

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 194) "فريق عمل مواصفات المنتجات الحيوية والتقييم السريري للأجهزة الطبية" بتبني المواصفة الدولية رقم (ISO 10993-6:2016) " التقييم الحيوي للأجهزة الطبية - الجزء السادس: اختبارات للآثار الموضعية بعد الزراعة"، والتي أصدرتها "المنظمة الدولية للتقييس" وذلك بلغتها الأصلية. وقد اعتمدت هذه المواصفة كمواصفة سعودية متبناة بالمطابقة بلغتها الأصلية وذلك في اجتماع مجلس الإدارة رقم () والذي عقد بتاريخ (14.././.. هـ) الموافق (20.././.. م).

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/TC194) "Biological and clinical evaluation of medical devices" has adopted the International Standard No. (ISO 10993-6:2016) "Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation" issued by "International Organization for Standardization" in its original language. This standard is identically adopted 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).

Scope

This part of ISO 10993 specifies test methods for the assessment of the local effects after implantation of biomaterials intended for use in medical devices.

This part of ISO 10993 applies to materials that are

- solid and non-absorbable,
- non-solid, such as porous materials, liquids, gels, pastes, and particulates, and
- degradable and/or absorbable, which may be solid or non-solid.

The test sample is implanted into a site and animal species appropriate for the evaluation of the biological safety of the material. These implantation tests are not intended to evaluate or determine the performance of the test sample in terms of mechanical or functional loading. This part of ISO 10993 can also be applied to medical devices that are intended to be used topically in clinical indications where the surface or lining might have been breached, in order to evaluate local tissue responses.

The local effects are evaluated by a comparison of the tissue response caused by a test sample to that caused by control materials used in medical devices whose clinical acceptability and biocompatibility characteristics have been established. The objective of the test methods is to characterize the history and evolution of the tissue response after implantation of a medical device/biomaterial including final integration or absorption/degradation of the material. In particular for degradable/absorbable materials, the degradation characteristics of the material and the resulting tissue response should be determined.

This part of ISO 10993 does not deal with systemic toxicity, carcinogenicity, teratogenicity or mutagenicity. However, the long-term implantation studies intended for evaluation of local biological effects might provide insight into some of these properties. Systemic toxicity studies conducted by implantation might satisfy the requirements of this part of ISO 10993. When conducting combined studies for evaluating local effects and systemic effects, the requirements of both standards is to be fulfilled.