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 V

CLASSIFICATION AND CONFORMITY ASSESSMENT

Section 2

Conformity assessment

Article 50

Mechanism for scrutiny of conformity assessments of class D devices

1 A notified body shall notify the competent authority of certificates it has granted for class D devices, with the exception of applications to supplement or renew existing certificates. Such notification shall take place through the electronic system referred to in Article 52 and shall include the instructions for use referred to in Section 20.4 of Annex I, the summary of safety and performance referred to in Article 29, the assessment report by the notified body, and, where applicable, the laboratory tests and the scientific opinion by the EU reference laboratory pursuant to the second subparagraph of Article 48(3), and where applicable the views expressed in accordance with Article 48(4) by the experts referred to in Article 106 of Regulation (EU) 2017/745. In the case of divergent views between the notified body and the experts, a full justification shall also be included.

2 A competent authority and, where applicable, the Commission may, based on reasonable concerns apply further procedures in accordance with Article 40, 41, 42, 43 or 89 and, where deemed necessary, take appropriate measures in accordance with to Articles 90 and 92.

3 The MDCG and, where applicable, the Commission, may, based on reasonable concerns, request scientific advice from the expert panels in relation to the safety and performance of any device.