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Traditional Chinese medicine — Gua Sha instruments

Médecine traditionnelle chinoise — Instruments Gua Sha

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 249, *Traditional Chinese medicine*.

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Introduction

Gua Sha, also known as Gua Sha therapy, is a traditional treatment based on the meridian-acupoint theory of traditional Chinese medicine (TCM). The specific Gua Sha instruments which have different shapes and materials are adopted to perform scraping action to the skin during the Gua Sha treatment so as to prevent or treat diseases.

Gua Sha has been used for more than two thousand years and has demonstrated medical benefits. In recent years, Gua Sha has proved, according to many clinical research projects, to be effective in treating more than 400 types of diseases. Now, it is widely accepted in many countries including China, United States of America, Europe, Australia, Japan, Korea and other Southeast Asian countries.

The purpose of this document is to guarantee the safety and performance of Gua Sha instruments, so as to promote the international trade of Gua Sha instruments and generalize the clinical application of Gua Sha therapy.

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Traditional Chinese medicine — Gua Sha instruments

1 Scope

This document specifies appearance, material, requirements of visual inspection, cleaning and disinfection, hardness, roughness, resistance to abrasion, exposure index of radionuclide activity, biocompatibility of Gua Sha instruments, as well as related information on package, transport and storage, labelling and instructions for use.

Electro-devices and other forms are outside the scope of this document.

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 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

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

ISO/IEC Guide 37, *Instructions for use of products of consumer interest*

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:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
Gua Sha
therapy consisting of scraping or applying friction to the skin surface without causing abrasion or injury to the skin

3.2
Gua Sha instrument
instrument made of hard material with different sizes and shapes for single or repeated usage during Gua Sha therapy

4 Appearance

4.1 Shape

A variety of shapes can be applicable as follows:

a) oval-shaped;

b) rectangle-shaped;

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