https://www.wto.org/spanish/news_s/news19_s/tbt_21jun19_s.htm

European Union - Medical devices regulation

The United States, supported by Canada, raised concerns regarding the implementation of the medical device regulations introduced by the European Union. The US, for instance, said that it is concerned about the insufficient number of bodies designated to test and certify products ("notified bodies") under the new regulation, and the lack of availability of implementing regulations, and therefore urged the EU to delay the implementation for three years to allow industries to adapt.

The EU said that the regulations will enter into force in May 2020 and May 2022. The EU is aware of the time limitations imposed on various stakeholders involved in the process, and the challenge of ensuring sufficient notified bodies. It also added that there will be transitional periods allowing manufacturers to place products in the EU market under the old directives until May 2024.