Surgical suture needles — Specification
National foreword

Uganda National Bureau of Standards (UNBS) is a parastatal under the Ministry of Trade, Industry and Cooperatives established under Cap 327, of the Laws of Uganda, as amended. UNBS is mandated to coordinate the elaboration of standards and is
(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 representatives of consumers, traders, academicians, manufacturers, government and other stakeholders.

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.

This Draft Uganda Standard, DUS DEAS 1018: 2019, Surgical suture needles — Specification, is identical with and has been reproduced from an East African Standard, DEAS 1018: 2019, Surgical suture needles — Specification, and is being proposed for adoption as a Uganda Standard.

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

Wherever the words, “East African Standard” appear, they should be replaced by “Uganda Standard.”
DRAFT EAST AFRICAN STANDARD

Surgical suture needles — Specification

EAST AFRICAN COMMUNITY
Foreword

Development of the East African Standards has been necessitated by the need for harmonizing requirements governing quality of products and services in the East African Community. It is envisaged that through harmonized standardization, trade barriers that are encountered when goods and services are exchanged within the Community will be removed.

The Community has established an East African Standards Committee (EASC) mandated to develop and issue East African Standards (EAS). The Committee is composed of representatives of the National Standards Bodies in Partner States, together with the representatives from the public and private sector organizations in the community.

East African Standards are developed through Technical Committees that are representative of key stakeholders including government, academia, consumer groups, private sector and other interested parties. Draft East African Standards are circulated to stakeholders through the National Standards Bodies in the Partner States. The comments received are discussed and incorporated before finalization of standards, in accordance with the Principles and procedures for development of East African Standards.

East African Standards are subject to review, to keep pace with technological advances. Users of the East African Standards are therefore expected to ensure that they always have the latest versions of the standards they are implementing.

The committee responsible for this document is Technical Committee EASC/TC 078, Healthcare and medical devices.

Attention is drawn to the possibility that some of the elements of this document may be subject of patent rights. EAC shall not be held responsible for identifying any or all such patent rights.
Surgical suture needles — Specification

1 Scope

This Draft East African Standard specifies the requirements, sampling and test methods for surgical suture needles.

2 Normative references

The following documents are 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.

ASTM A751-01, Standard Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products

ASTM F1089-02, Standard Test Method for Corrosion of Surgical Instruments

ASTM F1840-10, Standard Terminology for Surgical Suture Needles

ISO 6507-1, Metallic materials — Vicker hardness test — Part 1: Test method

ISO 24153, Random sampling and randomisation procedures

ISO 13402, Surgical and dental hand instruments — Determination of resistance against autoclaving, corrosion and thermal exposure

ASTM F3014 – 14, Standard Test Method for Penetration Testing of Needles Used in Surgical Sutures

ASTM F1874 - 98, Standard Test Method for Bend Testing of Needles Used in Surgical Sutures

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 attachment area
portion of the needle where the attachment of the suture takes place, for example, eyed, drilled and channel (see Annex A)

3.2 curvature
shape of the needle viewed in profile. Some common shapes include, but are not limited to: straight, 1/2 curve or “ski,” 1/8 circle, 1/4 circle, 3/8 circle, 1/2 circle, 5/8 circle, and compound curvature (see Annex A).
3.3 **strand**
fibre/suture used to hold body tissues together after a surgery or injury

3.4 **surgical suture needle**
surgical needle necessary for the placement of sutures in tissues

3.5 **swage**
any attachment method that uses mechanical force to crimp the end of the needle and firmly hold the suture in place.

4 Types

4.1 **Eyed suture needles**
Surgical suture needles that have a hole at the suture side of the needle. Eyed suture needles are categorized into closed eye or French (split/spring) eye.

4.2 **Swaged or eyeless needles**
Surgical suture needles that have a suture crimped within the needle. The suture strand is permanently attached needle by the manufacturer.

