DUS 2111

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Umbilical cord clamp — Specification

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Foreword

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(a) a member of International Organisation for Standardisation (ISO) and

(b) a contact point for the WHO/FAO Codex Alimentarius Commission on Food Standards, and

(c) the National Enquiry Point on TBT Agreement of the World Trade Organisation (WTO).

The work of preparing Uganda Standards is carried out through Technical Committees. A Technical Committee is established to deliberate on standards in a given field or area and consists of key stakeholders including government, academia, consumer groups, private sector and other interested parties.

Draft Uganda Standards adopted by the Technical Committee are widely circulated to stakeholders and the general public for comments. The committee reviews the comments before recommending the draft standards for approval and declaration as Uganda Standards by the National Standards Council.

The committee responsible for this document is Technical Committee UNBS/TC 14, *Medical devices*.

Umbilical cord clamp — Specification

1 Scope

This Draft Uganda Standard specifies the requirements, methods of test and sampling for umbilical cord clamps.

It does not include specifications for devices for dividing the umbilical cord after clamping.

2 Normative references

The following referenced documents referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 2859-1, *Sampling procedures for inspection by attributes -- Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

US ISO 10993, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply. ISO and IEC maintain terminological databases for use in standardization at the following addresses: — ISO Online browsing platform: available at http://www.iso.org/obp

3.1
umbilical cord
cord arising from the navel that connects the fetus with the placenta.

3.2
umbilical cord clamp
device used to constrict the umbilical cord to prevent blood loss from a newborn when the cord is divided. The clamp may stay on for several days on the remaining cord attached to the baby.

4 Material

4.1 The umbilical cord clamp shall be made of medical grade polymer material suitable for clinical use in hospitals.

4.2 The umbilical cord clamp shall be non-slip, disposable, sterile and non-toxic.

4.3 The finished umbilical cord clamp shall be presented in several colors.

5 Requirements

5.1 The clamp shall be sterile when tested in accordance with Annex B

5.2 The clamp shall provide safe security lock, with a click sound to indicate correct locking, to protect against accidental re-opening after clamping.

5.3 The clamp jaws shall be grooved and serrated to hold and occlude the umbilical cord securely without cutting through, thereby spreading the cord evenly across 6 mm arm and holds it firmly in place (see Figures 1 to figure 8).

