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 IEC 60601-2-62:2016 (E) IEC 60601-2-62:2013) " المعدات الكهربائية الطبية – الجزء ٢-٦٢: متطلبات خاصة لسلامة الأساسية والأداء لمعدات العلاجية عالية كثافة الموجات فوق الصوتية(HITU)" وذلك بلغتها الأصلية. وقد اعتمدت هذه المواصفة كمواصفة سعودية متبناة بالمطابقة بلغتها الأصلية وذلك في اجتماع مجلس الادارة رقم ( ) والذي عقد بتاريخ (../../١٤.. هـ) الموافق (../../٢٠..م).

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 IEC 60601-2-62:2016 (E) IEC 60601-2-62:2013) “Medical electrical equipment - Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment”, 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).

IEC 60601-2-62

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

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Medical electrical equipment –
Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment

Appareils électromédicaux –
Partie 2-62: Exigences particulières pour la sécurité de base et les performances essentielles des appareils ultrasonores thérapeutiques de haute intensité (HITU)

IEC 60601-2-62:2013

Scope

IEC 60601-2-62:2013 applies to the basic safety and essential performance of HIGH INTENSITY THERAPEUTIC ULTRASOUND EQUIPMENT. This International Standard adds or replaces clauses listed in the IEC 60601-1 that are specific for HIGH INTENSITY THERAPEUTIC ULTRASOUND EQUIPMENT. If a clause or subclause is specifically intended to be applicable to such equipment only, or to related systems only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to individual equipment and to systems, as relevant. Hazards inherent in the intended physiological function of the equipment or systems within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard. This standard can also be applied to
- therapeutic equipment for thrombolysis through exposure to high-intensity therapeutic ultrasound;
- therapeutic equipment for the treatment of occluding feeding vessels through exposure to high-intensity focused ultrasound;
- and equipment intended to be used for relieving cancer pain due to bone metastases.
This particular standard does not apply to
- Ultrasound Equipment intended to be used for physiotherapy (use IEC 60601-2-5 and IEC 61689);
- Ultrasound Equipment intended to be used for lithotripsy (use IEC 60601-2-36);
- Ultrasound Equipment intended to be used for dedicated hyperthermia devices; and
- Ultrasound Equipment intended to be used for phacoemulsification.

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