NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. **Notifying Member:** UNITED STATES OF AMERICA
   If applicable, name of local government involved (Article 3.2 and 7.2):

2. **Agency responsible:** Food and Drug Administration (FDA), Health and Human Services (HHS) [1233]
   Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:
   Please submit comments to: USA WTO TBT Enquiry Point
   Email: usatbtep@nist.gov

3. **Notified under Article 2.9.2 [ ], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other: X**

4. **Products covered (HS or CCCN where applicable, otherwise national tariff heading, ICS numbers may be provided in addition, where applicable):** Upper extremity prosthesis. Medical equipment (ICS: 11.040)

5. **Title, number of pages and language(s) of the notified document:** Medical Devices; Physical Medicine Devices; Classification of the Upper Extremity Prosthesis Including a Simultaneously Powered Elbow and/or Shoulder With Greater Than Two Simultaneous Powered Degrees of Freedom and Controlled by Non-Implanted Electrical Components (3 pages, in English)

6. **Description of content:** The Food and Drug Administration (FDA) is classifying the Upper Extremity Prosthesis Including a Simultaneously Powered Elbow and/or Shoulder with Greater Than Two Simultaneous Powered Degrees of Freedom and Controlled by Non-Implanted Electrical Components into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the upper extremity prosthesis including a simultaneously powered elbow and/or shoulder with greater than two simultaneous powered degrees of freedom and controlled by non-implanted electrical components' classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

7. **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety

8. **Relevant documents:** 81 Federal Register (FR) 71610, 18 October 2016; Title 21 Code of Federal Regulations (CFR) Part 890

9. **Proposed date of adoption:** 9 May 2014
   **Proposed date of entry into force:** 18 October 2016

10. **Final date for comments:** None

11. **Texts available from:** National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:
    https://members.wto.org/crnattachments/2016/TBT/USA/16_4555_00_e.pdf