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 بتبني المواصـــفة الخليجية رقم (GSO ISO 17511:2003 (E) ISO 17511:2016) "الأجهزة الطبية المخبرية التشخيصية – القياس الكمي للعينات الحيوية – سلسلة القياس (التتبع) لأجهزة المعايرة ومواد المراقبة" وذلك بلغتها الأصلية. وقد اعتمدت هذه المواصفة كمواصفة سعودية متبناة بالمطابقة بلغتها الأصلية وذلك في اجتماع مجلس الادارة رقم ( ) والذي عقد بتاريخ (../../..14 هـ) الموافق (../../..20م).

Foreword

Saudi Food and Drug Authority (SFDA) is an independent organization with 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 has adopted Standard No.(GSO ISO 17511:2016 (E) ISO 17511:2003) “In vitro diagnostic medical devices -- Measurement of quantities in biological samples -- Metrological traceability of values assigned to calibrators and control materials”, issued by “GCC Standardization Organization” in its original language. This standard is adopted identically in its original language and has been approved as national standard by SFDA board of directors in its meeting No ( ) Held on (/ / / AH) , agreed with (/ / G).

INTERNATIONAL STANDARD

ISO 17511

First edition
2003-08-15

In vitro diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values assigned to calibrators and control materials

Dispositifs médicaux de diagnostic in vitro — Mesurage des grandeurs dans des échantillons d'origine biologique — Traçabilité métrologique des valeurs attribuées aux agents d'étalonnage et aux matériaux de contrôle

Reference number
ISO 17511:2003(E)

Scope

ISO 17511:2003 specifies how to assure the metrological traceability of values assigned to calibrators and control materials intended to establish or verify trueness of measurement. The calibrators and control materials are those provided by the manufacturers as part of, or to be used together with, *in vitro* diagnostic medical devices.

External quality assessment (survey) samples, with proven commutability, whose values have been assigned by means of internationally agreed reference measurement systems or internationally agreed conventional reference measurement systems fall within the scope of ISO 17511:2003.

ISO 17511:2003 is not applicable to control materials that do not have an assigned value and are used only for assessing the precision of a measurement procedure, either its repeatability or reproducibility (precision control materials); control materials intended for intralaboratory quality control purposes and supplied with intervals of suggested acceptable values, each interval obtained by interlaboratory consensus with respect to one specified measurement procedure, and with limiting values that are not metrologically traceable; correlation between results of two measurement procedures at the same metrological level, purporting to measure the same quantity, because such "horizontal" correlation does not provide metrological traceability; calibration derived from correlation between the results of two measurement procedures at different metrological levels, but with quantities having analytes of different characteristics; metrological traceability of routine results to the product calibrator and their relations to any medical discrimination limit; and properties involving nominal scales, i.e. where no magnitude is involved (e.g. identification of blood cells).

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