NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

|  |  |
| --- | --- |
| **1.** | **Notifying Member:** Albania  **If applicable, name of local government involved (Article 3.2 and 7.2):** |
| **2.** | **Agency responsible:** Ministry of Health and Social Protection  **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:**  National Enquiry Point |
| **3.** | **Notified under Article 2.9.2 [****X],** **2.10.1 [****],** **5.6.2 [****],** **5.7.1 [****],** **other [****]:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Medical Devices |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft Law "On some amendments and additions to the law No. 89/2014 "On Medical Devices"" (6 page(s), in Albanian) |
| **6.** | **Description of content:** This Draft Law establishes the procedure of the registration of medical devices, selection of applicants, application procedures for registration, distribution, medical devices inspection, and administrative measures. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** The objective of the additions and amendments is related to the improvement of the regulatory procedures which lead to the increase of quality and standards of medical devices produced, imported or traded in the Republic of Albania, improvement of distribution, transportation and storage procedures by increasing the efficiency of medical devices. |
| **8.** | **Relevant documents:**   * Law No. 89/2014 "On Medical Devices" * [Council Directive 90/385/EEC](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31990L0385&locale=en) of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices * OJ No L 189 of 20 July 1990 * [Council Directive 93/42/EEC](http://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:31993L0042&locale=en) of 14 June 1993 concerning medical devices |
| **9.** | **Proposed date of adoption:** Not decided yet  **Proposed date of entry into force:** Not decided yet |
| **10.** | **Final date for comments:** 60 days from notification |
| **11.** | **Texts available from: National enquiry point [****X]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:**  General Directorate of Standardization WTO Enquiry Point - Albania Tel.: +355 42 22 62 55 Fax: +355 42 24 71 77 E-mail: [info@dps.gov.al](mailto:info@dps.gov.al) <http://www.dps.gov.al> |