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 8637-1:2017........................................................................................................................................

**Title.** Extracorporeal systems for blood purification -- Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators

**Scope:** ISO 8637-1:2017 specifies requirements for hemodialysis, haemodiafilters, haemofilters and haemoconcentrators, hereinafter collectively referred to as "the device", for use in humans.

ISO 8637-1:2017 does not apply to:

- extracorporeal blood circuits;

- plasma filters;

- haemoperfusion devices;

- vascular access devices;

- blood pumps;

- pressure monitors for the extracorporeal blood circuit;

- air detection devices;

- systems to prepare, maintain or monitor dialysis fluid;

- systems or equipment intended to perform haemodialysis, haemodiafiltration, hemofiltration or haemoconcentration;

- reprocessing procedures and equipment.

NOTE Requirements for the extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters are specified in ISO 8637‑2.

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**.