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 210) "فريق عمل مواصفات إدارة جودة الأجهزة الطبية" بتبني المواصـــــــفة الدولية رقم (IEC/TR 80002-3:2014) "برمجيات الأجهزة الطبية – الجزء 3 : النموذج المرجعي لعمليات دورة حياة برمجيات الأجهزة الطبية (IEC 62304) "، 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/TC 210) “Quality management and corresponding general aspects for medical devices” has adopted the International Standard No. (IEC/TR 80002-3:2014) “Medical device software -- Part 3: Process reference model of medical device software life cycle processes (IEC 62304)” 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 IEC 80002, which is a technical report (TR), provides the description of software life cycle processes for medical devices. The medical device software life cycle processes are derived from IEC 62304:2006, with corresponding safety classes. They have been aligned with the software development life cycle processes of ISO/IEC 12207:2008 and are presented herein in full compliance with ISO/IEC 24774:2010. The content of these three standards provides the foundation of this TR.

This TR does not address:

– areas already covered by existing related standards, e.g. the international standards that relate to the four standards used to build this TR (see Bibliography);
– FDA guidance documents; or
– software development tools.

This TR describes the PRM for medical device software development and is limited in scope to the life cycle processes described in IEC 62304:2006. The process names correspond to those of IEC 62304:2006. The mappings provided in Annex B are essential for the alignment between IEC 62304:2006 (which is based on ISO/IEC 12207:1995) and ISO/IEC 12207:2008, developed to address the detailed normative relationship between the two standards.

This technical report is not intended to be used as the basis of regulatory inspection or certification assessment activities.