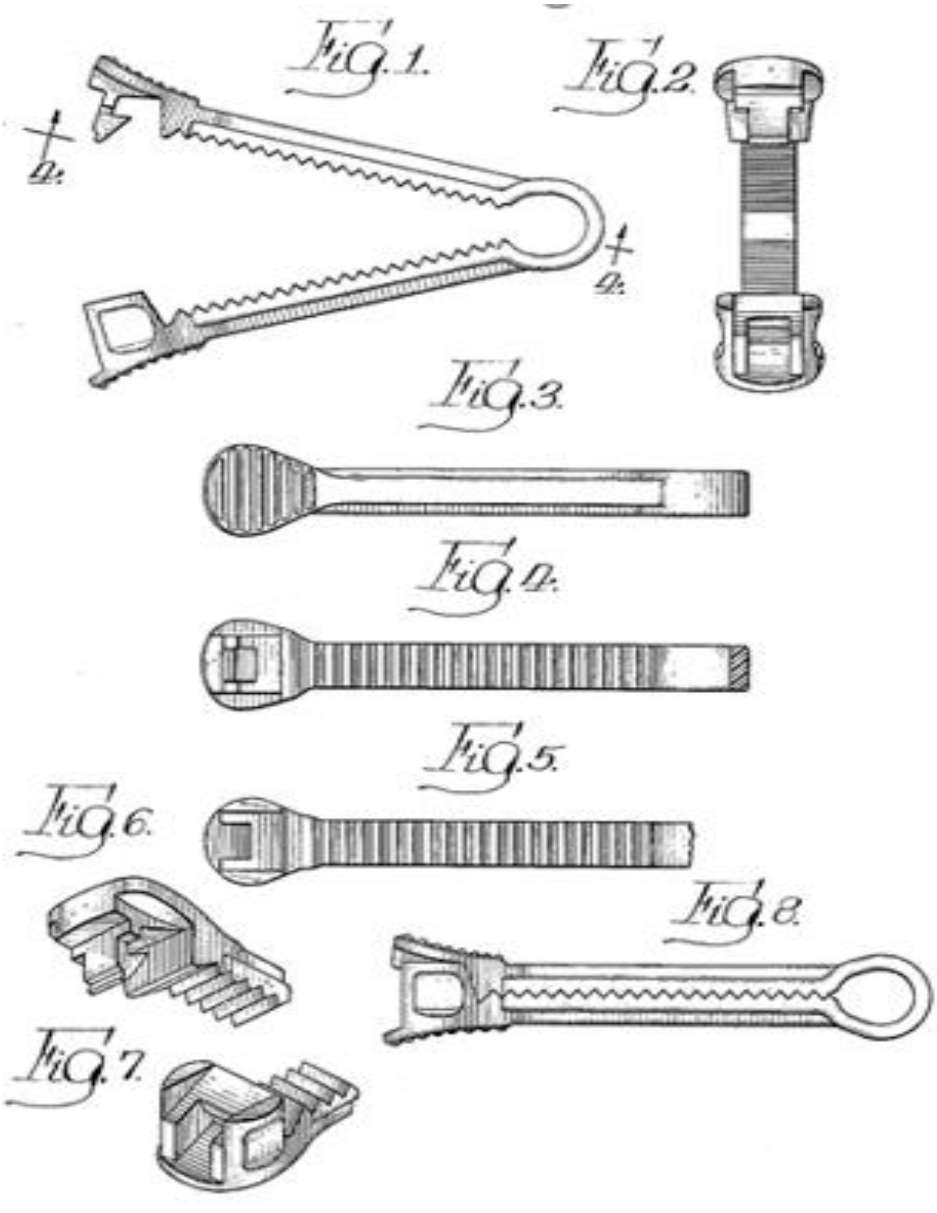

Figure 1: side elevational view of an umbilical cord embodying the new design .Figure 2: front elevational view

Figure 3: a view taken perpendicular to the top. Figure 4: Transverse cross-sectional view

Figure 5: a fragmentary view-showing top of the lower member thereof. Figure 6: an enlarged fragmentary top perspective view of the front of the lower member thereof. Figure 7: an enlarged fragmentary top perspective view of the front of the bottom member thereof. Figure 8: a side elevational view thereof closed position.

5.4 The clamp shall have a finger grip to ensure safe and easy handling.

5.5 The clamp shall be constructed to ensure that no breakage occurs while the clamp is in use.

5.6 The clamp shall maintain constant closing force on the cord as it dries and shrinks

5.7 The outer surface shall be smooth with rounded edges to prevent injury on the baby or snag on the newborn clothing.

5 Packaging

Umbilical Cord clamps shall be packaged in individual sterile pack that are of easy peel when opening.

6 Labeling

Each package of the umbilical cord shall be indelibly and legibly marked with the following information:

a) Manufacturer's name/ trade name and/or trade mark;

b) Date of manufacture;

c) Expiry date;

d) Product name as, 'UMBILICAL CORD CLAMP';

e) Batch/lot number;

f) Country of origin; and

g) With wordings like 'for single-use only', 'forbidden to use if package is damaged" Inserts in case of secondary packaging with direction for use.

7 Sampling

Sampling shall be done in accordance with ISO 2859-1.

8 Biocompatibility

The test for biocompatibility shall be carried by the manufacturer for which the certificate of conformity shall be provided. The umbilical cord clamp shall be non-toxic when examined in accordance with US ISO 10993 —1.

ANNEX
(normative)

Sterility

B.1 Introduction

The following culture media have been found to be suitable for the test for sterility. Fluid thioglycollate medium is primarily intended for the culture of anaerobic bacteria; however, it will also detect aerobic bacteria. Soya-bean casein digest medium is suitable for the culture of both fungi and aerobic bacteria.

B.2 Fluid thioglycollate medium

L-Cystine	0.5 g
Agar	0.75 g
Sodium chloride	2.5 g
Glucose monohydrate/anhydrous	5.5 g/5.0 g
Yeast extract (water-soluble)	5.0 g
Pancreatic digest of casein	15.0 g
Sodium thioglycollate or	0.5 g
Thioglycollic acid	0.3 mL
Resazurin sodium solution (1g/L of resazurin sodium), freshly prepared	1.0 mL
Water R	1 000 mL
pH after sterilization	7.1 ± 0.2

B.2.1 Mix the L-cystine, agar, sodium chloride, glucose, water-soluble yeast extract and pancreatic digest of casein with the water R and heat until solution is effected.

