Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Text with EEA relevance)

CHAPTER VII

POST-MARKET SURVEILLANCE, VIGILANCE AND MARKET SURVEILLANCE

Section 3

Market surveillance

Article 91

Procedure for evaluating national measures at Union level

1 Where, within two months of receipt of the notification referred to in Article 90(4), objections are raised by a Member State against a measure taken by another Member State, or where the Commission considers the measure to be contrary to Union law, the Commission shall, after consulting the competent authorities concerned and, where necessary, the economic operators concerned, evaluate that national measure. On the basis of the results of that evaluation, the Commission may decide, by means of implementing acts, whether or not the national measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).

2 Where the Commission considers the national measure to be justified as referred to in paragraph 1 of this Article, the second subparagraph of Article 90(7) shall apply. If the Commission considers the national measure to be unjustified, the Member State concerned shall withdraw the measure.

Where the Commission does not adopt a decision pursuant to paragraph 1 of this Article within eight months of receipt of the notification referred to in Article 90(4), the national measure shall be considered to be justified.

3 Where a Member State or the Commission considers that the risk to health and safety emanating from a device cannot be mitigated satisfactorily by means of measures taken by the Member State or Member States concerned, the Commission, at the request of a Member State or on its own initiative, may take, by means of implementing acts, the necessary and duly justified measures to ensure the protection of health and safety, including measures restricting or prohibiting the placing on the market and putting into service of the device concerned. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).