NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** Tanzania  **If applicable, name of local government involved (Article 3.2 and 7.2):** |
| **2.** | **Agency responsible:** Tanzania Bureau of Standards  **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:** |
| **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):** Laboratory medicine (ICS 11.100) |
| **5.** | **Title, number of pages and language(s) of the notified document:** CDC 16(6641) P3 Sterilized sodium chloride intravenous infusion (9 page(s), in English) |
| **6.** | **Description of content:** This Draft Tanzania standard covers chemical and biological requirements for a solution of sodium chloride in water for injections that has been manufactured and packed into suitable containers, sealed and sterilized. It also specifies the required marking. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Consumer information, labelling; Quality requirements |
| **8.** | **Relevant documents:**   * ISO 15747, Plastics containers for intravenous injection. * TZS 59, Water for analytical laboratory use - Specification and test methods. * TZS 773, Marking and labeling of pharmaceutical products-Specification * TZS 501/IS0 9001, Quality management systems - Requirements. * TZS 1967/IS0 13485, Medical devices - Quality management systems - Requirements for regulatory purposes. |
| **9.** | **Proposed date of adoption:** July 2020  **Proposed date of entry into force:** Upon declaration as a mandatory by the Minister for Industry, Trade and Investment |
| **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:**  Tanzania Bureau of Standards MOROGORO/Sam Nujoma Road, Ubungo  P O BOX 9524 Tel: +255 222450206 Email:[nep@tbs.go.tz](mailto:nep@tbs.go.tz) Website: [www.tbs.go.tz](http://www.tbs.go.tz)  <https://members.wto.org/crnattachments/2020/TBT/TZA/20_2956_00_e.pdf> |