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 194) "فريق عمل مواصفات المنتجات الحيوية والدراسات السريرية للأجهزة الطبية " بتبني المواصـــــــفة الدولية رقم (ISO 10993-2:2008) " التقييم الحيوي للأجهزة الطبية -الجزء 02: متطلبات رعاية الحيوان"، 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 10993-2:2008) “Biological evaluation of medical devices — Part 2: Animal welfare requirements” 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 part of ISO 10993 is aimed at those who commission, design and perform tests or evaluate data from animal tests undertaken to assess the biocompatibility of materials intended for use in medical devices, or that of the medical devices themselves. It specifies the minimum requirements to be satisfied to ensure and demonstrate that proper provision has been made for the welfare of animals used in animal tests to assess the biocompatibility of materials used in medical devices.

It also makes recommendations and offers guidance intended to facilitate future further reductions in the overall number of animals used, refinement of test methods to reduce or eliminate pain or distress in animals, and the replacement of animal tests by other scientifically valid means not requiring animal tests.

It applies to tests performed on living vertebrate animals, other than man, to establish the biocompatibility of materials or medical devices.

It does not apply to tests performed on invertebrate animals and other lower forms; nor (other than with respect to provisions relating to species, source, health status, and care and accommodation) does it apply to testing performed on isolated tissues and organs taken from vertebrate animals that have been euthanized.