APPENDIX GG  
ADOPTION PROPOSAL FORM

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

**KENYA BUREAU OF STANDARDS**

|  |  |  |
| --- | --- | --- |
| **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 15223-2:2010........................................................................................................................................

**Title.** Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied -- Part 2: Symbol development, selection and validation

**Scope.** ISO 15223-2:2010 specifies a process for developing, selecting and validating symbols for inclusion in ISO 15223-1.

The purpose of ISO 15223-2:2010 is to ensure that symbols included in ISO 15223-1 are readily understood by the target group.

If the symbol validation process detailed in ISO 15223-2:2010 has been complied with, then the residual risks, as defined in ISO 14971 and IEC 62366, associated with the usability of a medical device symbol are presumed to be acceptable, unless there is objective evidence to the contrary.

ISO 15223-2:2010 is not restricted to symbols intended to meet regulatory requirements or specified in regulatory guidelines on labelling.

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

...............................................................................................................................

...............................................................................................................................

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

...............................................................................................................................

...............................................................................................................................

Our Recommendations are as follows

...............................................................................................................................

...............................................................................................................................

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**.