

## تقديم

الهيئة العامة للغذاء والدواء جهة مستقلة الغرض الأساسي لها هو القيام بتنظيم ومراقبة الغذاء والدواء والأجهزة والمنتجات الطبية والتشخيصية، ومن مهامها وضع اللوائح الفنية والمواصفات في مجالات الغذاء والدواء والأجهزة والمنتجات الطبية سواءً كانت مستوردة أو مصنعة محلياً بواسطة لجان فنية متخصصة، وقد قام قطاع الأجهزة والمنتجات الطبية بالهيئة ضمن برنامج عمل الفريق رقم (SFDA/MDS/TC 249) "فريق عمل مواصفات أجهزة الطب الصيني" بتبني المواصفة الدولية رقم (ISO 19611:2017) "الطب الصيني التقليدي – أدوات الحجامَة لتفريغ الهواء"، والتي أصدرتها "المنظمة الدولية للتقييس" وذلك بلغتها الأصلية. وقد اعتمدت هذه المواصفة كمواصفة سعودية متبناة بالتعديل بلغتها الأصلية وذلك في اجتماع مجلس الإدارة رقم ( ) والذي عقد بتاريخ ( ..../..../١٤٠٠ هـ ) الموافق ( ..../..../٢٠٠٠ م ).

- التعديلات مشار إليها في ملحق التعديلات.

## Foreword

Saudi Food and Drug Authority (SFDA) is an independent organization with main purpose of regulating and monitoring of foods, drugs and medical devices. One of SFDA functions is to issue national Standards /Technical Regulation in the fields of foods, drugs and medical devices, whether imported or manufactured locally, through specialized technical committees (TCs). SFDA medical devices sector through the work program of technical committee (SFDA/MDS/TC 249) "Traditional Chinese medicine" has adopted the International Standard No. (ISO 19611:2017) "Traditional Chinese medicine — Air extraction cupping device" issued by "International Organization for Standardization" in its original language. This standard is adopted with modifications in its original language and has been approved as national standard by SFDA board of directors in its meeting No ( ) Held on ( ../..../14..AH), agreed with ( ../..../20..G).

- The modifications are mentioned in the Modifications Annex.

## **Scope**

This document specifies requirements for an air extraction cupping device which operates using negative pressure. This document includes requirements for the material, pressure, sterilization or disinfection, and packaging of the cupping device, as well as appropriate test methods.

The document is applicable to single-use type and multiple-use type devices.

This document does not apply to the suction pump used to create the negative pressure.

ملحق التعديلات

**Modifications Annex**

Project: SFDA.MD.249.DS.ISO 19611:2017

#	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	3		ge	<ul style="list-style-type: none"> <li>- Cupping therapy practice in the Middle East is actually <b>older than 1550 B.C.</b></li> <li>- Eber's papyrus which was written in 1550 B.C mentioned cupping therapy as a practice however the practice itself is <b>older than this date</b></li> <li>- Some of scientists also suggest that this papyrus was a <b>copy of an older one</b></li> </ul>	<p>In the Middle East, cupping therapy has been used <b>since 1550 B.C. for thousands of years</b></p>
2	v	Introduction	4		ge	<ul style="list-style-type: none"> <li>- This statement is <b>not clear and inaccurate</b></li> <li>- It does not contain the <b>required reverence for the prophet</b> of Islam Mohammad (PBUH)</li> <li>- Prophet Mohammad (PBUH) <b>did not</b> spread cupping by himself.</li> <li>- He got cupped and recommended cupping</li> <li>- "<b>Hijama</b>" is the Arabic name for cupping therapy</li> </ul>	<p>and widely spread <b>by Muhammad</b> as "<b>Hijama</b>" in the era of Islam when <b>prophet Mohammad (PBUH) get cupped and recommended cupping therapy to his followers.</b></p> <p>It is a popular therapy in Islamic countries</p>
3	1	3.1 cupping therapy			ge	<p>The cupping therapy may affect the body and increase bloodletting <b>in the same time</b></p>	<p>therapy in which cups are placed on the skin to create localized negative pressure by means of either heat or a suction pump, for affecting the surface of the body <b>or and/or</b> for increasing bloodletting</p>

4	1	3.2 bloodletting			te	Needle is <b>just one method</b> of pricking the skin, using <b>surgical blades</b> is another method and it is the <b>most popular method</b> in Islamic countries	therapeutic method of withdrawing blood by pricking the skin with a needle <b>or surgical blades</b> in order to treat or prevent illness and disease
5	3	4.2.1 Inner volume		Table 1	ed	Use decimal points to represent fractional numbers	$\pm 7 \rightarrow 7.0$ $\pm 5,5 \rightarrow 5.5$ $\pm 4,0 \rightarrow 4.0$ $\pm 2,5 \rightarrow 2.5$ $\pm 1,5 \rightarrow 1.5$
6	4	5.1 Biological compatibility		Table 2	ed		NOTE Testing <b>is shall be</b> done in accordance with the ISO 10993 series
7	6	7.2 a)			te	Indication of the manufacturer is " <b>mandatory</b> " according to SFDA regulation	a) the name or trademark or logo of the manufacturer <b>and/or and</b> supplier; <b>if applicable</b>
8	6	7.3 a)			te	Indication of the manufacturer is " <b>mandatory</b> " according to SFDA regulation	a) the name, address and trademark of the manufacturer <b>and/or and</b> supplier; <b>if applicable</b>

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