IMDRF International Medical Device Regulators Forum

Final Document

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Title: Statement regarding Use of IEC 62304:2006 "Medical device software -- Software life cycle processes"

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Use of IEC 62304:2006 "Medical device software -- Software life cycle processes" in each jurisdiction

Australia Therapeutic Goods Administration (TGA)	All medical devices are required to meet Australian Essential Principles (EPs)**.** IEC 62304 - *Software lifecycle process* (or equivalent or better) and IEC 62366 - *Useablity engineering* (or equivalent or better) are referenced in the supporting data form and compliance with these standards is used as evidence of compliance with the EPs.
Brazil National Health Surveillance Agency (ANVISA)	All medical devices must meet requirements of safety and effectiveness. IES 62304/2006 may be employed in technical reports (technical dossiers). It is currently not mandatory to be certified on that standard.
Canada Health Canada (HC)	In Canada, conformance to specific standards is not mandatory. However, evidence of conformity to recognised standards can be submitted to demonstrate that specific requirements of the Medical Devices Regulations have been met. HC publishes a list of recognised standards, and the level of evidence expected is "equivalent or better" to these recognised standards. IEC 62304:2006 is currently a recognised standard, and represents an accepted approach to the software development process for medical devices.
China China Food and Drug Administration (CFDA)	The IEC 62304:2006 had been translated into China industry standard: YY/T 0664-2008 equally and implement from 2009.6.1, it isn't mandatory standard, and just is recommended standard.
Europe European Commission (EC)	The corresponding European standard EN 62304:2006 is a European harmonized standard, which provides presumption of conformity with legal requirements on development lifecycle for software which are incorporated in medical devices and software which are medical devices in themselves. The use of this standard (to the extent specified in its Annex ZZ) provides one solution for compliance with the relevant legal requirements. Compliance with the legal requirements can however be ensured also by other means.
Japan Ministry of Health, Labour and Welfare (MHLW) Pharmaceuticals and Medical Devices Agency (PMDA)	IEC 62304:2006 is not referred to so far, but, for example, it may be used for rational explanation through a pre-market application process to satisfy the EPs that align with those defined in GHTF/SG1/N68:2012 *Essential Principles of Safety and Performance of Medical Devices*.

Russia Russian Ministry of Health Roszdravnadzor	In current regulation using of standards is voluntary in premarket MD evaluation. And Regulator does not recognize any standard which could provide presumption of conformity. But when on the market, some types of MD have to be certified for particular mandatory standards (list of mandatory standards and types of MD is available on Regulator's web site). It should be noted, that this regulation is to be canceled on 01/01/2016.
The United States of America US Food and Drug Administration (US FDA)	IEC 62304:2006 is recognized by the US FDA medical device program as a consensus standard for which a person may submit a declaration of conformity in order to meet a premarket submission requirement or other requirements to which a standard is applicable. US FDA by recognizing IEC 62304:2006 is acknowledging that the process activities and tasks identified in this standard when used with a good quality management system and risk management system can help assure safe design and maintenance of software used in medical devices.