تقديم

الهيئة جهة مستقلة الغرض الأساسي لها هو القيام بتنظيم ومراقبة الغذاء والدواء والأجهزة والمنتجات الطبية، ومن مهامها وضع اللوائح الفنية والمواصفات في مجالات الغذاء والدواء والأجهزة والمنتجات الطبية سواءً كانت مستوردة أو مصنعة محلياً، وقد قام قطاع الأجهزة والمنتجات الطبية بالهيئة ضمن برنامج عمل الفريق رقم (SFDA/MDS/TC 249) "فريق عمل مواصفات أجهزة الطب الصيني" بتبني المواصـــفة الدولية رقم (ISO 20308:2017) "الطب الصيني التقليدي – أدوات غوا تشا"، والتي أصدرتها "المنظمة الدولية للتقييس" وذلك بلغتها الأصلية. وقد اعتمدت هذه المواصفة كمواصفة سعودية متبناة بالمطابقة بلغتها الأصلية وقد تم إقرار تبني المواصفة/اللائحة من معالي الرئيس التنفيذي للهيئة بقرار رقم (.....) و تاريخ .....

Foreword

The Saudi Food and Drug Authority (SFDA) is an independent organization mainly responsible for regulating imported/local food, drug and medical devices which includes, inter alia, setting their standards. International Standard No. (ISO 20308:2017) "Traditional Chinese medicine — Gua Sha instruments" issued by "International Organization for Standardization" has been adopted identically in its original language. This standard is adopted with modifications in its original language as a national standard and approved by SFDA CEO decision No (…) on (date)

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.

ملحق التعديلات
Modifications Annex

Project: SFDA.MD.249.DS.ISO 20308:2017

#	رقم الصفحة Page No.	رقم البند/البند الفرعي Clause/Subclause No.	رقم السطر Line No.	فقرة/ صورة/ جدول Paragraph/ Figure/ Table/	نوع الملاحظة Comment type	الملاحظات Comments	التعديل Modification
1	v	Introduction		2nd Paragraph	ge	There is no solid scientific evidence for these historic and clinical claims for the Gua Sha instruments	**Delete:** ~~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.~~
2	1	4.1			ed		**Modify:** A variety of shapes can be ~~applicable~~ applied as follows:
3	2	5			ed		**Modify:** A variety of materials can be ~~applicable~~ applied as follows:

4	2	5			te	Use of buffalo-horns is improper and would cause difficulty in cleaning and disinfection	**Delete:** A variety of materials can be applied as below: ~~a) buffalo-horn;~~ a) bian-stone; b) jade; c) other materials.
5	3	6.2			ge		**Modify:** Gua Sha instruments for single or repeated use shall be cleaned and disinfected in accordance with ISO 17664 in order to avoid skin irritation and infection.
6	4	7.1			te	The term "should" is not proper to express any requirement (ISO/IEC Directives, Part 2), the term "shall" is the proper term	**Modify:** The material and design of this primary packaging ~~should~~ shall be such as to ensure
7	5	9.1.1 a)			te	Indication of the manufacturer is "mandatory" according to SFDA regulation	**Modify:** the name ~~or~~, trademark or logo of the manufacturer and~~/or~~ supplier**, if applicable**;
8	5	9.1.1 b)			te	There is no expression of the dimensions of Gua Sha instruments within the document !!	**Delete:** a description of the contents~~, including the designated metric size~~;
9	5	9.1.1 g)			ge		**Add:** dimension, in accordance with Annex B.

10	5	9.1.2 a)			te	Indication of the manufacturer is "mandatory" according to SFDA regulation	**Modify:** the name, address and trademark or logo of the manufacturer and~~/or~~ supplier, if applicable;
11	5	9.1.2 b)			te	There is no expression of the dimensions of Gua Sha instruments within the document !!	**Delete:** description of the contents, ~~including the designated metric size~~ …
12	5	9.1.2 b)			te	The Gua Sha instruments has been classified in the document according to their shapes and materials	**Modify:** description of the contents, ~~including the designated metric size~~, the quantity, ~~the classification~~ shape, and material;
13	6	9.1.2			te	Because it is a professional practice, and there are precaution and adverse events which may occur due to malpractice, a warning statement should be marked stating "It shall be used by or under supervision of a professional therapist"	**Add:** h) a warning stating that "It shall be used by or under supervision of a professional therapist".
14	6	9.2			ge	The instruction for use (IFU) shall be indicated in Arabic and English to fulfill the user needs	**Add:** The instructions for use shall be marked with at least the following information, in Arabic and English:
15	6	9. 2 b)			te	Indication of the manufacturer is "mandatory" according to SFDA regulation	**Modify:** the name and trademark of the product and~~/or~~ manufacturer;

16	6	9.2 c)			te	"Product license number" is not required to be marked within the "Instructions For Use (IFU)" according to SFDA guidances for completing MDMA	**Delete:** ~~product license number;~~
17	6	9.2 d)			te	"Product standard number" is not required to be marked within the "Instructions For Use (IFU)" according to SFDA guidances for completing MDMA	**Delete:** ~~product standard number;~~
18	6	9.2			ed		**Modify:** ~~e)~~ c) performance and structure of product; ~~f)~~ d) indications and contraindications; ~~g)~~ e) methods to use, disinfection method in particular; ~~h)~~ f) precautions.

Comment type: **ge** = general **te** = technical **ed** = editorial