NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **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) [1508]  **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](mailto: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):** Medical devices; accessories; Medical equipment (ICS 11.040) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Medical Devices; Classification of Accessories Distinct From Other Devices; Finalized List of Accessories Suitable for Class I (6 page(s), in English) |
| **6.** | **Description of content:** The Food and Drug Administration (FDA, we, or Agency) is classifying suitable accessories into class I as required by the FDA Reauthorization Act of 2017 (FDARA). The Agency has determined that general controls alone are sufficient to provide reasonable assurance of safety and effectiveness for these accessories. We made this determination based on the risks of the accessories when used as intended with other devices such as the parent or system. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:**   * 84 Federal Register (FR) 14865, 12 April 2019; Title 21 Code of Federal Regulations (CFR) Parts 876, 878 and 886; https://www.govinfo.gov/content/pkg/FR-2019-04-12/html/2019-07290.htm; <https://www.govinfo.gov/content/pkg/FR-2019-04-12/pdf/2019-07290.pdf> |
| **9.** | **Proposed date of adoption:** 13 May 2019  **Proposed date of entry into force:** 13 May 2019 |
| **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/2019/TBT/USA/19_2524_00_e.pdf> |