5 Requirements

5.1 **General requirements**

5.1.1 The surface of the suture needle shall be smooth and free from dents.

5.1.2 The suture needles shall be free from grinding marks, polishing dirt or the other material which could necessitate cleaning prior to sterilization.

5.1.3 The point of the needle shall be sharp except where otherwise specified.

5.1.4 The eye (swage) of the needle shall be clean and properly formed and shall be smooth from inside and outside.

5.2 **Chemical composition**
When tested in accordance with ASTM A751-01, the suture needles shall be made of stainless steel wires of either of the composition given in Table 1 or Table 2.
Table 1 — Chemical composition for surgical suture needles

<table>
<thead>
<tr>
<th>Element</th>
<th>Percentage %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbon</td>
<td>0.30 – 0.40</td>
</tr>
<tr>
<td>Manganese</td>
<td>1.00 max.</td>
</tr>
<tr>
<td>Phosphorous</td>
<td>0.045 max.</td>
</tr>
<tr>
<td>Sulphur</td>
<td>0.045 max.</td>
</tr>
<tr>
<td>Silicon</td>
<td>1.00 max.</td>
</tr>
<tr>
<td>Chromium</td>
<td>12.00 – 14.00</td>
</tr>
<tr>
<td>Nickel</td>
<td>1.00 max.</td>
</tr>
</tbody>
</table>

Table 2 — Chemical composition for surgical suture needles

<table>
<thead>
<tr>
<th>Element</th>
<th>Percentage %</th>
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</thead>
<tbody>
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<td>Carbon</td>
<td>0.60 – 0.75</td>
</tr>
<tr>
<td>Manganese</td>
<td>1.00 max.</td>
</tr>
<tr>
<td>Phosphorous</td>
<td>0.040 max.</td>
</tr>
<tr>
<td>Sulphur</td>
<td>0.030 max.</td>
</tr>
<tr>
<td>Silicon</td>
<td>1.00 max.</td>
</tr>
<tr>
<td>Chromium</td>
<td>16.00 – 18.00</td>
</tr>
<tr>
<td>Nickel</td>
<td>0.75 max.</td>
</tr>
</tbody>
</table>

5.3 Quality requirements

5.3.1 Hardness

When tested in accordance with ISO 6507-1, the hardness of the surgical suture needle shall be 525 HV to 625 HV (Vicker hardness).

5.3.2 Corrosion resistant

The surgical suture needle shall comply with the requirements for corrosion resistance given in F1089-02 when tested in accordance with ISO 13402.

5.3.3 Bend test

The surgical suture needles shall be tested in accordance with ASTM F1874 - 98. The straight suture needle shall deem to have failed as being too hard, if it breaks before the initial bend of 90° is achieved. There shall not be any permanent set in the curved suture needles after the test.

5.3.4 Penetration test

The penetration test of surgical needles shall be done in accordance with ASTM F3014 – 14. The piercing resistance shall be less than 25 g.
This test is applicable to all needles, except blunt point needles.

6 Packaging

The surgical suture needle shall be packed in suitable packets or containers that protect the needle from contamination and deterioration.

7 Labelling

The package shall be legibly and indelibly marked with the following information:

a) manufacturer's name and physical address;

b) product name;

c) batch number;

d) shape of the needle;

e) needle length;

f) curvature;

g) point configurations;

h) type of eye (either eyed or eyeless);

i) quantity of sutures needles;

j) warning/ precautions;

k) instruction for use; and

l) month and year of manufacture and expiry.

8 Sampling

Random samples of the product for test shall be drawn in accordance with ISO 24153. (Acceptance criteria - none shall fail).
Annex A
(normative)

Sizes shapes and dimensions

A.1 Schematic of a surgical suture needle

Figure A.1 ——Schematic of a surgical needle
A.2 Curvatures

Figure A.2 — Typical curvatures
A.3 Point configurations

Figure A.3 — Typical point configurations

A.4 Attachment end of surgical suture needles

Figure A.4 — Needle eye
Bibliography


