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DRAFT EAST AFRICAN STANDARD

Leather for orthopaedic use — Specification

EAST AFRICAN COMMUNITY

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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 063, Leather and Leather Products

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.

Leathers for orthopaedic use — Specification

1 Scope

This Draft East African Standard specifies requirements and test methods for leather intended for orthopaedic use.

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.

ISO 3380, *Leather — Determination of shrinkage temperature* ISO 5398-2:2009 *Leather — Chemical determination of chromic oxide content — Part 2: Quantification by colorimetric determination*

ISO 5398-1:2018 *Leather — Chemical determination of chromic oxide content — Part 1: Quantification by titration*

ISO 17075-1:2017 *Leather — Chemical determination of chromium (VI) content in leather — Part 1: Colorimetric method*

ISO 4045:2018 *Leather — Chemical tests — Determination of pH and difference figure*

ISO 2589:2016 *Leather — Physical and mechanical tests — Determination of thickness*

ISO 3377-1:2011 *Leather — Physical and mechanical tests — Determination of tear load — Part 1: Single edge tear*

ISO 3377-2:2016 *Leather — Physical and mechanical tests — Determination of tear load — Part 2: Double edge tear*

ISO 17236, *Leather — Physical and mechanical tests — Determination of extension set*

3 Terms and definitions

For the purposes of this standard, the following definitions shall apply:

3.1 Orthopaedic

Science related with the correction or prevention of deformities, disorders, or injuries of the skeleton and associated structures (such as tendons and ligaments)

4 Requirements

4.1 General Requirements

The leather shall be full grain

The leather shall have a natural (pearl) finish. Pigment finish shall not be used

Leather shall be strong, flexible and soft.

4.2 specific requirements

4.2.1 Leather material

The physical and chemical properties shall comply with the requirements given in Table 1, when tested in accordance with test methods specified therein.

Table 1 — Physical and chemical requirements

| Characteristic | Requirement | Test method |
|---|-------------|-------------------------|
| chromic oxide content (calculated on a moisture-free basis) max,% | 2.0 | ISO5398-1 ISO 5398-2 |
| Chromium (vi), max ppm | 3.0 | ISO 17075-1 |
| pH value, min. | 4.5-5.5 | ISO4045 |
| Thickness(mm), min | 0.8 | ISO 2589 |
| shrinkage temperature, min. | 70°C | ISO 3380 |
| Tear strength,N min | 25N | ISO 3377 |
| Static stretch (%), max | 20 | ISO 17236 |
| Set stretch (%), max | 8 | |

5 Marking/Labelling

5.1 Marking on unit leather

Each piece of leather shall be marked with the following information

- a) Size in square feet
- b) Trademark and or manufacturers name
- c) Country of origin
- d) Batch number
- e) Name "leather for orthopaedic use"

5.2 Marking on bulk Package

- a) Number of pieces in the bundle
- b) Size in square feet
- c) Trademark and or manufacturers name
- d) Country of origin
- f) Name "leather for orthopaedic use"

6 Packaging

The leather for orthopaedic use shall be packed in a way that it is protected from damage during storage and transportation.

7 Sampling

Sampling shall be done in accordance with ISO 2588