufacturer has its registered place of business shall notify the MDCG and the Commission of its decision. The decision shall be made available upon request.

Procedure only for classification issues – not qualification

LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

# Procedure if a Member State request the Commission to take action

At the request of a Member State the Commission shall after consulting the MDCG, decide, by means of implementing acts, on the following:

(a) application of Annex VIII to a given device, or category or group of devices, with a view to determining the classification of such devices;

(b) that a device, or category or group of devices, shall for reasons of public health based on new scientific evidence, or based on any information which becomes available in the course of the vigilance and market surveillance activities be reclassified, by way of derogation from Annex VIII.

4. The Commission may also, on its own initiative and after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in points (a) and (b) of paragraph 3.



# Practical aspects when turning to a competent authority

Assessment by MPA

- The request concerns a classification issue
- There is a dispute between the manufacturer and the notified body
  - If we receive a request from the manufacturer according to article 51 of MDR we will turn to the notified body to ensure that it is a dispute between the manufacturer and the notified body.
- Intended purpose of the device
- Rational from the manufacture and the notified body for their classification
- Information needed for a decision on classification (clinical information, IFU, labelling etc.)

If needed, an enquiry will be sent to other competent authorities.