APPENDIX GG  
ADOPTION PROPOSAL FORM

**STA/SDV/OP/04/F1**

**KENYA BUREAU OF STANDARDS**

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| **Document Type:** | **Adoption proposal** | |
| **Dates:** | Circulation date | Closing date |
| 23-08-2019 | 22-09-2019 |
| **TC Secretary** | **This form shall be filled, signed and returned to Kenya Bureau of Standards for the attention of Oyoo T.O.** | |

The Kenya Bureau of Standards intends to adopt the International Standards as detailed here below .............................................................................................................................................

**Number.** ISO 80369-7:2016........................................................................................................................................

**Title.** Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications

**Scope:** ISO 80369-7:2016 specifies dimensions and requirements for the design and functional performance of small-bore connectors intended to be used for connections in intravascular applications or hypodermic connections in hypodermic applications of medical devices and accessories.

EXAMPLES Hypodermic syringes and needles or intravascular (IV) cannulae with male and female luer slip connectors and luer lock connectors.

NOTE 1 The luer connector was originally designed for use at pressures up to 300 kPa.

ISO 80369-7:2016 does not specify requirements for the medical devices or accessories that use these connectors. Such requirements are given in particular International Standards for specific medical devices or accessories.

ISO 80369-7:2016 does not specify requirements for the following small-bore connectors, which are specified in other

International Standards:

- haemodialyser, haemodiafilter and haemofilter blood compartment ports (ISO 8637 and applicable portion of ISO 8638 referencing blood compartment ports);

- haemodialysis, haemodiafiltration and haemofiltration equipment connectors (ISO 8637);

- infusion system closure piercing connectors (ISO 8536‑4).

NOTE 2 Manufacturers are encouraged to incorporate the small-bore connectors specified in this part of ISO 80369 into medical devices or accessories, even if currently not required by the relevant particular medical device standards. It is expected that when the relevant particular medical device standards are revised, requirements for small-bore connectors, as specified in ISO 80369, will be included.

NOTE 3 ISO 80369‑1:2010, 5.8, specifies alternative methods of compliance with ISO 80369‑1:2010, for small-bore connectors intended for use with intravascular applications or hypodermic application medical devices or accessories, which do not comply with this part of ISO 80369.

We are therefore seeking views from potential users in respect of the same. The Standard is available at the Kenya Bureau of Standards Information Centre. Please tick and fill your preference of the listed option. (If the spaces provided are not enough, please attach a separate sheet of paper).

Adoption acceptable as presented

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Adoption proposal not acceptable because of the reason(s) below

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Our Recommendations are as follows

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Name and Signature (of respondent): ................................................

Position (of respondent): .....................................

On behalf of ......................................................................................... (Name of organization)

Date .........................................................................

**NOTE:** Absence of any reply or comments shall be deemed to be an acceptance of the proposal for adoption and **shall constitute an approval vote**.