NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

|  |  |
| --- | --- |
| **1.** | **Notifying Member:** Kingdom of Bahrain **If applicable, name of local government involved (Article 3.2 and 7.2):**  |
| **2.** | **Agency responsible:** Bahrain Standards & Metrology Directorate (BSDM)**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:** Ministry of Industry, Commerce & Tourism Kingdom of BahrainP.O. Box 5479 Tel.: +973 17574871 Fax: +973 17530730E-mail: bsmd@moic.gov.bh Web site: <http://www.moic.gov.bh> |
| **3.** | **Notified under Article 2.9.2 [****X],** **2.10.1 [****],** **5.6.2 [****X],** **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 and Accessories |
| **5.** | **Title, number of pages and language(s) of the notified document:** Technical Regulation Medical Devices and Accessories (9 page(s), in Arabic) |
| **6.** | **Description of content:** The Technical Regulation for Medical Devices and Accessories, drafted by Ministry of Industry, Commerce & Tourism in coordination with National Health Regulatory Authority (NHRA) aims to regulate the medical devices and accessories by specifying the mandatory safety and quality requirements set out in the National standards where the devices must comply. The TR ensures that the medical devices should be designed in such a way that, when used under the conditions and for the purposes intended will not compromise the clinical condition or the safety of patients, or the safety and health of users or other persons, and to facilitate market surveillance. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of Human health, Safety & Quality |
| **8.** | **Relevant documents:** * Draft Technical Regulation for Medical Devices & Accessories
 |
| **9.** | **Proposed date of adoption:** To be determined**Proposed date of entry into force:** Generally six months after publication in the Official Gazette |
| **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:** Ministry of Industry, Commerce & Tourism Kingdom of BahrainP.O. Box 5479 Tel.: +973 17574871 Fax: +973 17530730E-mail: bsmd@moic.gov.bh<https://members.wto.org/crnattachments/2019/TBT/BHR/19_4840_00_x.pdf> |