WORLD TRADE ORGANIZATION

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Page: 1/2

**Committee on Technical Barriers to Trade**

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# EUROPEAN UNION - MEDICAL DEVICE REGULATION (MDR) AND IN VITRO DIAGNOSTIC MEDICAL DEVICES REGULATION (IVDR)

## STATEMENT BY THE UNITED STATES TO THE COMMITTEE ON TECHNICAL BARRIERS TO TRADE 20 AND 21 JUNE 2019

The following communication, dated 23 July 2019, is being circulated at the request of the delegation of the United States.

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1. The United States supports the development and enforcement of a well-defined medical device regulatory system which assures the safety and performance of medical devices. However, the United States has serious concerns regarding the implementation of the MDR and IVDR, and our industry is worried about their continued access to the EU's USD 125 billion medical device market, USD 20 billion of which is supplied by U.S. products.

2. MDR/IVDR's implementation is behind schedule. Our industry has two particular concerns about this.

   i. One, there is an insufficient number of Notified Bodies (NBs) to perform certification activities under the MDR/IVDR.

   ii. And, two, the EU has drafted an insufficient number of the implementing acts needed to provide details about how industry can ensure that their products comply with the new product standards.

3. Can the EU provide an update on how many of the 58 NBs accredited to test and certify products under old directives are currently designated as operational under the new MDR and IVDR, and how many the EU expects to be designated as operational by the end of 2019? Our understanding is that DG GROW expects no more than 12 NBs to be designated as operational by the end of 2019. 12 NBs are not enough to provide sufficient capacity to ensure continued regulatory approvals by May 2020 and May 2022.

4. Only two of the eighteen implementing regulations have been issued, and as a result, EU standardizing bodies cannot begin work on developing the standards industry may use to comply with the MDR/IVMDR. Given, this backlog industry maintains that the product standards necessary for compliance with the MDR cannot be completed before the deadline.

5. The MDR and IVDR provisions for warehousing and a grace period, which are intended to provide transitional relief, are insufficient. The warehousing provision is insufficient because buyers and producers cannot predict demand, making it difficult to warehouse the right amount of product to meet that demand through the implementation delays. Moreover, warehousing is expensive, degradation is common with medical technology, and the technology itself can quickly become obsolete. The grace periods are insufficient because CE mark product registrations compliant with the old directives may expire before the end of the grace period, in 2024.

6. Given these concerns, we urge the EU to delay implementation by three years to allow for U.S. exporters to adapt to the new requirements.

7. If that is not possible, we urge the EU to allow for legacy products that are currently deemed safe to be sold on the market until 2024 and to ask Notified Bodies to provide new products, which require testing for the first time, with priority access to testing and CE marking certification over products being re-certified to the new requirements.