B.2.2 Dissolve the sodium thioglycollate or thioglycollic acid in the solution and, if necessary, add 1 M sodium hydroxide so that, after sterilization, the solution will have a pH of 7.1 ± 0.2. If filtration is necessary, heat the solution again without boiling and filter while hot through moistened filter paper.

B.2.3 Add the resazurin sodium solution, mix and place the medium in suitable vessels which provide a ratio of surface to depth of medium such that not more than the upper half of the medium has undergone a colour change indicative of oxygen uptake at the end of the incubation period. Sterilize using a validated process. If the medium is stored, store at a temperature between 2 °C and 25 °C in a sterile, airtight container.

B.2.4 If more than the upper one-third of the medium has acquired a pink colour, the medium may be restored once by heating the containers in a water-bath or in free-flowing steam until the pink colour disappears and cooling quickly, taking care to prevent the introduction of non-sterile air into the container. Do not use the medium for a longer storage period than has been validated. Fluid thioglycollate medium is to be incubated at 30 °C - 35 °C.

B.2.5 For products containing a mercurial preservative that cannot be tested by the membrane-filtration method, fluid thioglycollate medium incubated at 20 °C - 25 °C may be used instead of soya-bean casein digest medium provided that it has been validated as described in the growth promotion test.

B.3 Alternative thioglycollate medium

Where prescribed, justified and authorized, the following alternative thioglycollate medium may be used. Prepare a mixture having the same composition as that of the fluid thioglycollate medium, but omitting the agar and the resazurin sodium solution, sterilize as directed above. The pH after sterilization is 7.1 ± 0.2. Heat in a water-bath prior to use and incubate at 30 °C - 35 °C under anaerobic conditions.

B.4 Soya-bean casein digest medium

Pancreatic digest of casein	17.0 g
Papaic digest of soya-bean meal	3.0 g
Sodium chloride	5.0 g
Dipotassium hydrogen phosphate	2.5 g
Glucose monohydrate/anhydrous	2.5 g/2.3 g
Water R	1 000 mL
pH after sterilization	7.3 ± 0.2

B.4.1 Dissolve the solids in water R, warming slightly to effect solution. Cool the solution to room temperature. Add 1 M sodium hydroxide, if necessary, so that after sterilization the solution will have a pH of 7.3 ± 0.2.

B.4.2 Filter, if necessary, to clarify, distribute into suitable vessels and sterilize using a validated process. Store at a temperature between 2 °C and 25 °C in a sterile well-closed container, unless it is intended for immediate use. Do not use the medium for a longer storage period than has been validated. Soya-bean casein digest medium is to be incubated at 20 °C -25 °C.

The media used comply with the following tests given in E.6, carried out before or in parallel with the test on the product to be examined..

B.5 Sterility

Incubate portions of the media for 14 days. No growth of micro-organisms occurs.

B.6 Growth Promotion Test of Aerobes, Anaerobes, and Fungi

B.6.1 Test each lot of ready-prepared medium and each batch of medium prepared either from dehydrated medium or from ingredients. Suitable strains of microorganisms are indicated in Table E1.

B.6.2 Inoculate portions of Fluid Thioglycollate Medium with a small number (not more than 100 cfu) of the following microorganisms, using a separate portion of medium for each of the following species of microorganism: *Clostridium sporogenes*, *Pseudomonas aeruginosa*, *and Staphylococcus aureus*. Inoculate portions of alternative thioglycollate medium with a small number (not more than 100 cfu) of *Clostridium sporogenes.*F Inoculate portions of Soybean–Casein

B.6.3 Digest Medium with a small number (not more than 100 cfu) of the following microorganisms, using a separate portion of medium for each of the following species of microorganism: *Aspergillus brasiliensis, Bacillus subtilis*, and *Candida albicans*. Incubate for not more than 3 days in the case of bacteria and not more than 5 days in the case of fungi.

B.6.4 Seed lot culture maintenance techniques (seed-lot systems) are used so that the viable microorganisms used for inoculation are not more than five passages removed from the original master seed-lot. The media are suitable if a clearly visible growth of the microorganisms occurs

Table B1—. Strains of the Test Microorganisms Suitable for Use in the Growth Promotion Test

Test Microorganisms	
Aerobic bacteria	Fungi
Staphylococcus aureus ATCC 6538, CIP 4.83,NCTC 10788, NCIMB 9518, NBRC 13276	*Candida albicans* ATCC 10231, IP 48.72, NCPF 3179, NBRC 1594

Bibliography

[1] KS 2557:2018. *Umbilical cord clamp — Specification.*

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