



15 January 2020

(20-0409)

Page: 1/2

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>BURUNDI</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: Burundi Bureau of Standards and Quality Control (BBN) Boulevard de la Tanzanie N° 500 BP: 3535 Bujumbura, Burundi Tel: +25722221815/+25722221577 E- Mail: info@bbnburundi.org Website: www.bbn-burundi.org 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 [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): Surgical instruments and materials (ICS 11.040.30)
5. Title, number of pages and language(s) of the notified document: Surgical sutures — Specification — Part 1: Absorbable (20 page(s), in English)
6. Description of content: This Draft East African Standard specifies the requirements, sampling and test methods for absorbable surgical sutures.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety; Quality requirements; Harmonization
8. Relevant documents: <ul style="list-style-type: none">• ISO 10993 (all parts), Biological evaluation of medical devices• ISO 24153 — Random sampling and randomisation procedures• <i>British Pharmacopoeia</i>, 2017• ISO 11135:2014, Sterilization of health care products — Ethylene oxide• ISO 11137-1:2006, <i>Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices</i>• ISO 11137-2:2013, <i>Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose</i>

<ul style="list-style-type: none"> • ISO 11137-3:2017, <i>Sterilization of health care products -- Radiation -- Part 3: Guidance on dosimetric aspects of development, validation and routine control</i> • ISO 17665-1:2006, <i>Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices</i> • ISO/TS 17665-2:2009, <i>Sterilization of health care products -- Moist heat -- Part 2: Guidance on the application of ISO 17665-1</i> • ISO 11138-3:2017, <i>Sterilization of health care products -- Biological indicators - - Part 3: Biological indicators for moist heat sterilization processes</i> • US Pharmacopoeia 40, 2019 • US 1958-1:2019, <i>Surgical sutures — Specification — Part 1: Absorbable</i>
<p>9. Proposed date of adoption: To be determined</p> <p>Proposed date of entry into force: To be determined</p>
<p>10. Final date for comments: 60 days from notification</p>
<p>11. Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:</p> <p>Documentation and Information Centre Division at BBN Boulevard de la Tanzanie N° 500 BP: 3535 Bujumbura, Burundi Tel: +25722221815 or +25722221577 E- Mail: info@bbnburundi.org Website: www.bbn-burundi.org</p>