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 المواصـــفة الدولية رقم (ISO 18666:2015) "الطب الصيني التقليدي – المتطلبات العامة لأجهزة الكي"، 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 (../../1440 هـ) الموافق (../../2019 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 18666:2015) "Traditional Chinese Medicine – General requirements of moxibustion devices” 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 (../../1440 AH), agreed with (../../2019 G).

- The modifications are mentioned in the Modifications Annex.

Scope

This International Standard specifies the general requirements for configuration, materials, performance and safety requirements of moxibustion devices. It also specifies the minimum requirements for moxibustion materials used in moxibustion devices.

It is applicable across a wide range of moxibustion devices that uses moxa floss as the main combustion material and can remain on or over the body throughout the moxibustion process. It is applicable to moxibustion devices for both single and repeated usage.

This International Standard does not apply to devices that imitate moxibustion, such as electromoxibustion and infrared moxibustion devices that do not involve the use of moxa floss. It also does not apply to moxa floss used in direct moxibustion.

ملحق التعديلات
Modifications Annex

Project: SFDA.MD.84.DS.ISO 18666:2015

#	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	2	3.8			ge		**3.8** **fineness ratio of moxa floss** **relative** weight of the starting material (mugwort leaves) to the weight of the final product (moxa floss) presented in the form of a ratio
2	2	4.1.1			ge	Moxibustion devices' dimensions have been set for rectangular and circular shape in sub-clause 4.2.	**4.1.1 Size and shape** The sizes and shapes of moxibustion devices can be ~~**different**~~ **rectangular, circular or other** to perform moxibustion at a single point or over an area of the human body surface.
3	2	4.2	2		te	The International System of units (SI) shall be used (ISO/IEC Directives, Part 2, Subclause 9.3)	The dimensions of the moxibustion device shall be expressed in ~~**centimetres**~~ **millimetres** and specified as …
4	3	5.3.1.2	1		ed		~~**Moxa**~~ **Mugwort** leaves shall be stored under a dry and well-ventilated environment …

5	3	5.3.1.2	2		ed		or stored under **an artificial drying by heat** for 3 months before processing into moxa floss.
6	3	5.3.1.3	1		te	The term "should" is not proper to express any requirement (ISO/IEC Directives, Part 2), the term "shall" is the proper term	The minimum fineness of moxa floss ~~**should**~~ **shall** be in the ratio of 3:1,
7	3	5.3.1.5	1		ed		The quality and safety of moxa floss can be determined by visual or physical inspection ~~**and**~~ **or** the use of other inspection equipment such as a metal detector.
8	4	7.1.3	3		ge	"patient" is more proper expression than "recipient"	to ensure the temperature is within the acceptance limits of the moxibustion ~~**recipient**~~ **patient**.
9	4	7.1.4	1		ge		Moxibustion devices that remain on the human body surface ~~**shall**~~ **may** be either for single use or repeated use.
10	4	7.1.4	1		te		For repeated use, they shall have a **clean disposable** bottom or protective lining on the areas that come in contact with the human body surface to prevent any form of direct-contact infection or transmission. **Such means shall be made from materials that did not cause any allergy to the human skin**.

11	5	9.1 a)			te	Indication of the manufacturer is "mandatory" according to SFDA regulation	the name, trade-mark or logo of the manufacturer and~~/or~~ supplier ~~of moxibustion device~~**, if applicable**;
12	5	9.2 a)			te	Indication of the manufacturer is "mandatory" according to SFDA regulation	the name, trade-mark or logo of the manufacturer and~~/or~~ supplier ~~of moxibustion device~~**, if applicable**;
13	6	10.2	3		te	The term "should" is not proper to express any requirement (ISO/IEC Directives, Part 2), the term "shall" is the proper term	The moxibustion devices ~~should~~ **shall** have sufficient protection from accidental damage.
14	6	11			ed		**Instructions for use** ~~(to be provided by the manufacturer)~~
15	6	11 a)			ed		instructions for safe performance of the moxibustion device, including storage and maintenance~~, to be provided by the manufacturer~~;
16	6	11 a) 5)			ed		~~it is advised that~~ the moxibustion device should be administered and used under the direction or supervision of a qualified practitioner.

17	9	A.2.2.1 A.2.2.4			ge	The widely use of phantom model is not a clear advantage of this method and can be transferred to "**A.2.2.1 Principle**" section	**A.2.2.1 Principle** The purpose of this test is to determine the maximum moxibustion temperature achievable during intended use of the moxibustion device. **It is a widely used method in medical engineering experiments to substitute the human body**.

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