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 23500-2:2019........................................................................................................................................

**Title.** Preparation and quality management of fluids for haemodialysis and related therapies -- Part 2: Water treatment equipment for haemodialysis applications and related therapies

**Scope** 1.1 General

This document is addressed to the manufacturer and/or supplier of water treatment systems and/or devices used for the express purpose of providing water for haemodialysis or related therapies.

1.2 Inclusions

This document covers devices used to treat potable water intended for use in the delivery of haemodialysis and related therapies, including water used for:

a) the preparation of concentrates from powder or other highly concentrated media at a dialysis facility;

b) the preparation of dialysis fluid, including dialysis fluid that can be used for the preparation of substitution fluid;

c) the reprocessing of dialysers intended for single use where permitted for multiple uses,

d) the reprocessing of dialysers not specifically marked as intended for single use.

This document includes all devices, piping and fittings between the point at which potable water is delivered to the water treatment system, and the point of use of the dialysis water. Examples of the devices are water purification devices, online water quality monitors (such as conductivity monitors), and piping systems for the distribution of dialysis water.

1.3 Exclusions

This document excludes dialysis fluid supply systems that proportion water and concentrates to produce dialysis fluid, sorbent dialysis fluid regeneration systems that regenerate and recirculate small volumes of the dialysis fluid, dialysis concentrates, haemodiafiltration systems, haemofiltration systems, systems that process dialysers for multiple uses, and peritoneal dialysis systems. Some of these devices, such as dialysis fluid delivery systems and concentrates, are addressed in other documents such as ISO 23500-4 and ISO 23500‑5,

This document also excludes the on-going surveillance of the purity of water used for dialysis fluid, concentrate preparation, or dialyser reprocessing which is addressed in ISO 23500‑1.

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**.